Overall Goal & Objectives

Overall Goal

Pain is the one of the most common reasons patients visit a primary care physician (PCP). However, PCPs report time constraints and low levels of knowledge, confidence and satisfaction in managing chronic pain.[1-2] At the same time, the health care system has few pain specialists to care for many patients with chronic pain. Therefore, PCPs critically need more knowledge and resources for treating chronic pain, so they can provide evidence-based care and refer only the most challenging cases to specialists. **The overall goal of this proposal is to develop, implement, and evaluate a novel model of chronic pain care that supports PCPs in confidently delivering evidence-based pain care.** The new care model employs three elements:

1) **"Education" –** A web-based and in-person didactic education curriculum emphasizing the use of evidence-based approaches, including physical modalities and psychological approaches in addition to the traditional medical model of pain care.
2) **"Standardized data" –** A patient and practice staff oriented model for collecting standardized data in the electronic health record (EHR) to support data-driven medical decision making for chronic pain.
3) **"Decision support" –** EHR-based decision support that presents PCPs with recommended courses of treatment at the point of care based on patients' clinical histories and evidence-based pain protocols.

We will conduct a randomized experiment to test the effects of this care model on care quality, patient outcomes, satisfaction, and care costs and utilization. The experiment will sequentially phase in each intervention element in two family medicine practices in the University of Florida (UF&Shands) health system. This research will be carried out by a multidisciplinary team of experts in pain medicine, headache management, pain psychology, family practice, biostatistics, medical decision-making, and health information technology.

Key Objectives

1) To implement and test the effect of **Education**
2) To implement and test the effect of combined **Education** and **Standardized data**
3) To implement and test the effect of combined **Education**, **Standardized data**, and **Decision support**

We will phase in each of the three elements and test their effects on i) care quality, assessed as PCP adherence to evidence-based protocols for musculoskeletal (MSK) pain, including myofascial pain and spine pain, and headache pain, ii) patient's pain, functional, and psychosocial outcomes, iii) physician and patient satisfaction with care, and iv) cost and utilization of pain-related care. We designed the three elements of the care model to address established needs for improved knowledge, improved access to patient data, and efficient treatment guidance for time-constrained PCPs. We expect that providing PCPs with all three of

these elements will produce the largest improvements in outcomes when compared to a group of PCPs randomly assigned to no intervention (i.e., usual care).

Technical Approach
Current Assessment of Need in Target Area

Overview

Similar to national trends, pain care at UF&Shands varies in terms of source and quality. On one hand, sub-specialist pain care experts at the UF Pain and Spine Center conduct approximately 3,600 patient visits per year. Unfortunately, around 2,500 of those visits involve new patients who typically wait two months to be seen. On the other hand, PCPs, who can be seen more quickly and usually provide lower cost care, complete approximately 5,500 patient visits each year for the most common types of pain complaints. However, most PCPs are minimally trained in pain management, which calls into question the quality of their pain care relative to sub-specialists. Moreover, UF&Shands has high hospital admission rates for patients with pain who were previously seen by PCPs. And, patients have poor perceptions of pain care, as measured by satisfaction surveys. These data indicate that pain care delivered in UF&Shands primary care may be inadequate, ineffective, and not evidence-based. Therefore, UF&Shands PCPs and their patients would benefit from new tools that provide PCPs with a common understanding of best practices in pain management, consistently collect key patient data in the EHR, and integrate evidence-based protocols to guide point of care medical decisions.

Target area trends in PCP treatment, referrals, and satisfaction with pain care

Physician leaders in both family medicine (Schmidt, Co-investigator) and pain medicine (Hurley, Co-principal investigator) are key members of our project team. Over the last 3.5 years, Dr. Schmidt and Dr. Hurley have identified a need for more consistent and higher quality primary care pain management at UF&Shands. For example, over the last 3.5 years, 75% of referrals from PCPs to pain physicians have been for spine pain of an MSK origin, most commonly "low back pain" or "neck pain." The remaining referrals have been for headache, with a smaller proportion for neuropathic pain and generalized pain. In 60-80% of MSK referrals, PCPS indicate "failed medical management" and/or request that specialists "take over opioid prescriptions." In 90% of headache referrals, PCPs requests "help with managing headaches." In 80% of MSK and headache cases, PCPs have used opioids as the primary analgesic. PCPs have used non-opioid adjuvant medications, including anti-depressants and anti-convulsants, in less than 20% of the cases, muscle relaxants in 30% of cases and non-opioid analgesics in only 50% of cases. Upon presentation to the pain clinic, patients report moderate pain scores and low satisfaction with previous pain care. In summary, the limited number of pain physicians, low patient satisfaction with pain care, and high referral rates for patients who could be managed in primary care demonstrate a strong need for improving primary care pain management at UF&Shands.

Target area PCP challenges when managing chronic pain and opioid therapy

As further preliminary data for this proposal, Dr. Harle (Co-principal investigator) and Dr. Fillingim (Co-investigator) recently conducted formal qualitative interviews that validated the

need for improving and standardizing primary care pain management at UF&Shands and in north-central Florida generally. We conducted, transcribed, and qualitatively analyzed 15 in-depth interviews with local PCPs, 14 of whom were current or former PCPs at UF&Shands. These interviews focused on PCPs perceived needs and decision-making processes when managing chronic pain and chronic opioid therapy. We interviewed men and women who varied in age, experience, and comfort managing pain and prescribing opioids. **Our interviews elicited multiple themes that underscore the importance of the care model described in this application (Table 1).** Specifically, PCPs expressed concerns about the "subjective" nature of pain as well as needs for better diagnostic data, better medication risk and benefit data, and EHRs with better data and standardized decision support processes.

Table 1. PCP interview themes about decision making for patients with chronic pain

Theme	Description
Variable knowledge and comfort managing pain/prescribing opioids	• PCPs varied in their knowledge of pain management. Some had specialized training or CME credits in pain. Others lacked expertise and preferred that partners or specialists manage their patients with chronic pain. • Some PCPs explicitly said they were “not opioid prescribers.” Others said they commonly prescribe and are comfortable prescribing opioids.
Need for more objective and reliable patient data on pain and function	• PCPs described their distrust and disuse of pain scales, even though pain scores are collected in practice. • PCPs described subjective and inconsistent approaches to assessing patients’ functional outcomes. Most PCPs were unaware of and did not use validated scales for assessing and monitoring functional outcomes. • PCPs described their desire for using practice staff to collect more patient information on pain and function for use in treatment decisions.
Need for data to assess risk of opioid misuse and abuse	• Some PCPs were aware of but none used opioid risk screening tools. • PCPs described their desire for using practice staff and/or systems to more efficiently collect opioid-related risk information. • PCPs described inconsistent use and login problems when accessing the Florida prescription drug-monitoring database.
Need for EHR-based data and decision support	• Multiple PCPs described their willingness to continue opioids long-term with “trusted” patients. However, PCPs typically did not describe a consistent process for assessing benefits and risks associated with opioids. • Most PCPs were positive about EHR tools to make pain care more evidence-based, such as dashboards that summarize patient data, checklists, point-of-care reminders, and regulatory information.

Regional need for improved pain care

In our region, medical students, medical residents, and PCPs receive no formal training in pain management. In the UF medical school, pain management is covered in two lectures, one on neuroanatomy and one on opioid pharmacology. Therefore, it is unsurprising that physicians in our region typically treat pain by prescribing short acting opioids. However, using opioids for pain can lead to a number of unintended consequences: 4-26% of patients receiving opioids for pain abused those opioids, 26% used opioids for purposeful over-sedation, 39% increased opioid dose without a prescription, 8% obtained extra opioids from other doctors, and 18% used opioids for non-pain related purposes.[1-3] Furthermore, Florida has been called the epicenter of national prescription opioid abuse. In fact, three times as many opioids are sold in Florida than in states with the lowest sales.[4] As a result, in 2011, the Florida legislature passed the "Anti-Pill Mill Law,"[5] as a comprehensive plan to reduce prescription drug trafficking by physicians and pill mills. The bill includes standards of care for doctors who prescribe opioids and requires them to register with the Department of Health. This law has led to a large reduction in opioid sales and dispensing but has also reduced the number of PCPs willing to care for patients with pain. Many of these PCPs are unaware of how to use non-opioid pain treatments and unwilling to prescribe opioids for fear of legal liability. Together, these factors further demonstrate the need for PCP education and point of care tools when managing pain.

Primary audiences for this intervention

In the short term, our intervention will target family physician practices in the UF&Shands network in Gainesville, FL. We expect both PCPs and patients to benefit from the intervention. Our evaluation will provide new evidence regarding the value of a comprehensive, EHR and data-driven approach to educating and supporting PCPs in pain management. In the long term, we plan to extend our intervention to all family practices and general internal medicine practices in the UF&Shands system. Beyond UF&Shands, we expect to disseminate our care model to PCPs in other academic health centers and community practices nationwide.

Intervention Design and Methods

Intervention design overview

Our intervention combines PCP education, standardized data collection in the EHR, and EHR-based clinical decision support (Figure 1). In the UF&Shands health system and nationally, non-pain medicine physicians receive minimal training in pain management.[6] Therefore, first, our intervention includes **education designed and delivered by pain management sub-specialists**. This education will address PCPs' need for new knowledge about best practices in pain treatment. However, we don't expect education alone to meet patients' and PCPs' needs. PCPs also need patient-reported data that is reliable and easily accessible at the point of care. For example, before choosing whether to continue prescribing an opioid for chronic low back pain versus discontinuing and offering an alternate treatment, PCPs need data on associated risks and benefits. For example, benefits can be assessed from changes in pain and function since the patient began taking the opioid. Risks can be assessed from urine drug screen results, opioid screening tool results, pharmacy refill data, and indications of medication side effects. Therefore, second, our intervention will also implement new clinical processes that collect and

display a standard set of pain-related patient data via a **pain dashboard** in PCPs' EHR system. Third, our intervention will provide point-of-care guidance to PCPs' treatment decisions. Because PCPs are highly time constrained[7] and responsible for treating a wide range of complex and often co-morbid conditions, they require concise guidance about best practices. Therefore, our intervention will translate UF&Shands pain specialists' treatment protocols into EHR-based **brief treatment recommendation** alerts that suggest evidence-based treatments to PCPs. These alerts will be displayed in the EHR during visits by patients who meet relevant clinical criteria.

The three phases of our intervention will be developed, implemented, pilot tested, and then evaluated. To ensure success, our team is supported by clinical and administrative stakeholders from across UF&Shands.

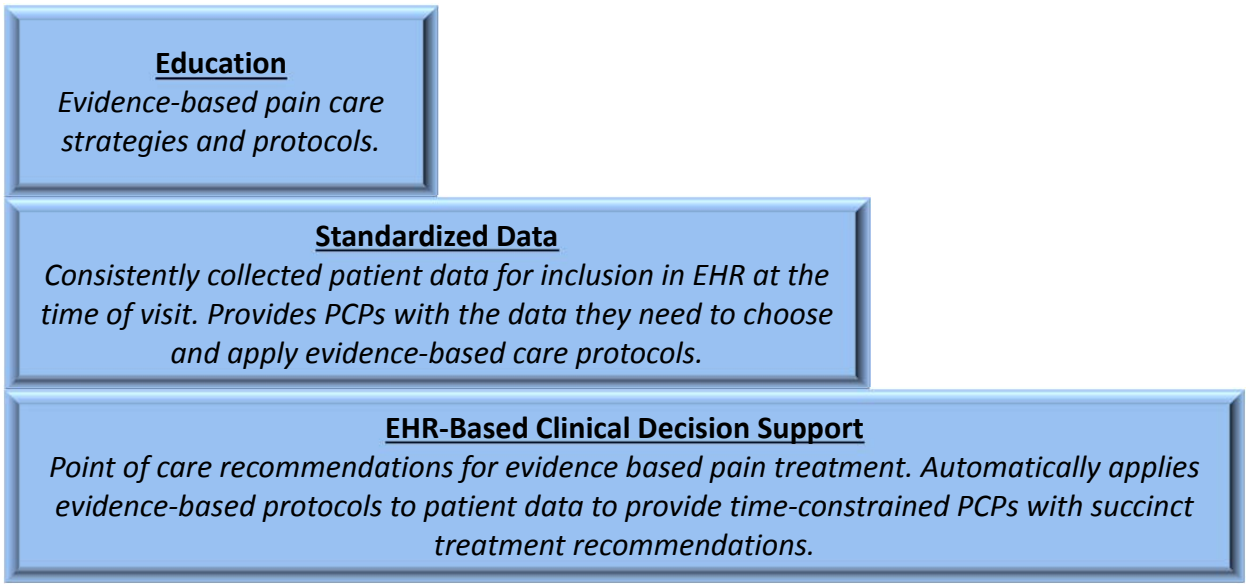

Figure 1. Overview of intervention's three phases

Intervention phase 1 – "Education"

We will implement a modular **education curriculum** emphasizing evidence-based, multimodal and multidisciplinary pain care, including physical modalities and psychological approaches in addition to the traditional medical model of pain care. The curriculum will be based on published evidence-based guidelines and systematic reviews.[8-10] The foundation for the curriculum already exists in the form of didactic lectures, pain treatment protocols, and other training materials that Dr. Hurley and others in pain medicine at UF&Shands have developed and delivered in recent years. In contrast to the piecemeal education that has been delivered previously at UF&Shands, the education we proposed will be systematically deployed, longer in duration, and designed to provide both general pain management education as well as specific training in managing the pain conditions targeted by this proposal. Moreover, based on the PCP needs derived from our recent qualitative interviews, the education will include training on structured and validated data collection instruments that PCPs can use to assess risks and benefits of different treatment modalities (e.g., opioids, non-opioid adjuvants, coping skills

training, physical therapy) and to assess patient changes in pain and function. Notably, our team is collaborating with Dr. Sean Mackey (see letter of support) who has developed clinical tools to collect patient-reported pain and function outcomes in EHR systems.[11] Therefore, one of the education modules will focus on patient-reported outcome measurement and the value of structured data for monitoring patients with chronic pain. Also, the education will include a module describing the clinical value of and how to use validated opioid screening tools to predict opioid-related risks of abuse and misuse.[12]

The education curriculum will combine web-based lectures and in-person didactic sessions led by pain management experts. Prior to enrolling PCPs in the evaluation, we will pilot test and revise the curriculum based on content and usability feedback from three family medicine PCPs. The pilot test PCPs will not participate in the subsequent evaluation study. The final curriculum will contain 8 hours of content (Table 2). Because clinical and administrative leaders at UF&Shands are supportive of this intervention and because PCPs are also interested in improving pain care, we expect the education to be well received and widely completed.

Table 2. Overview of education intervention content and duration

Module	Content area	Duration	Delivery mode
1	Overview of best practices in chronic pain management – physical diagnosis, evaluation and treatment	1 hour	Web
2	Care protocols for common chronic pain conditions: myofascial pain, axial or spine related pain, headache pain	3 hours	In-person (3 hour)
3	Chronic opioid therapy: assessing risks, benefits, and alternative treatments*	3 hours	Web (1 hour) In-person (2 hour)
4	Collecting and using data to manage chronic pain	1 hour	Web

**Module 3 will be based on FDA Risk Evaluation and Management Strategy (REMS) prescriber education blueprint for extended-release and long-acting opioid analgesics*[13]

Intervention phase 2 – "Standardized data"

After educating PCPs, we will implement a patient and practice staff oriented model for collecting standardized pain-related patient data in the electronic health record (EHR). These data will complement current processes through which PCPs obtain patient information for making treatment decisions. We plan to display critical patient data via a **pain dashboard** in the EHR for PCPs to view immediately prior to or during their visits with patients. Using validated scales, we will collect pain ratings (0-10), pain intensity, interference, pain catastrophizing, physical function, fatigue, depression, anxiety, and opioid risk (SOAPP-R). PCPs will be educated on the use and value of these scales during the education phase of the intervention. The pain dashboard will make these and other relevant data, such as opioid and other prescription history and urine drug screen results available in the EHR through a graphical interface. We expect the dashboard to help PCPs more fully understand their patients' conditions and make reliable, evidence-based decisions that lead to higher satisfaction and improved outcomes.

UF&Shands PCPs use the Epic Ambulatory EHR system. As part of this system, UF&Shands has implemented the Epic "MyChart" patient portal that allows patients to view portions of the medical record and communicate with their physicians through a secure web-based application. We plan to leverage this portal to allow patients with pain to self-report data in advance of their visit for inclusion in the pain dashboard. We will use email and other communication modes to ask patients to self-report these data prior to their PCP visits. For patients who are unable or unwilling to use the portal, we will employ front office or nursing staff to obtain the pain dashboard data from patients when they arrive for their PCP visit.

To effectively collect pain dashboard data from patients who are either at home or in clinics, we will also leverage Stanford University's National Pain Registry project. The project, being led by Dr. Sean Mackey, has developed workflows and information technology (IT) tools to survey patients with pain and capture their data in an EHR (Figure 2). These tools use instruments from the National Institutes' of Health Patient Reported Outcomes Measurement Information System (NIH PROMIS). The PROMIS measures and instruments are validated approaches to collecting patient reported data.[14,15] Dr. Mackey has agreed to make his Registry tools available to our team and to consult on their implementation at UF&Shands (see letter of support). At Stanford, Dr. Mackey's team has integrated the tools with their Epic EHR and reports high satisfaction among staff, physicians, and patients. Also, Dr. Mackey's technology relies on an open standard, open source framework. Therefore, we are confident that we can effectively implement the Registry tools in the UF&Shands system as part of our intervention. Furthermore, because the Registry tools are open-source, they offer a low-cost approach to collecting patient-reported data. Therefore, we expect that other health care providers will be more likely to adopt our care model in the future.

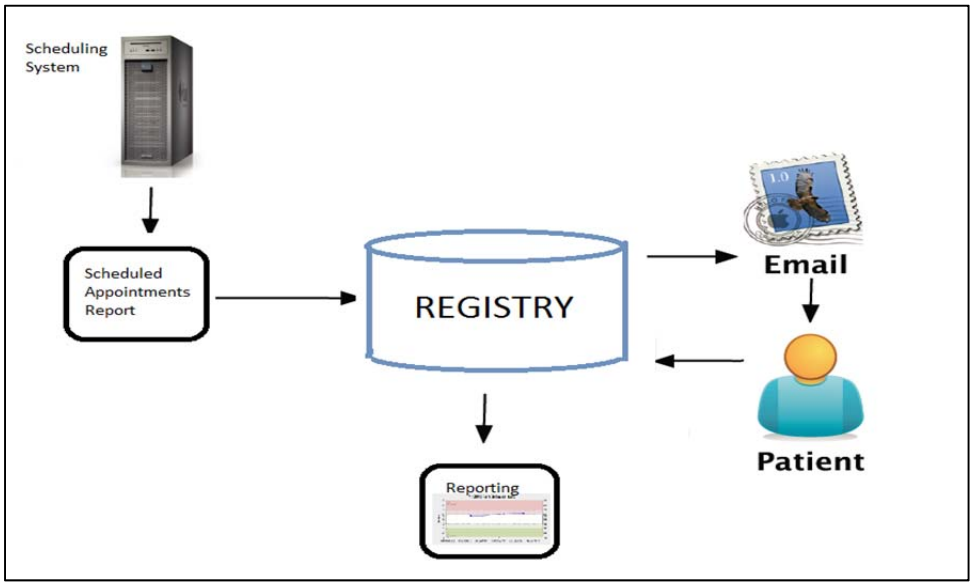

Figure 2. Example workflow for collecting patient-reported data using the (Source: Dr. Sean Mackey, unpublished presentation)

Intervention phase 3 – "Decision support"

The final intervention component will combine evidence-based knowledge and patient data to produce point-of-care guidance to PCPs managing patients with MSK and headache pain. Within the EHR, and coordinated with the pain dashboard, the decision support will deliver **brief treatment recommendations (BTRs)** for patients who meet specific clinical criteria. These BTRs will be patient condition targeted. For example, physicians caring for patients with MSK pain who are naïve to treatment will receive guidance regarding non-opioid therapies and appropriate medications choices. Within the EHR, we will use Epic "SmartSets" to link orders to drop-down menu choices. For example, patients with significantly elevated scores on mental health screening measures will have a BTR suggesting pain psychology and physical therapy consults that can be easily ordered via drop-down menus. Moreover, these BTRs and resulting orders will automatically populate the clinical note "plan" section. In addition to the brief recommendation and automated ordering, the decision support will provide convenient **links to more information** on pain protocols, opioid therapy guidelines, and medical evidence underlying these resources. Also, we will align the content of the linked information with the content of the education phase of the intervention. We expect this alignment to ensure PCPs receive consistent and reinforced guidance that increases their use of evidence-based care.

Overall, the decision support will provide PCPs with simple, timely, and relevant treatment recommendations based on medical evidence. Dr. Hurley and his pain physician colleagues have already developed protocols for the focal conditions in this proposal: myofascial pain, axial or spine related pain, and headache pain (e.g., see Figure 3). Also, the decision support will provide recommendations based on established clinical guidelines for chronic opioid therapy.[10,16] Notably, our goal is not to eliminate PCP judgment when treating chronic pain but to focus PCPs' attention on established evidence and best practices that are relevant to specific patients. Moreover, we aim to simplify the often daunting array of knowledge resources and patient information that are available to PCPs but not practically accessible during busy work days. We expect the BTRs to focus PCPs' attention on the treatments that would be recommended by pain specialists, thereby increasing PCPs' confidence and reducing their inclination to refer many patients to specialists. Finally, the links to more information will be helpful to those PCPs who are uncomfortable discussing pain and/or opioids with patients because of regulatory concerns or lack of knowledge. Specifically, the links will provide authoritative, "third-party" information that PCPs can refer to and convey to their patients.

We will work closely with UF&Shands administration and IT teams to design, test, and implement the decision support in the Epic EHR. We plan to leverage the EHR system's existing clinical reminder capabilities so that the pain management tools are feasible and well integrated with the workflows and system interfaces that are already familiar to PCPs.

Evaluation Design

Overview

We will conduct a randomized experiment in two family medicine clinics to compare the effect of the proposed intervention versus usual care. Half of the physician faculty in each clinic will be

randomized to receive the three-phase intervention. The remaining half will continue their current practice and serve as the control group. To isolate the marginal contribution of each phase of the intervention, we will first provide only education. Subsequently, we will add standardized data and decision support for the treatment group physicians. Before and after each phase begins, we will measure and compare treatment and control groups in terms of i) care quality, assessed as PCP adherence to UF pain protocols, ii) patient's pain, functional, and psychosocial outcomes, iii) physician and patient satisfaction with care, and iv) cost and utilization of pain-related care. We will obtain approval from the UF&Shands IRB prior to enrolling physicians or patients. Finally, during a six-month initial planning phase, we will work with Dr. Shuster (Co-investigator) to specific a detailed research design with complete power analysis. We will submit this design for review by the sponsor prior to beginning the experiment.

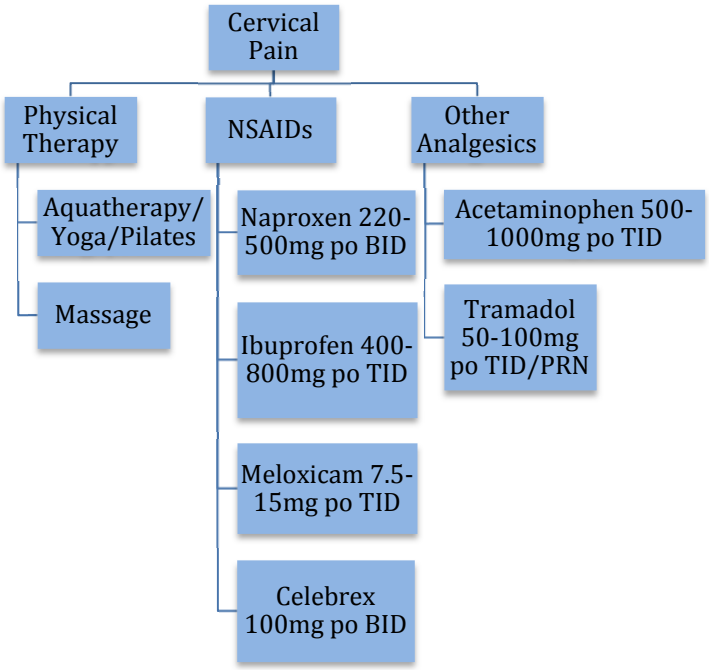

Figure 3. Example pain treatment protocol developed by Dr. Hurley and colleagues

Sample

Our evaluation will take place in the two largest UF&Shands family medicine clinics in Gainesville, FL. The two practice locations have 8 and 9 faculty PCPs respectively. We expect to enroll all faculty PCPs from each practice except Dr. Schmidt because he is a co-investigator on this project. Therefore, we expect to enroll 16 PCPs, 8 from each practice.

In terms of patients, our analysis will focus on adults who have chronic pain conditions and visit PCPs in the treatment or control group during the study period. Using the EHR scheduling and clinical systems, our research coordinator (i.e. project manager) will identify eligible patients. First, the research coordinator will identify patients with upcoming visits who have either a *recent* opioid prescription or a *recent* pain diagnosis (within 3-12 months of the upcoming visit). From this group, at the time of visit, the research coordinator will identify patients who have a *current* pain diagnosis or a *current* opioid prescription. Specifically, we will identify pain using

ICD9-CM diagnosis code from patient medical records that match one or more of the following diagnoses that are relevant to our focal pain conditions: 721.0, 721.3, 722.81, 722.83, 722.91, 723.1, 722.93, 723.0, 723.4, 723.8, 724.02, 724.2, 724.4, 729.1, 729.2, 729.5, 338.0, 338.1, 338.2, 338.4, 339, 346.0, 346.7, 350.1, 350.2, 350.9, 780.96, 784.0, 053.12. Based on their evidence of a pain condition lasting more than three months, these patients will be included in the study. As a preliminary understanding of sample size, in the 14 months spanning February 1, 2012 to March 31, 2013, approximately 2,210 unique adult patients with one of these diagnoses were seen across the two focal clinics. Moreover, of those patients, 1,343 had two or more documented instances of qualifying pain diagnoses. Therefore, in the 14-month proposed evaluation period, we are confident in obtaining a sufficiently large evaluation sample that includes multiple hundreds of patients in both treatment and control groups.

Procedure

Figure 4 summarizes the experimental procedure's timeline.

Recruitment and enrollment procedure – Our study team will first obtain informed consent from all PCPs. We will then randomly assign participating PCPs to treatment and control groups. Because of the small number of PCPs, we will use a stratified randomization procedure to control for PCP age and sex and to assign eight PCPs to the treatment group and eight PCPs to the control group.

Consistent with the procedures approved by the UF IRB, eligible patients with a recent pain diagnosis will be contacted via email and/or phone by their PCP, enrolled in the study, and asked to use an Internet-connected computer to log-in to the Epic MyChart patient portal and complete pain, function, and opioid risk assessment measurements (Table 3). These data will serve both as key outcome measures over the course of the study and as the standardized patient data that are provided to PCPs to aid treatment decisions. If patients are unable to report these data via MyChart, our study coordinator, in coordination with nursing staff, will be available on the day of their visit in the family medicine clinic to capture their data prior to seeing a physician. Our study coordinator will use a tablet computer to help patients report their data into a computer adaptive testing survey application that interfaces with the Epic EHR. Also, all patients will provide full informed consent before they are included in the evaluation.

Education procedure – After the six month planning period and after randomizing PCPs, we will introduce the education curriculum to treatment group PCPs and give them information on how to access the web-based content. Each in-person lecture will be offered at least twice at locations and times that are convenient to the participants. The lectures will only be available to PCPs assigned to the treatment group. Treatment group PCPs will log-in to a secure online training system. To measure actual exposure to the education, PCPs' login activity and in-person attendance will be tracked. We will allow three weeks for PCPs to complete the educational curriculum before collecting data on care quality, costs of pain-related care, PCP satisfaction, or patient outcomes. Also, the web-based content and in-person lecture materials will be made available to treatment group physicians for the duration of the study. The primary

analysis will follow an intent-to-treat approach, but secondary per protocol analyses will be conducted to exclude PCPs who do not complete the education.

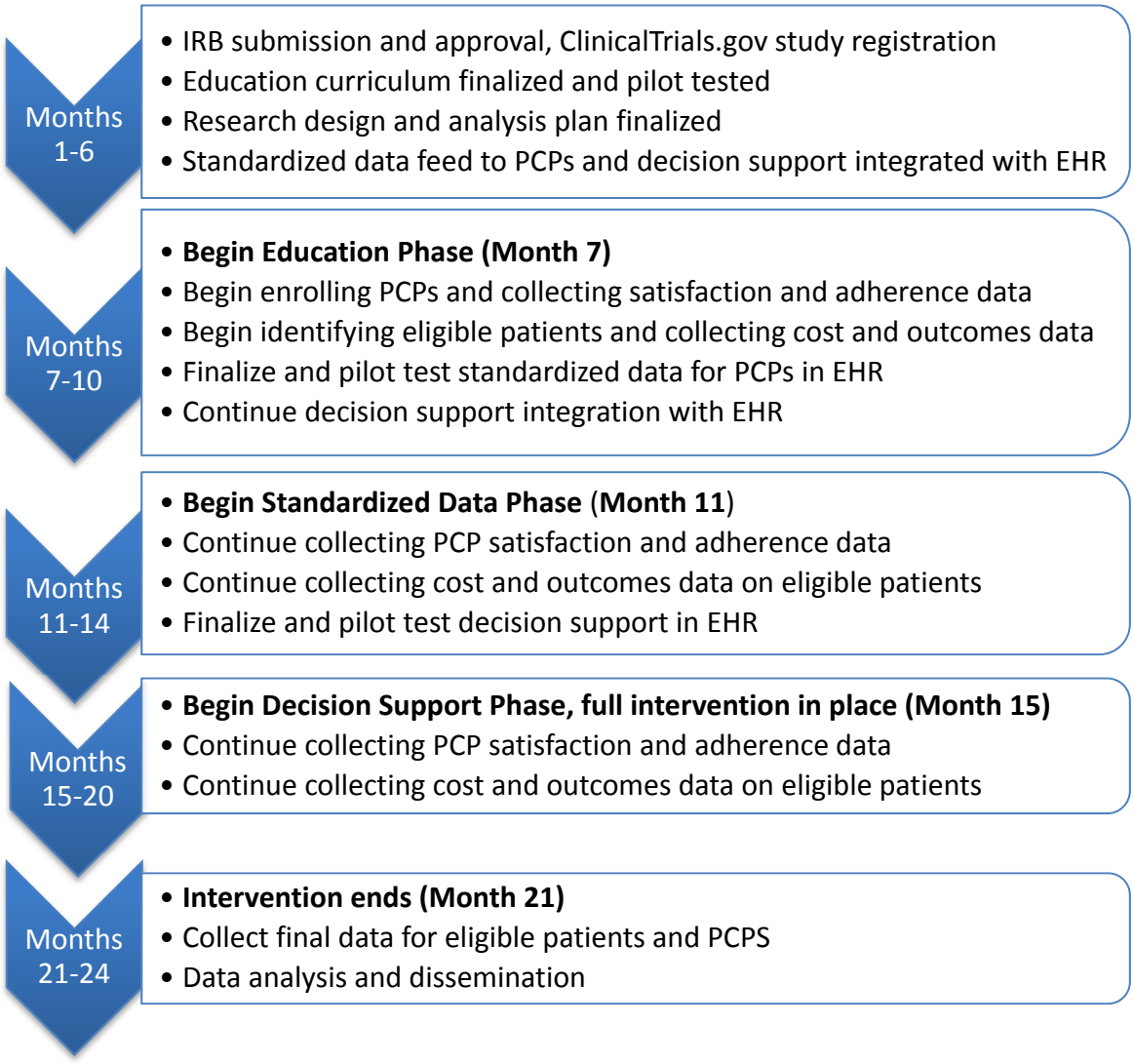

Figure 4. Overview of timeline for experimental evaluation of intervention

Standardized data procedure – The standardized data component of the intervention will be introduced to PCPs at the beginning of month 11. Prior to month 11, we will work with the UF&Shands clinical and Epic EHR teams to build and pilot test the technological and clinical workflow processes required for the patient-reported data to enter the EHR and be displayed to physicians via the **pain dashboard**. As described above, the data collection will rely on the National Pain Registry tools developed at Stanford and integrated with their Epic EHR system.

Decision support procedure – Five specific chronic pain protocols will provide the logic for the BTRs and links to more information at the beginning of month 15. Prior to month 15, we will work with the UF&Shands clinical and Epic EHR teams to build and pilot test the technological and clinical workflows associated with the decision support functions. We have budgeted for

both internal EHR programming staff and internal research informatics staff to ensure a successful implementation and the ability to collect relevant outcomes data.

Outcome Measures

Throughout the evaluation, we will assess multiple indicators of care quality, cost of pain-related care, patient outcomes and PCP and patient satisfaction (Table 3). Our research coordinator and PCP office staff will collect patient-reported outcomes using the EHR's patient portal, in person during office visits, or over the phone. Immediately following the three-week PCP education period, they will begin measuring these pain and functional outcomes and patient satisfaction. These data will be collected for the duration of the study. We will collect patient-reported outcomes prior to patient visits, immediately after patient visits, and monthly thereafter. Our research coordinator will oversee these procedures to ensure consistent, high quality data collection.

Our team of investigators will collect data on adherence to BTR measures, cost of care, and physician satisfaction through multiple internal data systems, including EHR audit tools, personnel survey tools, and the UF&Shands Integrated Data Repository (IDR). The IDR is a comprehensive clinical data warehouse that aggregates data from the Epic EHR and other clinical IT systems for research studies. The data for our evaluation will be extracted and loaded into the IDR using established IT processes. Notably, our team is well prepared to securely and efficiently collect and manage research data using the IDR. In particular, Dr. Harle is the UF faculty liaison to the IDR and works on a daily basis with the staff that load and extract research data from the IDR. For this study, Dr. Harle will work with an IRB-certified analyst who will extract and de-identify datasets that contain patient outcomes and relevant covariates (e.g., patient demographics, comorbidities) for analysis.

Data Analysis

We will statistically compare the intervention group to the control group across the outcome measures described above at multiple time points corresponding to the completion of each intervention phase. Also, we will compare patient outcomes and patient satisfaction for up to six months after their initial PCP visit to assess longer-term effects of the intervention.

The major comparative method for analysis will involve mixed linear models. The primary sampling unit will be the physician (N=16, 8 at each center with 4 of these on each treatment arm). Within each physician, the secondary sampling unit will be the patient (nested within physician). For variables that have baseline values, the dependent measure will be the change in last outcome score in the phase less that at baseline. For those scores that do not collect baseline scores, the dependent variable will be the post-test value. As a secondary analysis for those outcomes with repeated measures within a treatment phase, we will employ a repeated measures mixed model analysis with time nested within the patient, but we consider the final observation as the most clinically important an thus relegate repeated measures approach to secondary. The analysis will be conducted primarily by Dr. Harle with consultative and statistical programmatic support from Dr. Shuster, lead faculty and biostatistician in the UF Clinical and Translational Science Institute (CTSI) biostatistics core (see letter of support).

Table 3. Description of outcome measures

PCP measures	
Satisfaction – with managing chronic pain	Measured with literature-based survey scales at beginning of months 7, 11, 15, 19, 21. Data will be aggregated and extracted from IDR.
Quality – treatment choices consistent with BTRs (yes/no)	Measured at the visit level on an ongoing basis using EHR audit tools and IDR
Quality – Referrals to pain management, pain psychology***,*** physical therapy***;*** opioid, non-opioid Rx rates***;*** Use of urine toxicology screens; use of opioid risk screening tools	Measured at the visit level on an ongoing basis. Data will be extracted from EHR into the IDR for aggregate analysis.
Patient Measures	
Satisfaction – with chronic pain car received	Measured with literature-based survey scales following first PCP visit and monthly thereafter. Data will be aggregated and extracted from UF&Shands IDR.
Outcomes – pain ratings, pain interference, pain catastrophizing, physical function, fatigue, depression anxiety	Measured using validated scales from NIH PROMIS[15] and other published literature. Measured at first PCP visit and monthly thereafter.
Cost and Utilization Measures	
Specialist physician services	Measured as utilization and costs associated with pain and other specialist visits, including imaging and other tests. Data will be extracted from UF&Shands IDR.
Hospital services	Measured as utilization and costs associated with pain-related emergency department visits and hospitalizations (e.g., opioid related adverse drug events). Data will be extracted from UF&Shands IDR.
Non-physician services	Measured as utilization and costs associated with non-physician services (e.g., pharmacy, physical therapy). Data will be extracted from UF&Shands IDR.

Expected Change

We expect to observe statistically and clinically meaningful control-versus-intervention group improvements in patient pain and functional outcomes, PCP and patient satisfaction, care costs, and PCP use of recommended pain services, such as increased use of opioid screening tools, increased urine drug screens, and fewer pain specialist referrals. As this study's care model is a new and innovative venture, we cannot precisely quantify the expected differences on the basis of prior literature. As a preliminary estimate, we expect to see intervention group improvements ranging from 20-40% in the PCP behavior-oriented quality measures (e.g., PCP

use of recommended services, use of opioid screening tools, and pain specialist referrals). For the satisfaction, pain, and function measures, which are typically more difficult to affect, we expect 10-20% improvements in the intervention group relative to the control group. Dollar changes in costs are difficult to estimate because the intervention will likely increase some utilization (e.g. urine drug screening) and likely decrease other utilization (e.g. opioid prescriptions, imaging orders, and pain specialist referrals). However, we do expect the intervention to reduce high cost specialist visits and hospital service utilization.

Audience Engagement

We have strong support for this project from leadership in the UF College of Medicine and both family medicine and pain specialist faculty. With this support, we expect to obtain strong PCP engagement with the intervention. For the education phase of the intervention, we will track both online and in-person attendance to formally measure the extent to which PCPs complete the education. For the standardized data phase of the intervention, we will monitor completeness of the pain dashboard data elements. We will also continually monitor the three modes of patient data collection (i.e., patient portal, in-clinic, and phone) to ensure that patient data is reliably flowing into the EHR. We will also monitor PCPs' EHR use behavior to understand whether they are attending to the pain dashboard during visits with patients with pain. With respect to the decision support phase of the intervention, we will track the frequency with which BTRs are generated by the EHR for PCPs. We will also audit the EHR to measure the rate at which PCPs access the links to more information. Together, we expect these processes to maximize PCP engagement with the intervention and to let us fully interpret our evaluation results in light of PCPs' level of engagement.

Dissemination of Information

We will make the results of our program widely available. Within UF&Shands and regionally in Florida, we plan to disseminate our methods and results through seminars, grand rounds, and marketing of our education modules. Also, we expect to ultimately roll out the standardized data and decision support features of the intervention to family medicine and general internal medicine physicians across the UF&Shands health system in Gainesville and Jacksonville, FL. Also, we will collaborate with other academic health centers to conduct larger scale evaluations of our care model. Finally, we note that our interventions will be predominantly based on freely available education and measurement and informatics tools. We believe this approach will maximize the ability of many patients, physicians, and health systems to adopt and benefit from our intervention.

Nationally, we plan to disseminate our care model and outcomes to clinical and academic communities. We will publish our results beginning with submission of abstracts to professional meetings, such as the American Academy of Family Physicians, American Academy of Pain Medicine, American Pain Society, American Society of Regional Anesthesia and Pain Medicine, and Society for Medical Decision Making. We will follow these with manuscripts submitted to high-impact peer reviewed journals.

Detailed Workplan and Deliverables Schedule:

Narrative

Our research team investigators and staff will meet at least monthly for the duration of the project. The project Co-PIs and manager/coordinator will meet as a small group more frequently. Figure 4 (above) and the Table of Workplan and Deliverables Schedule (below) overview the proposed project's two year timeline and deliverables schedule. The first six months will involve five key studying preparation and planning activities: (1) IRB submission and approval; (2) ClinicalTrials.gov study registration; (3) finalizing and pilot testing the education curriculum; (4) specifying the final evaluation design and analysis plan; and (5) integrating the standardized data collection and decision support technologies in the UF&Shands EHR. We will deliver formal study updates to the sponsor quarterly or more frequently if requested. Quarterly updates to the sponsor will describe all implementation progress, data collection progress, data analysis progress, abstract/manuscript submissions, and any deviations from the plan described here. In the six month planning period, we will provide the sponsor with verification of our IRB approval and details of our design and analysis plan, including formal power analysis. We will begin recruiting physicians and identifying patients by month 6 and roll out the intervention based on the timeline shown in Figure 4. By the end of Year 1, we will submit abstracts describing the care model and presenting preliminary data to at least two national or international professional conferences. By the end of Year 1, to begin disseminating our care model to local PCPs, we will also deliver at least one local seminar to PCPs and/or clinical researchers who are not participating in our evaluation study. In Year 2, we will submit at least one additional abstract to a national or international professional conference and submit at least one manuscript to high-impact a peer reviewed clinical journal. In Year 2, we will also deliver at least two additional local seminars to PCPs and/or clinical researchers to disseminate our care model and results. In Year 2, we also expect to present one or both of our Year 1-submitted abstracts at national or international conferences. Finally, by the end of Year 2, we will prepare a draft grant proposal to seek funding for a study that further develops, evaluates, and disseminates our care model across multiple health systems and many more primary care practices.

Workplan and Deliverables Schedule Table

Planning Phase (Months 1-6)		
	Activity	**Deliverables**
Administrative	• Co-PI meetings (bi-weekly) • Full research team meetings (monthly) • Hire project manager/ coordinator • Hire EHR programmer	1. Quarterly progress reports 1 and 2 2. Completed education curriculum (web-based and in-person modules) 3. Evaluation study design specification, analytic plan, data management plan, and power analysis 4. Approved IRB protocol 5. ClinicalTrials.gov registration
Intervention	• Finalize and pilot education curriculum • Integrate standardized data collection in clinic workflows and EHR • Integrate decision support in clinic workflows and EHR	
Evaluation	• Finalize study design and analysis plan • Develop and submit IRB protocol	
Dissemination	N/A	

Education Phase (Months 7-10)		
	Activity	**Deliverables**
Administrative	• Co-PI meetings (bi-weekly) • Full research team meetings (monthly)	1. Quarterly progress report 3 2. Abstract 1 with care model and preliminary results submitted to professional scientific meeting
Intervention	• Rollout education curriculum to PCPs • Finalize and pilot standardized data collection • Integrate decision support in clinical workflows and EHR (*continued*)	
Evaluation	• Begin identifying, recruiting and enrolling PCPs and patients • Begin collecting data • Analyze preliminary data	
Dissemination	• Write and submit abstract • Attend local/national/international clinical and research conferences	

Standardized Data Phase (Months 11-14)		
	Activity	**Deliverables**
Administrative	• Co-PI meetings (bi-weekly) • Full research team meetings (monthly)	1. Quarterly progress report 4 2. Local presentation with care model and preliminary results to PCPs and clinical researchers 3. Abstract 2 with care model and preliminary results submitted to professional scientific meeting
Intervention	• Rollout standardized data (i.e. pain dashboard) • Finalize and pilot test decision support (*continued*)	
Evaluation	• Continue identifying, recruiting and enrolling PCPs and patients • Collect data (*continued*) • Analyze preliminary data (*continued*)	
Dissemination	• Write abstract(s) • Develop clinical and research presentations • Attend local/national/international clinical and research conferences	

Decision Support Phase (Months 15-20)		
	Activity	**Deliverables**
Administrative	• Co-PI meetings (bi-weekly) • Full research team meetings (monthly) • Renew IRB protocol	1. Quarterly progress reports 5 and 6 2. Yearly IRB protocol renewal 3. Local presentation with care model and preliminary results to PCPs and clinical researchers 4. National or international conference presentation(s)
Intervention	• Rollout decision support (i.e. BTRs and links to more information)	
Evaluation	• Continue identifying, recruiting and enrolling PCPs and patients • Collect data (*continued*) • Analyze preliminary data (*continued*)	
Dissemination	• Write abstract and manuscript • Develop clinical and research presentations (*continued*) • Attend local/national/international clinical and research conferences • Begin drafting follow-up grant proposal	

Dissemination and Close-out Phase (Months 21-24)		
	Activity	**Deliverables**
Administrative	• Co-PI meetings (bi-weekly) • Full research team meetings (monthly)	1. Quarterly progress reports 7 and 8 2. Local presentation with near-final results to PCPs and clinical researchers 3. Abstract 3 with near-final results submitted to professional scientific meeting 4. Manuscript submitted to peer-reviewed clinical journal 5. Draft grant proposal for follow-up study
Intervention	• End intervention and de-brief participating PCPs • Plan for widespread UF&Shands intervention rollout	
Evaluation	• End participant enrollment • End data collection • Analyze final data	
Dissemination	• Write abstract and manuscript • Develop clinical and research presentations (*continued*) • Attend local/national/international clinical and research conferences • Draft follow-up grant proposal (*continued*)	

References

1. Boscarino JA, Rukstalis M, Hoffman SN, et al. Risk factors for drug dependence among out-patients on opioid therapy in a large US health-care system. *Addiction.* 2010;105(10):1776-1782.

2. Fleming MF, Balousek SL, Klessig CL, Mundt MP, Brown DD. Substance Use Disorders in a Primary Care Sample Receiving Daily Opioid Therapy. *J Pain.* 2007;8(7):573-582.

3. Martell BA, O'Connor PG, Kerns RD, et al. Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction. *Annals of Internal Medicine.* 2007;146(2):116-127.

4. CDC. Prescription Painkiller Overdoses in the US. *Vital Signs* 2011; http://www.cdc.gov/vitalsigns/painkilleroverdoses/.

5. House Bill 7095. Prescription Drugs. 2011; http://flsenate.gov/Session/Bill/2011/7095.

6. Committee on Advancing Pain Research Care Education, Institute of Medicine. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.* The National Academies Press; 2011.

7. Østbye T, Yarnall KSH, Krause KM, Pollak KI, Gradison M, Michener JL. Is There Time for Management of Patients With Chronic Diseases in Primary Care? *The Annals of Family Medicine.* 2005;3(3):209-214.

8. American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. Practice Guidelines for Chronic Pain Management *Anesthesiology.* 2010;112(4):1-24.

9. Delitto A, George S, Van Dillen L, et al. Low back pain. *Journal of Orthopaedic and Sports Physical Therapy.* 2012;42(4):A1-57.

10. Manchikanti L, Abdi S, Atluri S, et al. American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: Part 2--guidance. *Pain Physician.* 2012;15(3 (suppl)):S67-116.

11. Stanford Center for Clinical Informatics. Open Source Pain Registry. 2012; https://clinicalinformatics.stanford.edu/projects/osregistry.html.

12. Butler SF, Fernandez K, Benoit C, Budman SH, Jamison RN. Validation of the Revised Screener and Opioid Assessment for Patients With Pain (SOAPP-R). *The Journal of Pain.* 2008;9(4):360-372.

13. FDA. FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioid Analgesics. 2013; http://www.fda.gov/downloads/drugs/drugsafety/informationbydrugclass/ucm277916.pdf.

14. Cella D, Riley W, Stone A, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. *Journal of Clinical Epidemiology.* 2010;63:1179-1194.

15. Revicki DA, Chen W-H, Harnam N, et al. Development and Psychometric Analysis of the PROMIS Pain Behavior Item Bank. *Pain.* 2009;146(1-2):158-169.

16. Chou R, Fanciullo GJ, Fine PG, et al. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J Pain.* Feb 2009;10(2):113-130.