

Simplified Pain Evaluation and Communication Tool utilizing the Electronic Record (**SPECTER**)
(Grant ID #: 16217447)

Co-PIs: John D. Markman, MD and Jennifer S. Gewandter, PhD
Co-investigators: Maria Frazer, BS, Xueya Cai, PhD (biostatistician)

Abstract

The challenge of reporting and interpreting the 0 – 10 numeric rating score (NRS) is a major barrier to optimal pain treatment in many clinical settings. In this study we propose to examine the potential benefit of adding a simple binary question to the NRS. Patients will be asked to report whether their pain is tolerable or intolerable (i.e., pain tolerability question) using the electronic medical record (EMR)-patient portal prior to their visit. This query may facilitate patient-clinician communication and provide a more complete picture of the patient's pain experience upon which to base treatment decisions. In a cluster randomized trial, primary care physicians in the University of Rochester Medical Center network will be randomized to the active group (i.e., patients receive pain tolerability question) or the control group (i.e., patients do not receive pain tolerability question). The pain tolerability question and follow-up questionnaires will be sent to patients via the Epic-based EMR-patient portal. The primary effectiveness analysis will compare patient satisfaction with clinician-patient communication between the active and control arms. Additional outcome measures will assess the feasibility of administering the pain tolerability question and outcomes questionnaires using the EMR-patient portal. If successful, the use of this pain tolerability question will be easily disseminated across the Epic and other EMR platforms nationwide. This study will also assess the feasibility of using the EMR-patient portal for comparative effectiveness research.

C. Proposal

3. Overall Goal and Objective The ultimate goal of this project is to reduce barriers to adequate pain assessment, accelerate sequential dose titration, and provide an evidence-based foundation for a simpler, time-saving, alternative to real time, in person delivery of a 0-10 numeric pain rating score as a prompt for optimizing analgesic management. This project will promote the use of the EMR patient portal in the primary care setting for: 1) the assessment of pain, 2) the optimization of pain treatment, and 3) the tracking of therapeutic decisions and outcomes. This tool will improve analgesic dose optimization for patients already receiving treatment and enhance the use of first line or combination analgesia for new patients.

The primary objectives of this proposal are to (1) demonstrate the feasibility of implementing a novel, binary, communication and decision-making tool for chronic pain treatment through the patient portal of the EMR system (2) evaluate its effects on the patient and clinician satisfaction with communication and (3) evaluate the feasibility of assessing pain outcomes via the EMR patient portal.

4. Technical Approach

a. Assessment of Need of Project

1. The Affordable Care Act and integrated health delivery systems are driving adoption of EMR patient portals to mitigate their growing access-to-care challenges¹, and surveyed providers have expressed enthusiasm for incorporating information provided by patients via personal health records into their clinical practice². Multiple patient problems and time constraints often relegate pain treatment to a lesser priority in primary care visits. The entry of a 0-10 numeric rating by a patient care technician into a computer becomes a proxy for pain assessment that precedes the clinician's greeting of the patient. Evaluation of the pain experience, however, is complex and every patient interprets the 0-10 scale differently. While the 0-10 score may provide valuable information when comparing a patient's score over many visits focused on a single pain problem, basing treatment decisions on this score can lead to sub-optimal choices in many clinical contexts³.

For this reason, we propose a simpler communication tool that reduces these existing barriers and limitations to the current method of pain reporting. A telephone-based intervention for pain was reported to be effective in a study by Kroenke et al⁴. Our proposal updates and extends the use of telemedicine with the use of an EMR patient-portal for more convenient asynchronous communication. Most of the evidence favoring the use of portal has focused on chronic conditions such as diabetes rather than optimizing pain treatment⁵. Literature searches of PubMed for evaluations of the clinical use of a simple tolerability question to increase patient-clinician communication regarding pain yielded no studies similar to the one we are proposing. Furthermore, the relatively new patient portal technology makes it unlikely that the use of this decision-making tool has been implemented and evaluated in this setting.

2. This project will target patients, nurse practitioners, physicians' assistants, and primary care physicians engaged in the treatment of chronic pain. The beneficiaries will be these clinicians

and patients, the institution endeavoring to drive adoption of EMR patient-portal technology platform to meet federal requirements¹, as well as future researchers who plan to utilize the EMR patient-portal for outcomes research purposes. Kaiser Permanente, an integrated system with 8.5 million users, utilizes the Epic system for its KP Health Connect Online. As of 2009 25% of Kaiser's users had signed up for the Health Connect system⁶, suggesting a platform developed in the Epic system could be easily disseminated to many clinicians and patients.

Innovation Three aspects of this project are highly innovative. (1) The network-wide implementation of a simple question that may be easier for clinicians to interpret than the traditionally used 0-10 NRS to aid patient-clinician communication has not been previously evaluated. (2) The use of the EMR patient portal to promote asynchronous communication from patient to clinician prior to an in person appointment is a timely concept that will prioritize pain treatment and begin to explore the feasibility of using the patient portal to enhance communication and enhance face- to- face visit interactions. (3) This project will link three technology platforms already in use at the University of Rochester—Epic, i2b2 and REDCap. These platforms enjoy widespread adoption nationwide and both i2b2 and REDCap are open source to allow easy nationwide dissemination of this technology architecture. (4) The primary care physician network includes practices affiliated with two hospitals in the Rochester area (Strong Memorial Hospital and Highland Hospital). Thus, successful implementation of this communication tool will demonstrate precedent for multi-system dissemination.

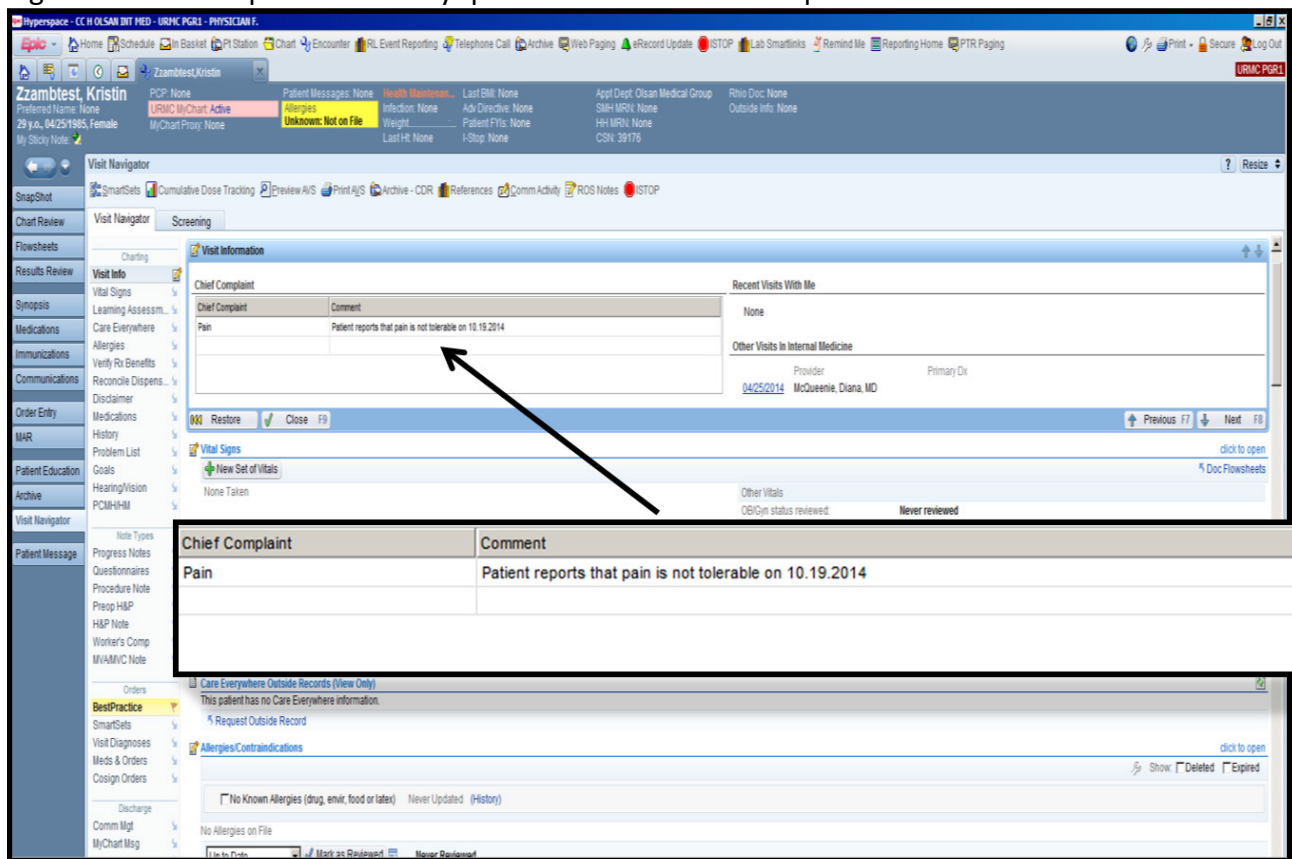
b. Project Design and Methods We propose to test the feasibility and effectiveness of this intervention in a randomized cluster trial. Our hypothesis is that pain can be more effectively managed by clinicians using the EMR-based decision making tool than with standard outpatient clinical practice alone, generally anchored in the 0-10 NRS for pain. Primary care clinicians in the Strong Memorial Hospital network will be randomized to the active or control group. Patients of the clinicians in the active group will be asked in the My Chart system “are you currently in pain? (Yes or No) And if so, is your pain tolerable?” (Yes, No, or Not Applicable, I am not in pain) 1 week prior to their primary care visit. The question will remain in the system up to one day prior to the visit, giving the patient 6 days to answer. The answer to this question will be displayed in eRecord. When a patient has answered the pain tolerability question the “MyChart surveys” icon will be magnified in bold font on the navigator bar, alerting the clinician to check the survey result. The navigator bar is displayed throughout patient interactions and throughout all subsequent documentation; it is the rudder by which a clinician navigates a patient visit. In addition, depending on the patients answer to the question, the phrase “pain is intolerable” or “pain is tolerable” will be displayed in the “Chief complaint” box (**Figure 1**), that is at the top of the same window. This box highlights the important issues for each patient and is the *first stop* when clinicians enter a record. If the patient selected “Not applicable, I am not in pain” no phrase will be displayed in the chief complaint box. Both a “tolerable” or “intolerable” response will be displayed in the box so that the clinician can consider this supplemental information with the 0-10 NRS pain score that is captured at the beginning of the in-person visit for a more complete picture of the patient’s pain experience. Patients will be selected from both the active and inactive treatment groups to receive follow-up surveys via

MyChart. We will use i2b2 based filters (i.e., i2b2 pain filters) to select patients who have (1) one of several pre-specified ICD-9 codes that indicate a pain diagnosis either in (a) the problem list or (b) the new visit diagnosis or (2) an active prescription of an analgesic medication. This method will allow identification of patients with ongoing and new onset pain.

Before implementing the pain tolerability question we will perform focus groups with patients in pain to ensure that the meaning of the word “tolerable” is readily understood by the target population. Based on the findings of these qualitative focus groups, the wording of the pain tolerability question may be modified; however, the core question will remain a dichotomous assessment of the patient’s perception of pain tolerability.

We will create a training module for the clinicians consisting of a short power point based webinar that outlines the two places that the survey results will appear (i.e., the navigator tool bar and the “chief complaint” box in addition to creating relevant modules for the routine training updates and ongoing communication related to the Epic EMR system. We will emphasize that this question was filled out by the patient and will ask the clinician to consider the answer to this question when assessing the patient and weighing treatment options.

Figure 1. Result of pain tolerability question in the “chief complaint box”



c. Design of Outcomes Evaluation Feasibility Outcomes

We will use this study to characterize the feasibility of utilizing the EMR patient-portal to enhance patient-clinician communication about pain. We will assess the percentage of patients that are enrolled in MyChart who answer the pain tolerability question before their physician visit and (2) the percentage of clinicians who (a) reviewed the tolerability question prior to the patient visit and (b) report that they would like to implement this question in their regular practice. We will also use this study to evaluate the feasibility of using the EMR patient-portal to perform outcomes research in an outpatient population reporting pain. We will assess the percentage of patients who (1) complete the follow-up surveys (see effectiveness outcomes below), and (2) report that they would be willing to answer more questions about their pain in the EMR patient-portal in the future and if so how frequently (i.e., once a week, once a month, once a year).

Effectiveness Outcomes

Patients of clinicians randomized to both active and control groups who are enrolled in the EMR patient portal and identified by the i2b2 pain filters will be sent an email indicating that there is something new item in their EMR patient-portal. Once they login to portal they will be asked to complete the patient-reported outcome surveys. The primary efficacy outcome will be patient satisfaction with their communication with their clinician, which will be evaluated using a 5-point likert scale that asks “How satisfied were you with your discussion with your doctor regarding your pain? [0 – completely satisfied, 3– somewhat satisfied, 5- totally unsatisfied]. Patients will be sent this question 1 week after their physician appointment. We chose 1 week for this outcome measure to minimize the length of recall required to answer this question. At this time patients will also be asked if they have initiated their prescribed treatment using the question: “Have you started the treatment that your doctor prescribed during your last doctor’s appointment? For example, started taking a medication or going to physical therapy.” The remainder of the outcomes will be assessed 1 month after the visit to allow sufficient time for the prescribed treatment to begin working. These outcome measures include the following (1) patient global assessment of change that asks patients “Considering all of the ways that your pain affects your life, please rate how you feel compared to before your last visit with your primary care physician [1- very much better, 2- somewhat better, 3- the same, 4- somewhat worse, 5- much worse] (2) The 0 – 10 numeric rating score for pain that asks patients to “please rate the intensity of your pain [0- no pain, 10 – worst pain imaginable]; (3) The pain tolerability question (i.e., “Is your pain tolerable?” [Yes, No, Not Applicable, I am not in pain); (4) The pain interference question from the Brief Pain Inventory (i.e., “Please mark the number that best describes, over the past 24 hours, how your pain interfered with your”: general activity, mood, walking ability, normal work, relations with other people, sleep, enjoyment of life [0 – did not interfere, 10 – completely interferes]. Patients who were prescribed an opioid at their physician visit will also be sent an opioid side effect survey that asks about opiate side effects, including nausea, fatigue, and constipation using a 0 – 10 NRS. See Table 1 for a summary of the outcome variables.

In addition to the patient reported outcomes, we will identify the number of physician visits that occur within the 6 months after the patients original physician visit. We will also hold focus groups with participating clinicians to assess whether they thought that the tolerability question enhanced their communication with their patients or altered their prescribing

practices. We will also ask them for suggestions on how the utilization of this type of communication tool could be improved. We will share with them the data from their patients' follow-up questionnaires and ask them if the feedback is helpful and something that they would like to see implemented clinically.

Data Analysis

Univariate analyses will be performed to examine data distributions, potential outliers and missing data, in which mean, median, and standard deviation will be presented for continuous variables, and proportion will be presented for categorical variables. To test the feasibility of utilizing MyChart to manage patients' pain, patient response rate to MyChart questions will be computed among all patients in the intervention group. In addition, patient characteristics will be compared between respondents and non-respondents in the intervention group. Two sample independent t-tests or nonparametric Mann-Whitney tests will be performed for continuous variables under normal or non-normal assumption; and Chi-square tests or Fisher's exact tests will be performed for categorical variables depending on cell sizes in the contingency tables. Furthermore, a generalized linear mixed (GLMMIX) model will be performed to test the association between the likelihood of a patient to respond to a MyChart question and patient characteristics to explore possible response patterns⁷. The GLMMIX model can be expressed as

$$\text{Ln} \left(\frac{P_{ij}}{1-P_{ij}} \right) = \beta_0 + \boldsymbol{\beta X} + \varepsilon_i, i = 1, 2, \dots, n_j, j = 1, 2, \dots, J.$$

In the GLMMIX model, P_{ij} is the probability of responding to a MyChart question, β_0 is the intercept, \mathbf{X} represents patient characteristics, and $\boldsymbol{\beta}$ represents coefficients corresponding to patient characteristics. In addition, the random effect ε_i accounts for patient clustering effect within physicians, and it is assumed to follow the compound symmetry correlation structure.

To test the outcome effectiveness, we will first compare patients responding to the surveys to those who don't. Specifically, patient characteristics will be compared to test whether respondents are different from non-respondents at intervention and control groups separately. Two sample independent t-tests or nonparametric Mann-Whitney tests will be performed for continuous variables under normal or non-normal assumption; and Chi-square tests or Fisher's exact tests will be performed for categorical variables depending on cell sizes in the contingency tables. Patients' satisfaction scores will then be compared between intervention and control group based on the per-protocol principle using the Mantel-Haenszel tests⁷. We will further perform a GLMMIX to test the association between patients' satisfaction scores (ranked from 1 to 5) and the intervention status when patient characteristics are controlled for. The GLMMIX model can be expressed as

$$\text{Ln} \left(\frac{P(Y_{ij} \leq k)}{1 - P(Y_{ij} \leq k)} \right) = \alpha_k + \beta_1 I_{ij} + \boldsymbol{\beta X} + \varepsilon_i,$$

$$i = 1, 2, \dots, n_j, j = 1, 2, \dots, J, k = 1, 2, 3, 4, 5$$

In the GLIMMIX model, P_{ij} is the probability of having survey score less than or equal to a specific value of k (K ranked from 1 to 5), α_k is the intercept for each category of the satisfaction score, I_{ij} is the indicator of intervention status (1 for intervention and 0 for control), X represents patients' characteristics, and β represents coefficients corresponding to patients' characteristics. In addition, the random effect ε_i accounts for patient clustering effect within physicians, and it is assumed to follow the compound symmetry correlation structure. All analyses will be performed in SAS 9.4® at the two-tailed significance level of 0.05.

Power Calculation

Our preliminary data showed that approximately 160,000 patients were clustered within 116 primary care physicians in the University of Rochester electronic medical record (EMR) system, and approximately 24000 (15%) of them had diagnosis of pain in their medical histories. We first assumed that only 19,200 (80%) patients have MyChart access. We then conservatively assumed that 20-30% of physicians will choose not to participate in this study, which further reduced our sample to 13,241 patients clustered within 80 physicians. In addition, we assumed the non-response rate among patients will be 20%. Thus, our final sample would include 10,593 patients clustered within 80 physicians, which equals approximately 132 patients per physician. The power calculation was performed based on Donner's approach^{9,10} for cluster randomization trials. When the standard deviation of the satisfaction score was assumed to be 2, and the intraclass correlation coefficient of patients clustered within physicians was assumed to be 0.10, we would have 92% power to detect a difference of 0.5 in the patient satisfaction questionnaire between the intervention and the control groups (alpha=0.05, two sided).

The study results will be presented at the American Pain Society annual meeting and published in a peer-reviewed journal focused on pain management or primary care regardless of study outcome. Additional methodology abstracts, posters, and manuscripts will be developed for publication that characterize: 1) EMR-based cluster trial design, 2) validity of supplementing the NRS pain meaningful use measure with tolerability responses and 3) a linked information technology architecture (EMR-i2b2-REDCap) for comparative effectiveness research. Furthermore, if the intervention is found to be feasible and increase patient satisfaction or favorable perception of communication, it will be implemented as part of clinical practice in the Strong Memorial Hospital system and promoted widely to other integrated health care systems.

Table 1. Project outcome variables

Primary outcome variable	
Feasibility of utilization	% of MyChart-enrolled patients who answered the tolerability question % of clinicians that reviewed the tolerability question prior to the visit % of clinicians that would like to adopt the platform into their usual practice
Impact	Patient satisfaction with patient-clinician communication (7-point Likert scale)
Secondary outcome variables	

Feasibility of utilization	% of patients who complete the follow-up surveys % of patients willing to answer more questions about their pain in MyChart How often patients are willing to answer questions
Impact	Patient Global Impression of Change (7-point Likert scale) Pain intensity (0 – 10 NRS) Pain interference with life (Brief Pain Inventory) Opiate side effect survey Number of clinician visits in the 6 months following initial PC visit % of patients referred to a pain specialist, emergency room visits, and specialist referrals in the 6 months following PC visit % of clinicians that found the tolerability question enhanced communication (Yes vs. No) % of clinicians that felt the tolerability question affected treatment decisions (Yes vs. No)

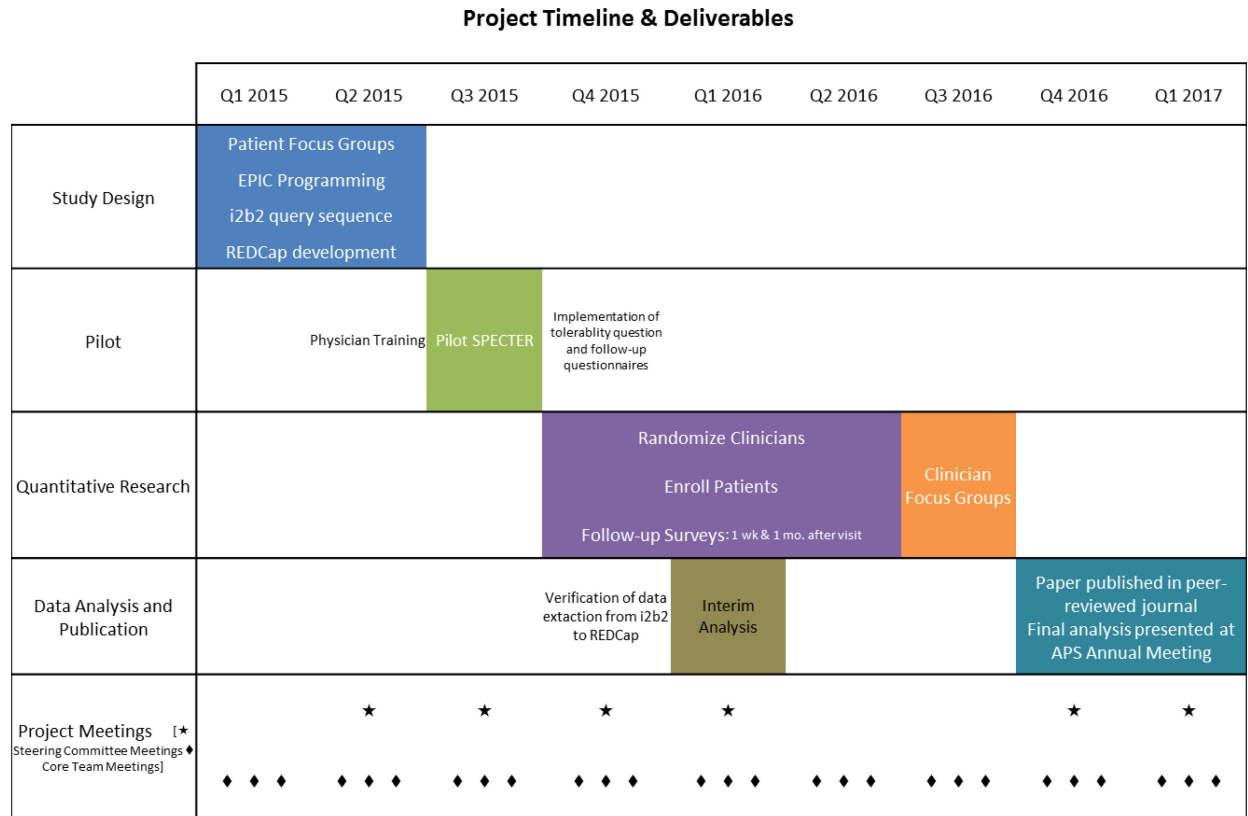
5. Detailed Work plan and Deliverable Schedule

From January to June 2015 (i.e. Q1 and Q2 2015) we will hold focus groups with patients to assess understanding of the tolerability question and modify wording as necessary. During this window, IRB authorization of the final protocol as well primary care network vetting of the finalized protocol through the CTSI will take place. During this project launch period, programming architecture of the tolerability question in the EMR patient-portal and i2b2 filter sequence for outcomes assessment will be developed and enter initial beta testing. Development of follow-up survey questions to be delivered through the portal and extracted via REDCap for analysis will also commence during this time period. Content for the clinician training module will be developed and participating physicians will be engaged through previously-developed education channels and special communications through the primary care network.

Three months (Q3 2015) will be dedicated to the implementation and beta testing of the tolerability question and the follow-up questionnaires (“front end”) as well as the outcome reporting function (“back end”). The pilot sample will include 20-50 patients. Patient engagement with MyChart (i.e., patient-portal) delivered pre-visit materials will be examined at the time of the outpatient encounter as well as response rates as documented in the EMR visit navigator. Confirmatory assessments of eRecord documentation of patients completing the tolerability questions will be performed. Analyses of patient receipt of email prompts pre and post visit will be conducted along with confirmation of data capture using the REDCap extraction protocol.

The cluster-randomized trial phase of data collection will open to participating practices in Q4 of 2015 for a period of 12 months (October 2015 – September 2016). The final 6 months (October 2016 – April 2017) will be dedicated to data analysis and abstract, poster, and manuscript preparation (Figure 2).

Figure 2. Project Timeline



Possible Publications: A feasibility paper, A paper describing the cluster trial, A paper describing the concept of tolerability, A methods paper on technical specs

6. References

1. Woodcock, E.W. "How Patient Portals Create Value for Patients—and Fulfill Meaningful Use Requirements." Intuit Health. 2010 (www.medfusion.net).
2. Huba N, Zhang Y. Designing patient-centered personal health records (PHRs): health care professionals' perspective on patient-generated data. *J Med Sys.* 2012;36:3893-905
3. Krebs E, Carey T, Weinberger M. Accuracy of the Pain Numeric Rating Scale as a Screening Test in Primary Care. *J Gen Intern Med* 2007;22:1453-8.
4. Kroenke K, Theobald D, Wu J, Norton K, Morrison G, carpenter J, Tu W. Effect of telecare management on pain and depression in patients with cancer. *JAMA.* 2010;304:163-71.
5. Schnipper JL, Linder JA, Palchuk MB, Einbinder JS, Li Q, Postilnik A, Middleton B. "Smart Forms" in an electronic medical record: documentation-based clinical decision support to improve disease management. *J Am Med Inform Assoc.* 2008;15:513-23.
6. Emont S. Measuring the impact of patient portals: what the literature tells us. Prepared for the California Health Care Foundation. 2011 (<http://www.chcf.org/~media/media%20library%20files/pdf/m/pdf%20measuringimpactpatientportals.pdf>).
7. McCulloch CE, Searle SR, Neuhaus JM. *Generalized, linear, and mixed models*: Wiley. New York; 2008.
8. Agresti, A. 2002. *Categorical Data Analysis (2nd Ed.)*. NY: John Wiley & Sons, Inc.
9. Donner, A. and Klar, N. 1996. 'Statistical Considerations in the Design and Analysis of

Community Intervention Trials.' *The Journal of Clinical Epidemiology*, Vol. 49, No. 4, 1996, pages 435-439.

10. Donner, A. and Klar, N. 2000. *Design and Analysis of Cluster Randomization Trials in Health Research*. Arnold. London.

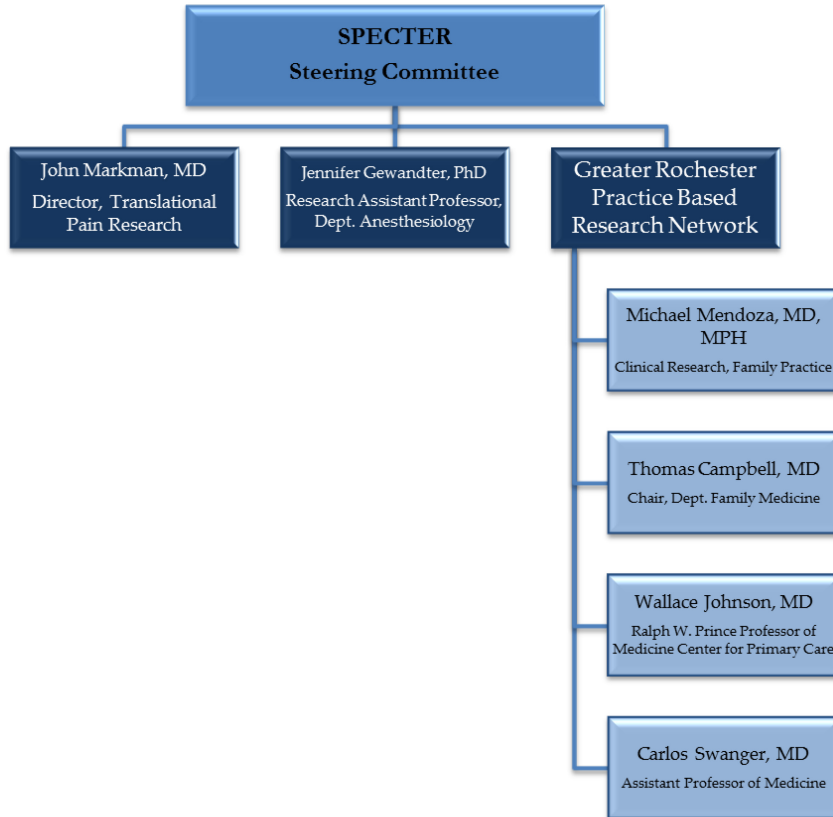
D. Organizational Detail

1. Leadership and Organizational capability

The co-principal investigators will lead a diverse study team that includes project management, clinical coordination, information technology, and biostatistics/outcomes analysis functions. The project team will leverage both its clinical knowledge as well as extensive experience conducting clinical research. Over the last several years, TPRP has conducted 17 clinical research projects including 8 industry-sponsored trials and 9 investigator-initiated interventional and observational studies. Key therapeutic areas of research include: chronic post-surgical pain, chronic low back pain, chronic back pain and opioid induced constipation, chronic peripheral nerve pain, painful diabetic neuropathy, post-herpetic neuralgia, and lumbar spinal stenosis. The TPRP was recognized as the only academic Center of Excellence by the American Pain Society in 2013 in large measure due its track record completing clinical research projects of this scope and complexity.

The three technology platforms that are crucial to project execution are all currently in use by the program and the TPRP staff has a track record of completing modifications of the EMR interface for the purpose of clinical investigation. Substantial technical support will be required to design the patient portal queries, EMR visit navigator modifications, EMR-infolded physician and patient survey tools, in addition to i2b2-based outcomes analytics.

The leadership of the primary care network is comprised of experienced clinical researchers with backgrounds in primary care (internal medicine and family practice). These regional physician leaders have endorsed SPECTER and agreed to participate on the project steering committee. The support of this leadership group will facilitate the participation of the primary care providers and their patients. The primary care network involvement will also improve the likelihood of dissemination of the study results in channels beyond the subspecialty pain community.

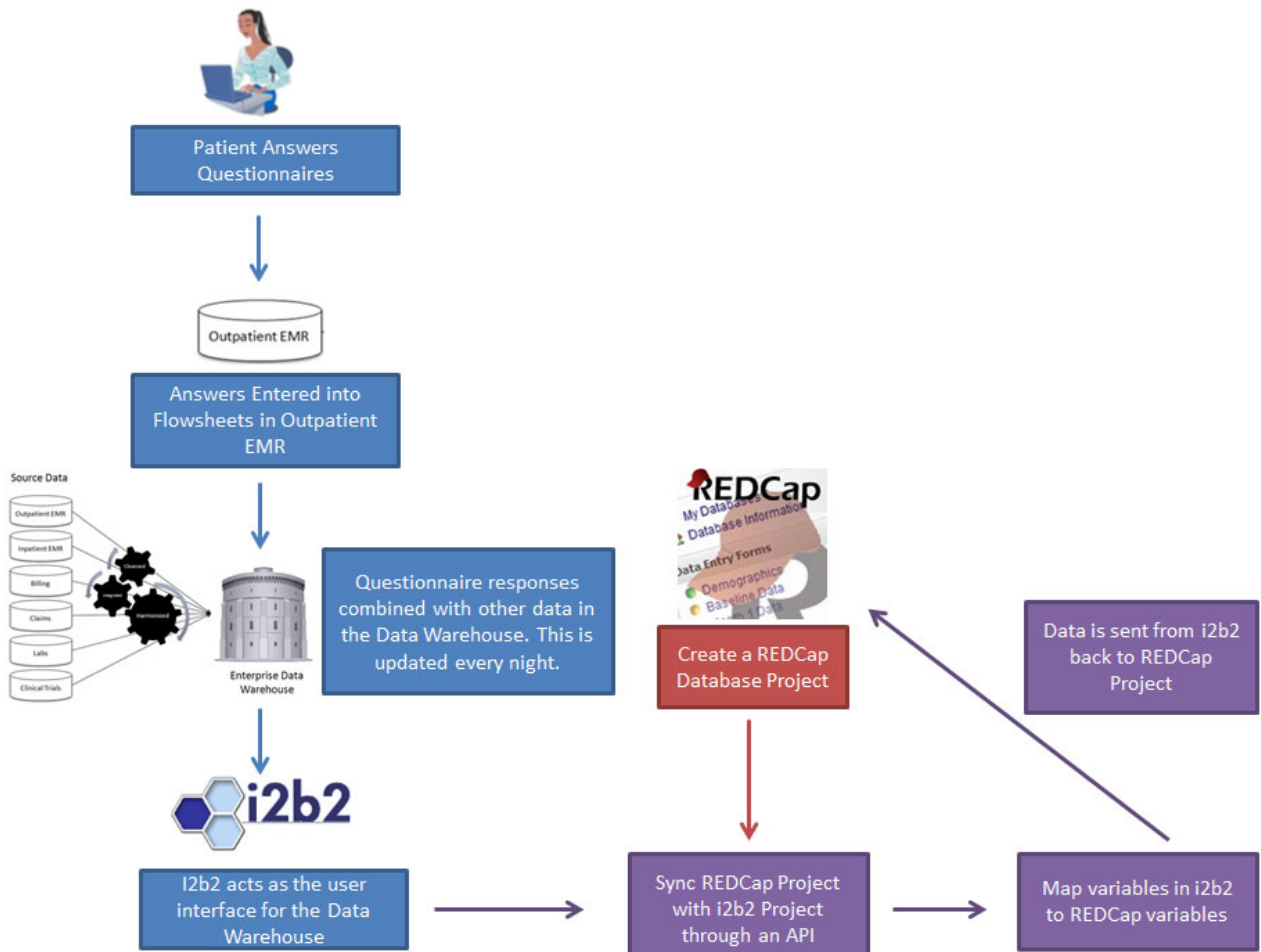


2. Staff Capacity:

Maria Frazer will be the lead project manager for this project. She is currently an integral member of the University of Rochester Translational Pain Research Program (TPRP) and has experience coordinating large projects and using electronic data platforms in outcomes research. She will have 50% of her time devoted to this project. Part time contracting of a data management specialist, an information technology specialist, and a biostatistician will be utilized to successfully execute the project and analyze the data.

The Translational Pain Research Program of the University of Rochester School of Medicine Department of Neurosurgery directed by Dr. Markman will coordinate the project. Collaborators will include the co-PI Dr. Gewandter in the Department of Anesthesiology Clinical Research Center, Dr. Xueya Cai in the Department of Biostatistics, and the leadership of the Departments of Family Practice and Internal Medicine.

Figure 1. Data flow diagram



G. Letter of Commitment

SCHOOL OF MEDICINE AND DENTISTRY

Center for Primary Care



MEDICINE *of* THE HIGHEST ORDER

Wallace E. Johnson, MD
Director, Center for Primary Care
Associate Chair for Primary Care, Department of Medicine

October 13, 2014

Dear Pfizer IGL&C Grants Committee:

I am writing this letter of support for the SPECTER study under the direction of Dr. John Markman in the Translational Pain Research Program. This innovative study offers the opportunity to improve a major barrier to adequate pain assessment in the primary care setting using the patient portal of the electronic medical record.

The University of Rochester Primary Care Network comprises 26 offices over three counties, 116 physicians and a panel of 160,000+ patients. The Network is affiliated with two hospitals, the University of Rochester Medical Center/Strong Memorial Hospital which is a quaternary referral center and Highland Hospital which is a tertiary hospital.

The Network offices achieved NCQA Level 3 Patient-Centered Medical Home (PCMH) certification in January 2012. The Network was re-certified by NCQA under the latest, more stringent standards again in January 2014. While NCQA certification is a major step, "certification" is not our real goal: We believe we can accomplish a true practice transformation given by leveraging our institutional backing, our relationship with the major regional insurers, and our unparalleled health information technology.

The Primary Care Network linkages enable us to engage in wide-spectrum "observational comparative effectiveness research" on clinical interventions made at the office level such as the proposed SPECTER study.

Please feel free to contact me with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Wallace E. Johnson" with a stylized flourish at the end.

Wallace E. Johnson, M.D.