

A. Goal: The goal of this study is to create and evaluate an electronic health record (EHR)-based strategy that promotes best practices in pain management for a large, multi-site primary care community health center network—the Institute for Family Health (IFH). The IFH comprises 19 full-time federally qualified health centers that provide primary care to over 85,000 highly diverse, economically disadvantaged and medically underserved patients in Manhattan, the Bronx, and Mid-Hudson Valley, New York. Our preliminary data show that chronic pain is prevalent in this population (27%) and long-term opioid therapy is commonly used. Like other primary care physicians (PCPs), those employed by the IFH rely on Health Information Technology (HIT) to promote best practices. This technology can potentially be used to expand therapeutic options for pain management and promote the safe and effective use of opioid therapy when this approach is indicated. The proposed study will establish a collaboration between the IFH and the Department of Pain Medicine and Palliative Care (DPMPC) at Beth Israel Medical Center, New York to create a novel and generalizable electronic health record (EHR)-based solution with physician education and other support, and evaluate this intervention in 6 of the IFH practices using a two-arm, randomized, waitlist-controlled design. The primary outcome analysis will assess changes in pain severity between treatment and control groups. Secondary analyses will evaluate both between-group differences in other patient-reported outcomes (pain interference, anxiety and depressive symptoms, health-related quality of life, and problematic drug-related behaviors) and within-patient changes in relevant variables for up to 1.5 years; formal and informal costs of pain care; and PCP uptake of the intervention and satisfaction.

Objectives: The goal of this project will be accomplished through a new collaboration between the IFH and the DPMPC, which will have the following objectives:

1. Create a novel EHR-based program, the ***Pain Management Support System for Primary Care (PMSS-PC)***.
2. Implement the PMSS-PC and an associated education/support program at 6 IFH primary care practice sites in Manhattan, the Bronx, and the Mid-Hudson Valley.
3. Evaluate the PMSS-PC in terms of both process and outcome data:
 - a. Evaluate uptake by the extent to which PCPs access and use the program and PCP satisfaction with the program.
 - b. Evaluate the effects of the PMSS-PC on patient-reported outcomes, including pain severity, pain interference, anxiety and depressive symptoms, health-related quality of life, satisfaction with pain care, and problematic drug-related behaviors by comparing patients whose physicians differed in access to the program.
 - c. Evaluate the effects of the PMSS-PC on cost of pain care by comparing post-implementation costs with the pre-implementation period.

B. Technical Approach: Both chronic pain and prescription drug abuse are enormous national public health problems (1, 2). Neither can be addressed without interventions that target the economically disadvantaged, medically complex populations treated by PCPs. The IFH's 19 full-time health centers employ 150 PCPs and serve over 85,000 predominantly low-income patients. Our census data demonstrate the high diversity of this population: of the 79% who

are adults 18 years or older (N=68,128), 15% are 18-24 years old, 71% are 25-64, 11% are 65 and older, and 62% are women. Among all patients, 33% are White non-Hispanic/Latino, 28% Hispanic, 22% African American non-Hispanic/Latino, and 2% Asian American.

The population has a high prevalence of chronic pain complicated by medical and psychiatric comorbidities. Access to pain care other than pharmacotherapy is limited, and PCPs' knowledge about pain treatments varies. Opioids are prescribed often, but practice variation raises concerns about the extent to which best practices are followed. A comprehensive approach is needed to improve access to high-quality pain care. Health Information Technology (HIT) can be the key to such an approach, and the IFH has an established track record in the use of EHR-based programming that promotes best practices. The proposed collaboration between the IFH and the DPMPC will meld this expertise in EHR-based programming with content expertise in pain medicine to create a generalizable HIT solution to the problem of PCP variation in the capacity to deliver safe and effective pain care.

1. Current Assessment of Need in Target Area:

To demonstrate the need for the proposed program, we evaluated various EHR-based data sources from 2011-2012, which together describe both the New York City and the Mid-Hudson practices of the IFH.

Prevalence of Pain

An analysis of pain scores obtained at the time of patient visits to the IFH practices suggest that nearly one-third of patients in the IFH population have clinically significant pain and about 1 in 5 patients have unrelieved, chronic moderate to severe pain for at least 3 months. Specifically, during May 2012, 9,189 patients attending IFH practices in New York City and the Mid-Hudson Valley provided pain scores. Of these patients, 27% (2,502) reported moderate or severe pain (3 or greater on a 0-5 numeric rating scale) during that visit and 16% had moderate to severe pain (3 or greater) on three or more consecutive monthly visits during the subsequent one-year period. The following diagnoses were most prevalent: back/lumbar/cervical pain (acute, chronic, unspecified); arthritis (osteoarthritis, rheumatoid arthritis, generalized joint pain, and other), and acute injury (contusion, sprain, fracture, and rupture).

Prescribing Patterns

During 2012, a total of 2,742 patients received multiple opioid prescriptions. More Caucasians (46%, N=1,252) were opioid-treated than other racial/ethnic groups (Table 1). Approximately half of those receiving opioids were older than age 50. Chronic pain patients who received opioid therapy were frequently prescribed both a long-acting opioid and a short-acting opioid for breakthrough pain.

Table 1: Prevalence of Prescribed Opioids by Racial/Ethnic Status: January-December 2012

	Total Patients	Opioid Therapy (%)
Asian American	1,833	26 (1)
African American	19,586	638 (23)
Caucasian	30,493	1,252 (46)

Multi-racial/American Indian or Alaskan/Native Hawaiian/other Pacific Islander	3,564	80 (3)
Declined/not collected/unavailable/other race	28,166	746 (27)
Total	83,642	2,742

	Total Patients	Opioid Therapy (%)
Hispanic/Latino	25,383	701 (26)
Not Hispanic/Latino	49,016	1,836 (67)
Not collected/unknown	9,243	205 (8)
Total	83,642	2,742

During May 2012, 133 physicians wrote a total of 2,536 prescriptions for opioids or NSAIDs for 2,127 patient visits. Approximately 16% of patient visits during this month ended with an opioid prescription; the most prevalent were oxycodone, tramadol, and methadone. The number of prescriptions per physician ranged from 1 to 155 during this month. The use of risk management strategies during the same period was limited even among high prescribers of opioids; urine drug-screening was used only 214 times during this month.

Provider Needs

Between January and March 2011, 77 PCPs who work for the IFH participated in a survey designed to evaluate prescribing patterns and documentation in the EHR system. According to chart reviews conducted for patient visits, 74% of all patients receiving opioids had a documented pain assessment and only 60% had a record of imaging results, consults, or a thorough history and physical examination to substantiate the diagnosis for which the controlled medication was being prescribed. Only 44% of the physicians performing the chart reviews reported that they would be comfortable refilling prescriptions as a covering provider. The results of this survey highlighted the variable clinical confidence and practice patterns in pain management in these settings and the lack of organizational standards for this work. As a result of the survey, the IFH developed a controlled substance policy and review committee. A follow-up survey completed in December 2011 suggested some improvement and underscored the need for more effort: 60% of physicians performing chart reviews expressed comfort with refilling prescriptions as a covering physician.

The proposed study dramatically addresses the related problems of poorly controlled pain in a complex population and provider need for practice support in pain management. We will create a novel EHR-based program—the ***Pain Management Support System for Primary Care (PMSS-PC)***—and evaluate it in 6 IFH practices, which together provide care to nearly 50,000 racially and ethnically diverse patients in Manhattan, the Bronx, and Mid-Hudson Valley. The new program is designed to affect PCP practice behavior and PCPs are expected to benefit through enhanced competency, confidence, and skills for treating pain. Patients receiving care from these PCPs are expected to directly benefit in terms of pain control and related outcomes. Potential reductions in the formal and informal costs of pain care related to the intervention may lead to additional patient, societal, and system benefits. After the study is completed, the

PMSS-PC will be disseminated to the rest of the IFH practices and made available to others nationally to use or adapt in the public domain.

2. Intervention Design and Methods:

The proposed intervention includes a novel EHR-based solution—the PMSS-PC—and an education/support program for PCPs in 6 large practice sites. Based on our preliminary data (see above), 16% of 47,209 patients in these 6 practices are expected to have moderate to severe chronic pain for ≥ 3 months. Thus, we expect this intervention to influence the care of at least 7,553 patients after its launch in the 6 practices ($47,209 \times .16$). We will collect longitudinal data from a sample of 600 of these patients. The methods are as follows:

Intervention: The team of DPMPC and IFH experts assembled for this project will adapt current evidence-based guidelines and best practices to create recommendations for pain assessment, use of primary disease-modifying therapy, strategies for management of acute pain, selection of therapies for long-term use, referral for non-pharmacologic therapies, and implementation of pharmacotherapy using non-opioid analgesics, “adjuvant” analgesics, and opioid analgesics. Most practice sites have access to various non-pharmacological therapies, including physical therapy, acupuncture, hypnotherapy, and cognitive-behavioral therapy, and these modalities will be referenced in the PMSS-PC. Variation in the availability of these modalities should not affect the evaluation strategy because of random assignment of the practices (see below). All analgesic prescribing will promote safety, proper dosing, and timely reassessment. Opioid-related best practices will focus on patient selection, risk stratification, structuring therapy commensurate with risk, opioid trial periods, assessment of outcomes, and management of non-adherence behaviors. The use of buprenorphine for pain will be incorporated.

This material will be programmed into the EHR primarily using a “best practice alert” format, which is already integrated into the system and used to promote best practices in health screening, and management of various chronic diseases, such as diabetes (see *Appendix 1*). Other elements that will be built in the EHR for this project include: informational screens, checklists, documentation requirements, and validated practice support tools. For the opioid section, the tools will include the CAGE-AID Questionnaire (3) to screen patients for substance use problems, the Opioid Risk Tool (4) for risk stratification, and the Pain Assessment and Documentation Tool (5) developed by our study team to help monitor treatment outcomes (see *Appendix 2*).

Concurrent with the EHR-based PMSS-PC, we will prepare an education/support program for PCPs that will include on-site education by a clinician educator (MD, PharmD or Nurse Practitioner pain specialist), 20-minute CME webinars on pain management, and a model of case review involving groups of providers reviewing challenging cases. We will plan on quarterly meetings of the latter groups, followed by transcription and dissemination of case discussions across the IFH network to illustrate best practices. The on-site education will be didactic and experiential, teaching skills that range from safe prescribing practices to motivational interviewing and reflective listening to promote trusting relationships with patients. These interactions also will explore specific PCP attitudes and beliefs about pain and

pain treatment that may enhance practice patterns and clinical management. Member of our study team have expertise with the application of these techniques in our prior studies (6).

Implementation: During the 3 month start-up study period, IRB approval for data collection will be obtained. Following this period, all practices participating in the project will enter another 3-month period for baseline data collection (see timeline Figure). Baseline data will be collected both from patients who meet entry criteria and sign consent, and from PCPs who agree to participate and also provide consent (see below). After this baseline period, 3 randomly-selected practices will implement the PMSS-PC and education/support program, while the 3 other practices will enter into a waiting period. Approximately 6 months later (see timeline Figure below), a second set of baseline data will be obtained from the 3 practices in the ‘wait control’ group and the program will be implemented in these practices.

Enhancing Implementation Fidelity: The implementation of the new PMSS-PC at each of the practices will involve a formal roll-out strategy and the availability of technical support and roll-out benchmarking—a model that has been used successfully by the IFH in the past (7). Ongoing discussions among collaborators on the IFH and DPMPC team have identified strategies for enhancing PCP uptake of the EHR-based solution and education/support program. These strategies, which will be incorporated into the roll-out, include the scheduled presence of a specialist-level clinician educator at each practice site and identification of a local practice champion at each site to address barriers and facilitators to uptake and encourage PCP participation.

3. Evaluation Design: A randomized controlled study design will be used to evaluate the impact of the PMSS-PC on pain and other patient-related and cost outcomes. We also will evaluate uptake of the program by the PCPs, and their satisfaction with it over time.

Participants and Eligibility: Adult (age ≥ 18 years) patients who are treated at the IFH will be eligible for participation in the study if the following inclusion/exclusion criteria are met:

- 1) Any type of chronic pain, defined as affirmative responses to all of the following questions:
 - a. Have you had pain in your body for the past three months or more?,
 - b. Is this pain often strong?, and
 - c. Does your pain stop you from doing things or does it make you very sad or nervous?;
- 2) English or Spanish as the primary language;
- 3) Willingness to complete questionnaires three times;
- 4) A commitment to return to the practice; and
- 5) No evidence of psychopathology or cognitive impairment severe enough to prevent informed consent or completing the survey instruments.

Possible participants for the trial will be identified by a Research Coordinator (RC) during practice hours by a 6-month look-back at pain scores and prescriptions listed in the EHR. Specifically, patients who have two or more recordings of pain scores of 3 or more on the 5-

point scale, or who are receiving long-term NSAID or opioid therapy, will be approached in the clinic or telephoned by the RC. If the patient is interested in participating, an eligibility checklist will be completed and those meeting all eligibility criteria will be asked to sign consent and complete the study questionnaires. Patients who are met in the practice will complete the questionnaires on a computer tablet; those who are telephoned will be able to provide consent by mail and complete the questionnaires at home either by pencil-and-paper (with return by mail), or by telephone interview.

Randomization and Data Collection: The proposed intervention will include six practices in the IFH. These will include 2 practices each in Manhattan, the Bronx, and the Mid-Hudson Valley. For randomization, practices will be blocked according to geographic location and randomly assigned to condition within block. One set of three practices will be randomly assigned to implement the intervention in month 6, after start-up and baseline data collection (Phase 1 implementation) (see timeline Figure). The other set of three practices will implement the intervention in month 14, after a wait period and a second baseline data collection (Phase 2 implementation).

Two baseline assessment periods will be completed prior to Phase 2 implementation; this will be done for two reasons: 1) to ensure that both groups will be assessed immediately before the intervention and then again 6 months later and 2) to allow statistical control of any between-group pre-treatment differences. The third assessment of the Phase 2 group at months 20-22 is another strength of this design; it will allow analyses that assess whether the effect of the intervention improves over time or whether Phase 2 patients “catch up” to Phase 1 patients.

Patients who attend the three practices in Phase 1 implementation (who have provided baseline assessment during months 3-6) will be re-contacted during later visits to complete two follow-up outcome assessments, the first during months 12-14 and the second during months 20-22. As noted, patients who attend the three practices that are assigned to Phase 2 implementation (who have provided baseline assessment during months 3-6 and during months 12-14) will be re-contacted during a later visit to complete one follow-up outcome assessment during months 20-22. Thus, patient assessment periods will occur simultaneously in all 6 practices in both intervention arms for the same duration of time (see timeline Figure).

Measures: Prior to the start of the intervention, patients and PCPs will complete a baseline questionnaire packet. This packet will include items that profile the respective samples, and for the patients, validated questionnaires that will be repeated at intervals during the project period. Additionally, process data will be collected from the EHR to evaluate uptake of the PMSS-PC by the PCPs.

Sample characteristics: Data to profile the patient sample will include: a) sociodemographics (age, sex, racial/ethnic status, primary language, marital/partnership status, educational level, employment status, annual household income, and insurance status); b) pain and pain treatment characteristics (pain diagnosis, pain severity, pain interference, and use of analgesics and interventional therapies); c) medical and psychiatric comorbidities, and d) social and family

history. For Spanish-speaking patients, the 5-item Language Use subscale of the *Marin and Marin Acculturation Scale* (8) will be used to assess linguistic acculturation. This subscale has good internal consistency and convergent validity (8) and assesses respondents' proficiency and preferences for speaking a given language in a particular context (e.g., which language do you read and speak; in which language do you think); items are rated using a 5-point Likert-type scale ranging from 1, "Only Spanish" to 5, "Only English" and are summed to create a subscale score. In addition, patients will be asked to respond to questions that evaluate the informal costs associated with pain care during the prior year.

PCP data will include demographics, practice site, level of training, years in practice, number of patients treated, and pain treatment practices, attitudes, and beliefs.

Patient Measures at Baseline and Outcome Evaluation: These measures will evaluate pain, other outcomes, and costs associated with pain care (see *Appendix 3*). All measures will be available in English and Spanish.

Pain and Pain Treatment Characteristics will include pain severity measured using the *Brief Pain Inventory Short-Form* (BPI-SF) (9). This widely-used and valid instrument measures average and worst pain during the past week on a series of 0-10 numeric rating scales. Factor analysis has identified a pain severity factor, which has good internal consistency, ranging from 0.80 to 0.87. Initial short-term (1 day to 1 week) reliability for ratings of pain "worst" (0.93) and "usual" or "average" pain (0.78) is high (10). Additionally, pain disability will be assessed using the 8-item *Patient Reported Outcomes Measurement Information System Short Form-Pain Interference* (PROMIS®-PI) (11). It measures the extent to which pain hinders engagement with social, cognitive, emotional, physical, and recreational activities, sleep and enjoyment in life over the past seven days. A score of 50 is the average for the U.S. general population with a standard deviation of 10. A higher PROMIS T-score represents greater pain interference. The Cronbach's α coefficient for the PROMIS-PI was 0.99, with reliability ranging from 0.96 to 0.99 for T-scores ranging from 50-80.

Health-related Quality of Life will be measured using the *PROMIS® Global Health-Short Form* (PGHSF, 12), a 10-item measure representing multiple domains that assesses self-reported global health. THE PGHSF measures general health, quality of life, mental health, physical health, pain, fatigue, social function, and emotional distress. (The effects of the pain item will be statistically accounted for during data analyses). Responses are rated on a 5-point Likert-type scale ranging from 1 to 5, except average pain which is rated on a 0-10 scale but recoded into a 5-point scale. The total raw score (range: 10 to 50) is converted to a standardized T-score with a mean of 50 and a standard deviation of 10. The scores can also be scored into two subscales, Global Physical Health and Global Mental Health. A higher T-score indicates better global health. The measure has a high internal consistency reliability of 0.92 and item-scale correlations ranging from 0.83 to 0.80 (12). The scale has been used to predict EuroQoL (EQ-5D) Index Scores (13).

Anxiety and Depressive Symptoms will be assessed using the *PROMIS® Anxiety-Short Form (PASF, 14)* and *Depression-Short-Form (PDSF, 14)*, 8-item measures that assess self-reported psychological symptoms in the past week. The *PASF* measures fear, anxious misery, hyperarousal, and somatic symptoms related to arousal. The *PDSF* measures negative mood, views of self, and social beliefs, as well as decreased positive affect and engagement. Responses are rated on a 5-point Likert-type scale, ranging from 1, “Never” to 5, “Always.” The total raw score (range 8 to 40) is converted to a standardized T-score with a mean of 50 and a standard deviation of 10. A higher T-score indicates greater anxiety or depression (15). Both measures have high internal consistency with the mean adjusted item-total correlation for the anxiety scale = 0.79, and 0.83 for the depression scale. The Cronbach’s α coefficients are 0.93 and 0.95, respectively (14). Both scales have been used in medical populations (16).

Problematic Drug-related Behaviors will be assessed when patients are prescribed opioid therapy for pain. These behaviors will be evaluated using two self-report measures, the *Current Opioid Misuse Measure (17)* and *Aberrant Drug Behavior Items (ADBI, 18)*. The *COMM* is a 17-item self-report measure assessing prescription pain medication use, and behaviors and attitudes. Items are assessed over the past 30 days, and involve human interactions, moods, rage, medication intake, and medication-related problems. Items are measured on a 5-point Likert-type scale ranging from 0, “Never” to 4, “Very often”. The scale has good internal reliability ($\alpha \geq 0.86$) and indicates whether the patient is abusing medications or exhibiting addictive behaviors (17). The *ADBI* (18) includes 12 questions in a self-report measure that assesses: overuse of prescription medicine, using alcohol or illegal narcotics in combinations with prescription medications, intoxication levels, and other dangerous behaviors or events related to the misuse of prescribed medicine (18, 19). Responses are measured on a frequency scale ranging, from “Never” to “4 or more times”.

In addition to these outcome measures, patient global satisfaction with pain care will be assessed using face-valid items administered every three months. Items will be rated using 7-point Likert-type scales developed for this project during start-up.

Costs associated with pain care will be assessed from EHR utilization reports and hospitalization data when available, and informal costs, assessed by patient interview, will measure spending on transportation, drugs, non-drug treatments, domestic support, and child care. We have used these items in our prior published studies (20, 21). For comparison, formal costs of pain care for the 12 month period preceding the intervention also will be obtained from the EHR; informal costs for the period prior to the implementation will be obtained through questions added to the baseline questionnaire.

PCP Satisfaction Measure: PCP satisfaction and self-rated use of the education/support program and the PMSS-PC will be elicited from all the professionals directly involved with the care of the patients. Items will be rated using 7-point Likert-type scales developed for this project during start-up. These will be administered every three months to all the physicians in the six practices.

Process Measures: Process measures are intended to evaluate the PCPs' uptake of the intervention and patient access to treatments. The EHR will be queried at four-month intervals to access this information. The program will be able to reveal the number of times that the PCP clicked on a Best Practice Alert related to pain, the number of times that a practice support tool or checklist was perused and completed, and the number of times that any educational document linked to the program was accessed. The EHR also will be queried to evaluate which pain treatments were prescribed and whether pain-related strategies (e.g., use of urine drug screening) were used. These treatments (including medications and referral for non-pharmacological therapies) will be compared to the six-month period prior to the roll-out of the program, again through interrogation of the data in the EHR.

Data Analysis

Analysis for Objective 3a. (Intervention Uptake): The process measures and PCP satisfaction items will provide information related to the uptake of the proposed intervention. These variables will be assessed in terms of time after the launch of the intervention, both within each of the implementation groups and between them during the last evaluation period. These analyses will evaluate the frequency of uptake variables using chi-square tests and changes over time in these variables and satisfaction using repeated measures ANOVA. Other analyses will categorize providers by high vs. low uptake and evaluate mediators (patient-, provider-, and practice-related) using logistic regression. We will also evaluate associations between the degree of PCP satisfaction toward the intervention and specific process variables (e.g., use of educational documents).

Analysis for Objectives 3b. and 3c. (Intervention Effects): The primary test will assess a difference in pain intensity (BPI-SF scores) between Phase 1 and Phase 2 patients during months 12-14 (when Phase 1 patients have been treated by PCPs exposed to the intervention for at least 6 months and Phase 2 patients have been treated by PCPs with no exposure to the intervention). A multilevel analysis approach will be specified to account for nesting effects (patients within physician within site). Treatment phase will be modeled at the physician level. The use of a mixed model approach will allow us to test the effects of a variety of other variables of interest as they relate to pain severity, including patient characteristics (e.g., disease), physician characteristics (e.g., adherence to the program), and their interaction. Group differences in pain severity will be tested again at the third assessment during months 20-22 (when Phase 1 patients have been treated by PCPs exposed to the intervention for at least 14 months and Phase 2 patients have been treated by PCPs with at least 6 months of exposure to the intervention). Secondary analyses will evaluate other outcomes using the same models; these include pain interference (PROMIS®-PI total score), anxiety symptoms (PASF total score), depressive symptoms (PDSF total score), health-related quality of life (PGHSF, total and subscale scores), and problematic drug-related behaviors (COMM total and subscale scores and ADBI total score).

Data also will be modeled longitudinally to test within-patients change over the three assessments as moderated by treatment condition (Phase 1 versus Phase 2). With baseline data prior to the intervention, longitudinal data from varying time periods of assessment, and

process data about PCP fidelity to the intervention, we also will be able to explore relationships between the intervention “dose” trends (e.g., time of exposure to the intervention, or at a physician level, differences in the extent to which the Best Practice Alerts are used) and effects on patient pain, function, or health-related quality of life.

A pre-post analysis of pain care costs will be conducted between baseline and the last outcome assessment that will evaluate the relationship between change in cost and change in pain.

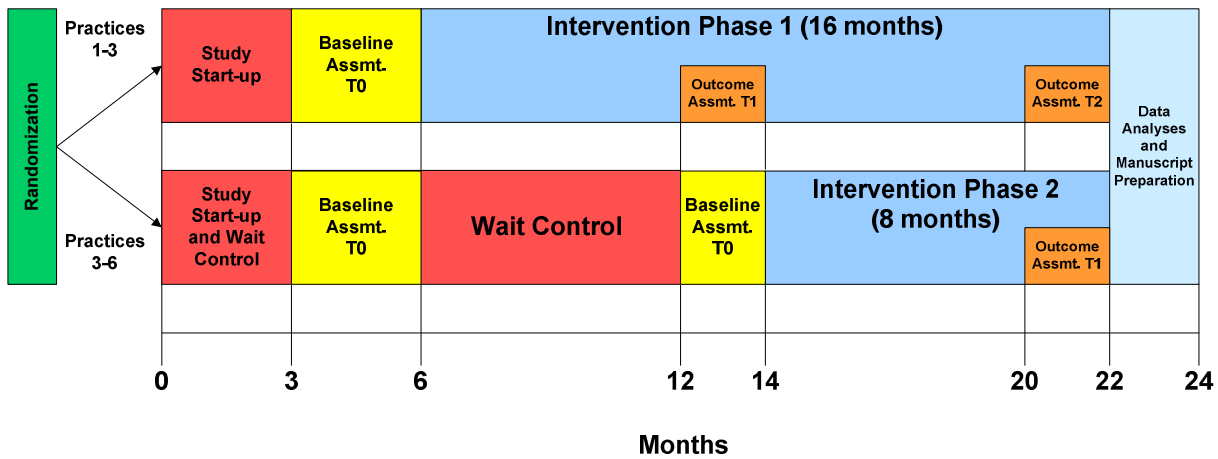
Sample Size and Power Analysis: The 6 practices of the IFH that will participate in the proposed study have a total census of 47,209 patients and employ 90 PCPs. Of the 47,209 patients, we anticipate that 16% (N=7,553) will have persistent, moderate to severe chronic pain and be eligible to participate. Of this number, we will randomly approach 1,225 patients and anticipate a minimum 70% acceptance rate (N=857) and a 30% attrition rate (N=600). Prior studies at the IFH have demonstrated high recruitment and retention rates, with retention in recent studies ranging from 72%-78% (7, 22, 23). Thus, we anticipate a final sample size of 600 patients completing all study measures by Year 2.

A multilevel power analysis using Optimal Design suggests that the proposed research will be amply powered with this sample size (24). For the purposes of power calculation, we selected the worst pain score on the Brief Pain Inventory-Short Form as the primary outcome. We assumed from our previous research (6) and the work of others (25, 26) that a $\geq 30\%$ reduction in baseline pain intensity at study end is considered to be a clinically meaningful improvement that would reasonably be expected (27). Assuming a starting average pain score of 5 and standard deviation of 2, a 30% reduction would yield an effect size of .75 standard deviation units (28-30). Patients will be treated by 90 physicians within six sites, yielding an average of approximately 7 patients per physician and 15 physicians per site. We have assumed that 25% of the variation in pain scores will be attributable to physician factors (i.e., intra-class correlation of .25). We have further assumed that blocking by geographic region will account for 5% of physician variability and that effect sizes may vary somewhat by site. Given these parameters, the model is highly powered (.99) and remains so assuming a more modest effect size of .50 (.84). In addition, the power of the study design will be improved by the inclusion of baseline covariates, which were not included in the power analysis. Thus, even assuming variability in the parameter estimates described above, the proposed design provides a robust test of the primary study hypothesis.

Dissemination Plan: The IFH will disseminate the PMSS-PC to all its sites after the completion of the study. Both the PMSS-PC and education program for PCPs will be generalizable to other PC practices nationally. Our commitment will include sharing of this program and publication of our results in leading journals and presentation at scientific conferences. Links to the practice support tools and other educational content (e.g., CME webinars) will be made available on websites for both the DPMPC (www.StopPain.org) and the IFH (www.institute2000.org).

Timeline:

Study Design: Creating and Evaluating a Primary Care Electronic Health Record (EHR)-based Model for Best Practices in Pain Management for an Underserved Population



C. Detailed Workplan and Deliverables Schedule

Deliverable Schedule: Grant period – July 2013 – July 2015	Completed by date
Randomization and Study Start-up	
1. Study team led by Dr. Russell Portenoy (PI, proposed study) will adapt current evidence-based guidelines to create recommendations for pain assessment, use of primary disease-modifying therapy, management strategies for acute pain, selection of therapies for long-term use, referral for non-pharmacologic therapies, and implementation of pharmacotherapy using non-opioid analgesics, “adjuvant” analgesics, and opioid analgesics.	9/30/2013
2. Non-pharmacological therapies will be referenced in the PMSS-PC as guided by pain experts (Dr. Portenoy, PI and Dr. Lara Dhingra, Co-I, proposed study).	9/30/2013
3. Obtain IRB approval at both study institutions – BIMC & IFH. Hire and train both Research Coordinators. Creation of study of study database. Programming of eight computer tablets.	9/30/2013
4. Study team will develop face-valid items for assessment of patient global satisfaction with pain care and PCP satisfaction with the program. Translation of patient consent form and specific study questionnaires not available in Spanish by certified medical translator.	9/30/2013
Preparation for Intervention Launch–Phase 1 Implementation	
5. Programming of EHR using a “Best Practice Alert” format, informational screens, checklists, documentation requirements, and validated practice support tools. Alpha and beta testing of PMSS-PC. Preparation for PMSS-PC in-serving on-site by IFH HIT team.	11/30/2013
6. Complete baseline data collection from patients.	12/31/13
7. Prepare content for the comprehensive PCP education/training program that will include technical support for the EHR, roll-out benchmarking, on-site education by a clinician educator, and 20-minute CME webinars on pain management (case review involving groups of providers discussing challenging cases).	12/31/13
8. On-site in-servicing by IFH HIT team for the first set of three practices.	12/31/13
Intervention Launch–Phase 1 implementation	
9. Intervention roll-out with PMSS-PC.	1/2/14
10. Identify and trouble-shoot problems with PMSS-PC. Fix bugs in program.	1/31/14
11. First quarterly on-site meeting with clinician educators providing PCP support with using PMSS-PC.	1/31/14
12. Second quarterly on-site meetings with clinician educators providing PCP support with using PMSS-PC.	5/31/14
13. Complete 1 st outcome assessment.	8/31/14
14. Third quarterly on-site meetings with clinician educators providing PCP	9/30/14

support with using PMSS-PC.	
15. Fourth quarterly on-site meetings with clinician educators providing PCP support with using PMSS-PC.	1/31/15
16. Complete 2 nd outcome assessment.	4/31/15
Preparation for Intervention Launch–Phase 2 implementation	
17. Complete 1 st baseline data collection from patients.	12/31/13
18. Complete 2 nd baseline data collection from patients.	8/31/14
19. On-site in-servicing by IFH HIT team for the second set of three practices.	8/31/14
Intervention Launch–Phase 2 implementation	
20. Intervention roll-out with PMSS-PC.	9/1/14
21. First quarterly on-site meeting with clinician educators providing provider support with using PMSS-PC.	9/30/14
22. Second quarterly on-site meetings with clinician educators providing provider support with using PMSS-PC.	1/31/15
23. Complete outcome assessment.	4/31/15
Team Meetings	
24. Twice monthly senior leadership team meetings (48 meetings starting 7/21/13)	4/31/15
25. First quarterly study team meeting.	7/31/13
26. Second quarterly study team meeting.	10/1/13
27. Third quarterly study team meeting.	1/2/14
28. Fourth quarterly study team meeting.	4/1/14
29. Fifth quarterly study team meeting.	7/1/14
30. Sixth quarterly study team meeting.	10/1/14
31. Seventh quarterly study team meeting.	1/2/15
32. Eighth quarterly study team meeting.	4/1/15
Provider ‘Challenging Cases’ CME Webinars	
33. First provider CME webinar for first set of three practices.	2/29/14
34. Second provider CME webinar for first set of three practices.	4/30/14
35. Third provider CME webinar for first set of three practices.	6/30/14
36. Fourth provider CME webinar for first set of three practices.	8/31/14
37. Fifth provider CME webinar for all six practices.	10/31/14
38. Sixth provider CME webinar for all six practices.	12/31/14
39. Seventh provider CME webinar for all six practices.	2/28/15
40. Eighth provider CME webinar for all six practices.	4/30/15
41. Data analysis and manuscript preparation.	7/1/15
42. Disseminate EHR model, program content, and results to other PC practices through publication, presentation, and community outreach.	7/1/15

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