A. COVER PAGE

Title
Redesigning Chronic Pain Management in Primary Care: Improving Coordination, Outcomes, and Experience

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Abstract: 247 words

At the Palo Alto Medical Foundation (PAMF), a multi-specialty integrated ambulatory-care delivery network of Sutter Health in Northern California, we are changing the culture around what it means to take care of patients with non-cancer chronic pain (CP). Through a CP Management Redesign (CPMR) program, we are shifting from an outdated model that promotes procedures and medicines as a means to alleviate symptoms to a care-coordinated approach that empowers patient autonomy in guided self-management. Our CPMR targets primary-care providers, appropriate specialists, community-dwelling CP patients, and their families/caregivers.

The **primary objectives** of the CPMR are to: (i) ***Educate*** providers on evidence-based management of CP; (ii) ***Develop*** Electronic Health Record (EHR) tools, Shared Medical Appointments, and web-based content to facilitate CP management; (iii) ***Evaluate*** the implementation and impact of the CPMR program; and (iv) ***Disseminate*** findings, share best practices, and implement the program throughout Sutter Health.

We will evaluate the implementation process using the RE-AIM framework. We will use data from the PAMF EHR, administrative databases, and patient and provider surveys to assess program impact. Using a combination of methods, including interrupted time-series analysis and a matched-control comparison with patients across four Sutter Health ambulatory-care regional divisions, we will measure: (i) medication (opioid) prescribing patterns; (ii) patient-reported pain and functional outcomes; (iii) care coordination; (iv) provider engagement/satisfaction; patient engagement/satisfaction; and (v) healthcare costs.

We *hypothesize* that the CPMR program will reduce and make opioid use safer; improve care coordination, patient outcomes, and patient and provider experience; and reduce costs.

B. TABLE OF CONTENTS

C. PROPOSAL

C1. Overall Goals and Objectives

Like most of the United States, opioid prescribing for non-cancer chronic pain (CP) in California has increased dramatically over the last decade. A study of the California Workers' Compensation System found that prescriptions for schedule II opioids increased nearly six-fold from 1.3% in 2002 to 7.3% in the first-half of 2013.[1] Deaths associated with opioid analgesics in California have increased 16.5% since 2006.[2] In response to this public health issue, the California Department of Public Health established a working group to explore opportunities to address opioid misuse, and in October 2014 the Medical Board of California revised its guidelines for prescribing controlled substances for pain.[3] At the same time, the Agency for Healthcare Research and Quality released a report, which found limited evidence to support chronic opioid treatment in CP management; in fact, evidence showed that opioids increase the risk of harmful effects in a dose-dependent manner.[4] If there were ever a need for a "call to action" to change the status quo in CP management, that time is now.

The majority of healthcare providers and patients expect that successful outcomes equate to patients being pain-free. Most still believe CP represents a failure in diagnosis and/or in finding the right procedure or enough medications to cure the problem.[5] Patients and their healthcare providers seek pain relief as a primary treatment goal. Without understanding and accepting that some pain cannot be cured, primary-care providers (PCPs) often turn the locus of control for pain management to external providers. The result is increased opioid prescribing, fragmented care, and rising healthcare costs, but no real solution to the "pain" problem.

At the Palo Alto Medical Foundation (PAMF), a multi-specialty integrated ambulatory-care delivery network of Sutter Health in Northern California, PCPs and many specialists are challenged with patients whose care needs are focused on alleviating pain symptoms associated with chronic conditions. As a result, we are changing our culture around what it means to take care of CP patients. We are shifting from an outdated model that promotes procedures and medicines as a means to cure the underlying etiology of pain, or alleviate symptoms, to a care-coordinated approach that empowers patient autonomy in guided self-management. To this end, our multi-disciplinary providers (PCPs and appropriate specialists) will collaborate with a local pain management expert, Managed Care medical directors, PAMF and community behavioral health and complementary medicine providers, and our patients and their families/caregivers. Together, we will change the framework for CP management through a CP Management Redesign (CPMR) program. In applying for this funding we seek to better evaluate this effort.

The **primary objectives** of the CPMR are to: (i) ***Educate*** providers on evidence-based management of CP; (ii) ***Develop*** Electronic Health Record (EHR) tools, Shared Medical Appointments (SMAs), and web-based content to facilitate CP management; (iii) ***Evaluate*** the implementation and impact of the CPMR program; and (iv) ***Disseminate*** findings, share best practices, and implement the program throughout PAMF and Sutter Health.

C2. Technical Approach

PAMF is dedicated to improving patient-centered outcomes, including the experience and quality of care. Senior Leadership at PAMF has recognized CP as a priority due to its prevalence, economic impact, and burden on patients' quality of life. Leadership is committed to developing and implementing the CPMR program throughout all PAMF Divisions (Palo Alto, Camino, Santa Cruz, Alameda) (see **Letter of Commitment from Drs. Slavin and Vilardo**), and PAMF physicians are eager for the program to begin. This program includes educating providers and developing appropriate resources for the evidence-based management of CP, and is targeted at providers, CP patients, and their families/caregivers.

Provider education will begin with a series of Continuing Medical Education (CME)-accredited Boot Camps, which will be presented by Dr. William Brose, a locally-based, nationally recognized pain management expert and advisor to the California Medical Board on pain (see **Letter of Commitment from Dr. Brose**). The focus of the Boot Camps will be to improve: (i) knowledge of current evidence-based best practices in CP management and guidelines on opioid prescribing; (ii) providers' confidence in their ability to management CP; (iii) EHR documentation and CP care coordination; (iv) referral to pain specialists and SMAs; (v) use of non-pharmacological interventions (including behavioral therapy, physical therapy, and complementary community services [acupuncturists, chiropractors]); and (vi) support for patient empowerment in self-management.

With Dr. Henry Thai, PAMF EHR Physician Champion, we will develop and customize EHR tools to facilitate CP management, including documentation of pain intensity and functional scores, morphine equivalent dosing, and use of point-of-care resources (see **Letter of Commitment from Dr. Henry Thai**). EHR tools will also facilitate documentation of patients' risk for opioid abuse, and referrals to pain consultants, psychologists, physical therapists, community services, and SMAs. SMA content will be developed by Dr. Brose and Dr. Bronstein. Dr. Brose will provide up-to-date information that skilled PAMF clinicians will deliver directly to patients. A "rapid cycle" improvement process will be used, involving patient, caregiver, and provider feedback, to optimize the SMA content and process for PAMF. Additional content will be offered to patients and their caregivers online (e.g., PAMF website and MyHealthOnline, a secure patient messaging portal). In addition, Dr. Simran Singh, a PAMF psychiatrist, will oversee development of behavioral health resources to support coordination between PAMF and community providers/services for CP patients (see **Letter of Commitment from Dr. Singh**).

We will evaluate the implementation of the CPMR program using the RE-AIM framework.[6] We will carry out a robust, valid evaluation of the impact of the CPMR program with data from the PAMF EHR, administrative databases, and patient and provider surveys. Using a combination of methods, including interrupted time-series analysis and a matched-control comparison with patients across the four other Sutter Health ambulatory-care regional divisions, the following outcome measures will be used to assess CPMR impact: (i) medication (opioid) prescribing patterns; (ii) patient-reported pain and functional outcomes; (iii) care coordination; (iv) provider engagement/satisfaction; patient engagement/satisfaction; and (v) healthcare costs. Through rapid cycle improvement processes, evaluation of implementation, and evaluation of impact, we will identify any areas where gaps remain and further changes are needed. Following this

evaluation, which will be carried out in collaboration with the PAMF Research Institute, findings will be disseminated throughout Sutter Health, with the goal of sharing best practices, involving local providers and administrators in adapting the program as appropriate, and implementing it system-wide.

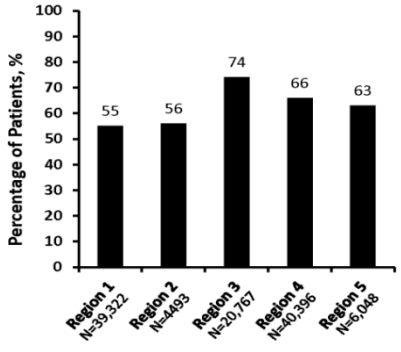
This project is responsive to the RFP and aligns with the Triple Aim framework developed by the Institute for Healthcare Improvement.[7] Through the CPMR program, we seek to: (1) **improve the patient experience of care** by providing clinicians and patients with the knowledge and tools to better manage CP and to shift treatment goals from complete pain relief to better functional status and quality of life; (2) **improve population health** through safer medication use, including but not limited to opioids; and (3) **reduce the overall cost of care** through improving care coordination and minimizing unnecessary use of healthcare resources.

C3. Current Assessment of Need in Target Area

Methods. The PAMF CPMR program has been informed by a thorough baseline assessment. We collected data retrospectively from the Sutter Health EHR to identify patients with non-cancer CP. Patients were included in the evaluation if they had ≥2 ICD-9 encounter diagnoses for a CP condition in 2012 that were ≥30 days apart and had ≥1 encounter of any type prior to 2010 to confirm prior health system contact. Patients were excluded if they had an ICD-9 diagnosis for a malignancy in the two years prior to 2010 or had surgery in the three months prior to the first CP encounter in 2012. Data were extracted on patient characteristics and the catchment area of Sutter Health (one of five ambulatory-care regional divisions) in which the patient received care. We also performed longitudinal analyses of opioid prescriptions written between 2001 and 2013, regardless of ICD-9 diagnoses for CP. As a complement to this quantitative analysis, we spoke directly with providers to better understand their needs in CP management.

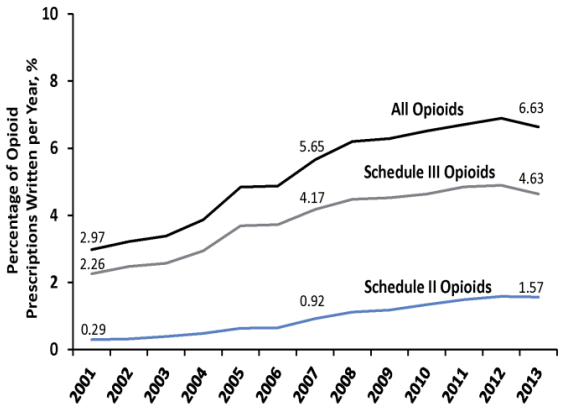
Results of Quantitative Analysis. Among 915,554 active Sutter Health patients in 2012 with sufficient EHR history, we identified 120,481 patients (13%) meeting the above criteria for non-cancer CP. Altogether, 111,026 patients (92%) were prescribed a pain medication in 2012. Of these, 69,093 (63%) were prescribed an opioid analgesic. Opioid prescribing across the five regional divisions at Sutter Health ranged from 55% to 74% (**Figure 1**). We explored predictors of opioid prescribing with multivariable logistic regression models (see **Appendix 1**). After controlling for individual CP conditions, females had 8% lower odds of having an opioid prescribed than males; patients with an overall greater disease burden and those with more concurrent CP conditions, each, had 50% higher odds of having an opioid prescribed; African Americans had 17% higher odds of having an opioid prescribed than non-Hispanic whites, whereas patients of all other races/ethnicities, including Asian Americans, had lower odds; Medicare and Medicaid beneficiaries had 34% and 177% higher odds, respectively, of having an opioid prescribed than commercially-insured beneficiaries.

FIGURE 1. Opioid Prescribing by Region. Percentage of chronic pain patients prescribed an opioid among those with any pain medication in 2012 (N=111,026).



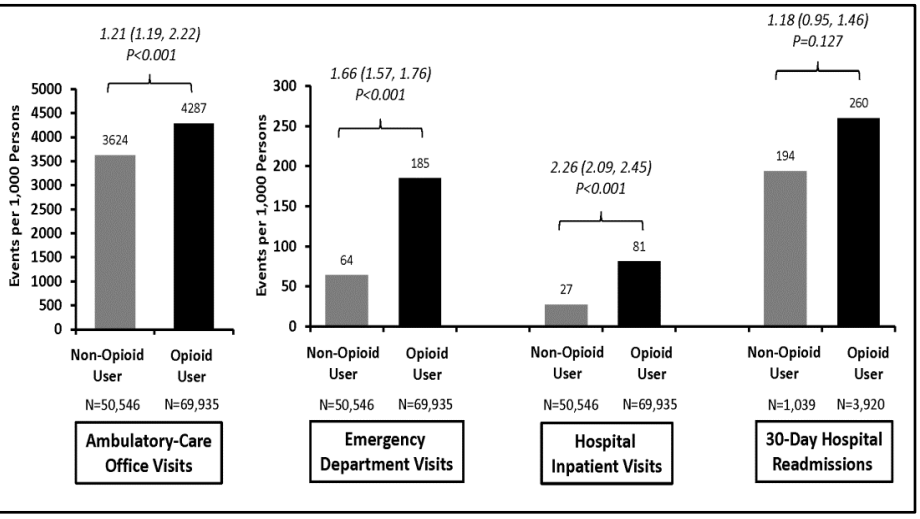
As a proportion of total prescriptions, opioid prescribing increased from 3% in 2001 to 6.6% in 2013, representing a 2.2-fold rise (**Figure 2**). The proportions of prescriptions written for schedule-II and schedule-III opioids have increased 5.4- and 2-fold, respectively, during this time. Schedule-II opioids comprised one-quarter of all opioid prescriptions written in 2013, a figure that has more than doubled since 2001 (see **Appendix 2**).

FIGURE 2. Trends in Opioid Prescribing over Time. Percentage of opioids prescribed per year among all prescriptions written.



Healthcare utilization rates in 2012 were higher among CP patients prescribed opioids than those not prescribed opioids in that year (**Figure 3**). After statistical adjustment for patient demographics, clinical characteristics, and use of healthcare resources in the previous six months, rates of ambulatory-care office visits, emergency department visits, and hospitalizations in 2012 were, respectively, 21%, 66%, and 126% higher in opioid users vs. non-opioid users. Among CP patients with a primary hospitalization in 2012 (N=4,959), 30-day hospital readmission rates were numerically higher among opioid-users than non-opioid users; however, this was not statistically significant after adjusting for important confounders.

FIGURE 3. Healthcare Utilization by Opioid Use. Events per 1,000 persons with CP in 2012 shown for each type of healthcare resource. Adjusted incident rate ratios (95% CI) for Opioid Users versus Non-Opioid Users (referent) were derived from negative binomial regression models with statistical adjustment for patient age, sex, race/ethnicity, disease burden, number of pain conditions, and prior utilization



The Santa Cruz Division of PAMF currently has one SMA for CP management, titled "Healing Pain", which has been available since November 2013. In 2014, attendance was modest. A total of 122 unique patients attended this SMA; patients attended an average of approximately two sessions (range, 1-7). Overall, electronic documentation of SMA referrals was poor.

Results of Qualitative Analysis. PAMF Providers from the Family Medicine Department said the following about managing patients with CP.

- *Provider 1: "...[chronic pain patients] are some of the most challenging as well as time consuming patients…primary care providers are not well educated on the best care for chronic pain patients. Our training (and the knowledge base) was inadequate at the time that most of us were trained."*
- *Provider 2: "The way chronic pain patients are managed now often results in chaos and confusion for the patient as well as for the provider and staff. "*

Gaps and Opportunities. Our baseline assessment highlights several gaps in care, offering significant opportunities to improve the management of CP. These gaps will be directly addressed by the CPMR program and are aligned with the RFP goals and Triple Aims of improving the Patient Experience of Care (PE), Population Health (PH), and reducing the Cost of Care (CC), (**Table 1**). The CPMR program targets providers, CP patients, and their caregivers.

TABLE 1. Gap Analysis

Gaps in Care	Opportunities (Triple Aim Alignment)
Non-cancer CP affects more than one in ten patients at Sutter Health, and primary-care providers are challenged with the current pain management system	▪ Give providers the necessary knowledge and tools to better and more confidently manage patients with CP **(PE, PH)** ▪ Set pain management expectations, shifting from complete pain relief to self-empowered goals of improved functional status and quality of life **(PE, PH)**
The vast majority of CP patients receive pharmacologic treatment, and of those, two-thirds are prescribed opioids	▪ Promote use of non-pharmacological interventions and skill building through SMAs and behavioral health support systems **(PE, PH)** ▪ Improve coordination of care with pain specialists and other healthcare professionals (pain psychologists, physical therapists, and other community providers) **(PE, PH, CC)**
Opioid prescribing is increasing, and differs across Sutter Health's regions. Regardless of CP condition, opioid prescribing across CP patients varies based on demographics	▪ Standardize practices of opioid prescribing, ensure appropriate duration and safe dosing of therapy in compliance with Medical Board of California guidelines **(PH, CC)**
Opioid use is associated with higher rates of utilization of most healthcare resources	▪ Minimize *chronic* opioid use/misuse to prevent unnecessary harm **(PH, CC)**
Modest use of CP SMAs in a single PAMF Division; poor documentation of referrals	▪ Widen reach of CP SMAs throughout PAMF **(PE, PH, CC)** ▪ Improve documentation and track referrals within and outside the system **(PE, PH, CC)**

C4. Project Design and Methods

Overview. The CPMR program will be implemented and evaluated across PAMF's four divisions. The CPMR program comprises CME-accredited Boot Camps and the development of resources for providers and patients and families/caregivers. Overall, we expect to impact approximately 500 PAMF providers who typically manage CP patients or prescribe opioids, including PCPs (i.e., physicians, physician assistants, and nurse practitioners) and appropriate specialists (e.g., neurologists, physiatrists, rheumatologists). Importantly, this program will have the opportunity to impact nearly 45,000 patients with non-cancer CP at PAMF. Ultimately, we hope that this program will reach all of Sutter Health's patients with non-cancer CP, which is estimated at more

than 120,000. This project, including implementation and evaluation, will be conducted over a 20-month period.

Boot Camps. Dr. Bronstein (PI) and Dr. Brose are developing content for CME-accredited Boot Camps. We expect to run four 2.5 hour sessions, one at each PAMF Division, with approximately 125 attendees at each session. Boot Camps will focus on shifting the culture of managing CP, moving toward an understanding that "the tissue is not the issue". The goals of the Boot Camps are to improve: (i) knowledge of current evidence-based best practices in CP management and guidelines on opioid prescribing; (ii) providers' confidence in their ability to manage CP; (iii) EHR documentation and care coordination; (iv) referral to pain specialists and SMAs; (v) use of non-pharmacological interventions (including behavioral therapy, physical therapy, and complementary community services); and (vi) support for patient empowerment in CP self-management.

Content will be delivered by Drs. Bronstein and Brose, but other presenters are scheduled to speak on the topics of behavioral assessments and treatments, CP rehabilitation, physical therapy, and self-management. See **Appendix 3** for the Boot Camp agenda and learning objectives.

CME-accredited Boot Camps will go beyond documentation of attendance as a means of assessing course completion. For the successful adoption and sustainability of the CPMR program, it is necessary to fully engage providers, and ensure they understand educational content and are willing and able to apply this knowledge in clinical practice. To this end, in developing Boot Camp content, we have adopted components of the "Integrated Planning and Assessment Throughout Learning Activities" framework, as described by Moore and colleagues.[8] Boot Camp concepts will be reinforced through case studies in which providers can demonstrate their knowledge during real-time polling (www.polleverywhere.com). Following Boot Camps, providers will participate in simulated-SMAs, in which the core content of patient education will be presented and modeled. In this setting, providers will have the opportunity to role play and receive feedback from Dr. Brose in real-time. CME accreditation for simulated-SMAs is underway.

We are developing questionnaires to assess providers' satisfaction with Boot Camps and simulated-SMAs, as well as their engagement and knowledge. Drafts of provider questionnaires are shown in **Appendix 4**. Based on Moore's framework, questionnaires were designed to evaluate whether providers' needs were met and their confidence in treating patients with CP; other data collection (above) will determine whether they "*know what* to do", "*how* to do", and "can *show how* to do". We will administer the questionnaires immediately before and after the Boot Camp and simulated-SMAs, and at three and six months follow-up. We will survey providers at multiple time points because it is possible that, immediately after attending a Boot Camp or simulated-SMA, providers may feel less confident in their CP management skills than they did before; this, however, will improve over time as they apply their new skills and use the available EHR and system resources. Their satisfaction with the Boot Camp and simulated-SMAs also may increase with experience.

EHR Resources. We are developing EHR-embedded resources appropriate for point-of-care use. These include tools for documenting–patient-reported pain intensity and functional interference, risk of opioid use/misuse, and referrals. Resources will also allow providers to develop

structured care plans, obtain informed consent for opioid use, and execute pain contracts. These components are discussed in detail below.

1. *Patient-Reported Pain Intensity and Interference*. Providers will be able to document in the EHR patient-reported pain intensity and functional impact of CP using the validated PEG three-item-scale (**Appendix 5**) adopted from the Brief Pain Inventory survey.[9] PEG was specifically designed for use in clinical practice, as opposed to a research setting, and measures pain intensity (P), interference with enjoyment with life (E), and interference with general activity (G). This very brief tool will help providers to quickly assess the severity of pain and interference with function; set realistic goals for achieving improvements in pain symptoms and quality of life; evaluate discrepancies between patient perceptions of functional status and other test results/observations; and develop a care plan that is consistent with treatment goals. Furthermore, the survey will be used at follow-up encounters to track improvements or setbacks and modify patients' care plans accordingly. Because this information will be documented in the EHR, it will be visible to all providers who care for patients at Sutter Health.

2. *Opioid Use/Misuse & Risk Stratification*. Newly developed EHR tools will facilitate documentation of appropriate opioid morphine equivalent dosing, which is not available in the current EHR system. Furthermore, providers will have access to point-of-care resources for counseling patients on appropriate opioid use, obtaining informed consent, and executing pain contracts. Providers will also be able to assess a patient's individual risk for opioid abuse using a validated opioid risk tool (see **Appendix 6**).[10]

3. *Structured Care Plans*. A significant contributor to fragmented care for patients is the lack of structured care plans. We will build a platform in the EHR for structured CP care plans that are visible to all providers to facilitate care coordination.

4. *Referrals*. Another contributor to fragmented care is poorly documented referrals. In the current system, referrals may be only captured (inconsistently) in chart notes. EHR tools are being developed to track when referrals are made and to which type of provider or service (e.g., SMA), both within and outside the Sutter Health system. These referrals can subsequently be reconciled. For example, when a PCP refers a patient to a pain specialist she can document this in discrete fields in the EHR. When the patient visits the specialist, at least within the Sutter Health system, the specialist can document that the patient sought the referral; this will be visible to the PCP and all other providers. If the referral was not sought by the next visit, the PCP can determine from patient self-report if the referral was never sought or if care was sought from a provider outside of the Sutter system. In combination with structured care plans that are visible to all providers, improved documentation of referrals in the EHR will augment care coordination, which ultimately can help reduce costs.

SMAs. Patients and providers working together in group settings, such as in SMAs, can build communities of support for patients. SMAs for chronic medical conditions have been shown to improve patients' satisfaction with care and quality of life,[11,12] and reduce emergency department visits.[13] PAMF has SMAs for various conditions, including but not limited to cardiac disease, diabetes, and weight management. Currently, one SMA, "Healing Pain", is available to CP

patients in the Santa Cruz Division. Dr. Bronstein is working with Dr. Brose to develop content for additional SMAs, which will be available in late 2015 within all PAMF Divisions, so as to have wider reach to patients. We will develop two "core" SMAs, which will promote guided self-management of pain, and shift expectations of treatment from complete pain relief to improved functional status and quality of life. We may develop additional SMAs focusing on topics that may be of interest to patients based on areas identified in the "core" SMAs (e.g., mindfulness techniques). Dr. Brose will provide up-to-date information to skilled PAMF providers, who will become the local experts. PAMF experts will then deliver SMAs directly to patients. Dr. Brose will initially attend provider-delivered SMAs to give feedback. SMAs will be put through a "rapid cycle" improvement process using patient, caregiver, and provider feedback at the conclusion of each session to optimize their format for our population.

We will also administer the PEG questionnaire at the outset of each SMA to assess patients' pain intensity and functional interference. Additional questionnaires are in development to assess patients' satisfaction and engagement. Drafts of patient questionnaires are shown in **Appendix 5**. Research staff will follow-up with patients three months after the SMA to re-administer the PEG and satisfaction/engagement surveys. We will recruit and incentivize patients to complete follow-up questionnaires with $25 gift cards for up to 1,000 participants.

Web-Based Resources. Additional content will be offered to patients and their caregivers online (e.g., PAMF website (http://www.pamf.org) and MyHealthOnline, a secure patient messaging portal). MyHealthOnline is available to all PAMF/Sutter Health patients to communicate with their physicians about non-emergency matters; make appointments; view test results, medications, immunizations, and medical history; and access a wide range of health resources. Links to condition-specific content can be "pushed out" to patients proactively, as appropriate.

Mental Health Services. Integration with behavioral health services is crucial to success in changing and supporting change in patients' beliefs and behaviors around CP. Dr. Singh, a PAMF psychiatrist, will oversee behavioral health resources for PAMF patients. PAMF Administration supports hiring a pain psychologist dedicated to this project. Dr. Singh will supervise the psychologist as well as other identified personnel (health coaches or mental health navigators) to assist in triage of patient referrals to behavioral health services. Patients may require individual psychological assessment, or may be directed to internal or external resources. We will develop SMAs for psychological skills building for CP patients. Separate from the "medical" SMAs where medications may be adjusted, the focus will be on delivering content on coping skills and reinforcing content delivered in the medical SMAs. SMAs build therapeutic communities, and improve access to a pain psychologist. This is particularly important as community therapists do not generally have the same understanding and messaging around pain issues as do pain psychologists. With the help of Dr. Brose, we will identify appropriate community therapists to serve as "pain partners". We will capture behavioral health referrals in our EHR smart set. We will track referrals to measure compliance in keeping internal appointments or to confirm that patients have kept outside appointments. In addition, Dr. Brose employs a pain psychologist (Dr. Jacome). We anticipate that Dr. Jacome will assist in developing content for the "psych" SMAs, and serve as a consultant to our PAMF pain psychologist.

Peer-to-Peer Consultations: Part of PAMF's administrative contract with Dr. Brose includes his ability to be available to physicians for individual consultations. Dr. Brose had access to the EHR. In reviewing cases with the PAMF providers, he will provide feedback to them in real time to assess how well they "know what to do" and "know how to do".

C5. Evaluation Design

Overview. The CPMR program has been designed to improve various outcomes, at the population, provider, and patient levels. Population outcomes will include monthly estimates of opioid prescribing rates, SMA referrals/attendance, and use of EHR resources by providers to document referrals, opioid dosing, risk assessment, and use of pain contracts. These ***continuous measurements*** will help to ***evaluate the implementation and impact of the program***. Provider-level outcomes include: (i) provider knowledge, skills, CP management, engagement and satisfaction; (ii) care coordination; and (iii) opioid prescribing patterns. Patient-level outcomes include: (i) patient engagement and satisfaction; (ii) patient-reported pain and functional outcomes; and (iii) healthcare costs. Provider- and patient-level outcomes are displayed in **Table 2** (next page). Each outcome has been operationalized into one or more measurements that will be captured at discrete points in time before and/or during the intervention. Based on the interval of data collection, we will perform appropriate analyses to assess outcomes. Analyses are described in detail subsequently. Outcomes at all levels will be measured overall and within each of the four PAMF Divisions. Division and provider comparisons will control for potentially relevant differences in regional resources and patient populations. We will focus the analysis on the 20-month funding period, but PAMF is committed to evaluating the impact of the program beyond this period, especially as CPMR is implemented throughout the Sutter organization.

We will use the RE-AIM framework to assess implementation of the program. The components of this framework and related measures are presented below in **Box 1**.

BOX 1. RE-AIM Framework for Healthcare Program Implementation	
REACH	▪ Proportion of CP care providers who attended Boot Camps and simulated-SMAs, overall and by PAMF Division ▪ Proportion of all CP patients and of referred CP patients attending SMAs, overall, by PAMF Division, and by provider
EFFICACY	▪ Primary Outcomes – Decreased opioid prescribing rates – Decreased average morphine equivalent dosing – Increased provider compliance with CP management guidelines, including use of pain/functional assessment, appropriate opioid dosing and quantity dispensed, use of pain contracts for patients prescribed opioids.
ADOPTION	▪ Proportion of clinics across Sutter Health that intend to and that subsequently adopt the CPMR program
IMPLEMENTATION	▪ Proportion of PAMF Divisions that adopt each CPMR component ▪ Ratings of Boot Camp value by providers and of SMA value by providers and patients, overall and by PAMF Division
MAINTENANCE	▪ Sustained offering of CPMR components (Boot Camps for new providers, SMAs, use of EHR assessment, dosing, and tracking tools, referral to internal and external resources) ▪ Sustained reductions/improvements in primary outcomes (as described above)

TABLE 2. Outcomes for Evaluation				
PROVIDER-LEVEL OUTCOMES				
Outcome(s)	**Measurement(s)**	**Interval of Data Collection**	**Analysis**	**Source**
Provider Engagement and Satisfaction	Satisfaction with Boot Camp and simulated SMAs	At end of Boot Camp/SMA, and 3 and 6 months after	Pre/post	Provider Survey
	Satisfaction with support for CP	At the start and end of Boot Camps/SMA, and 3 and 6 months after		
	Knowledge of CP management			
	Confidence with CP management			
Care Coordination	Documented provider referrals (SMAs, specialists)	Monthly after Boot Camp	Trend	EHR
Medication Prescribing	Opioids prescribed	12 months prior to and after Boot Camp	Time Series/MC	EHR
	Documentation of and appropriate morphine equivalent dosing	Monthly after Boot Camp	Trend	
	Opioid risk assessment			
	Use of pain contract and obtained informed consent			
PATIENT-LEVEL OUTCOMES				
Outcome(s)	**Measurement(s)**	**Interval of Data Collection**	**Analysis**	**Source**
Patient Engagement and Satisfaction	MyHealthOnline messaging with providers (count of encounters)	12 months prior to and after start date*	Time Series/MC	EHR
	SMA attendance	Monthly after start date*	Trend	
	Satisfaction with SMAs	At the end of the SMA and 3 months after	Pre/post	Patient Survey
	Confidence in self-managing pain	At the start and end of the SMA and 3 months after		
	Use of web-based content	Monthly after start date*	Trend	Web Traffic
Patient-reported pain outcomes	Pain and interference with enjoyment and function	At index date, and naturally occurring follow-up	Trend	PEG 3-item scale
		At SMA and 3 months after	Pre/post	
Healthcare costs	Healthcare encounters	Monthly, 12 months prior to and after start date*	Time Series	EHR
	Medicare-normalized costs			

CP, chronic pain; MC, matched-control analysis; SMA, shared medical appointment;
*Start date is patient's first ambulatory-care encounter with a provider after provider has completed Boot Camp

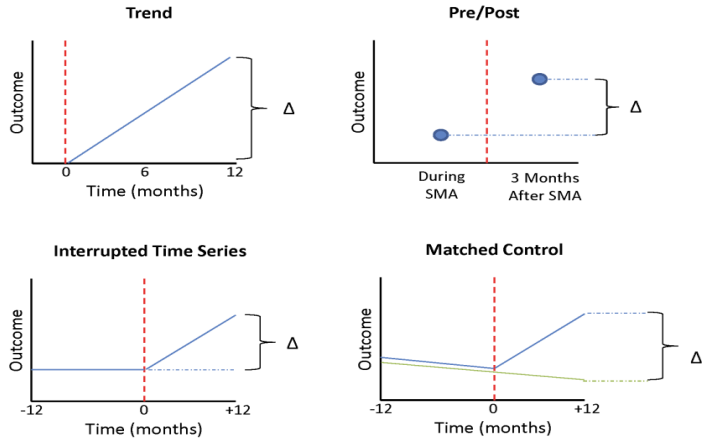
Populations of Interest. For provider and patient level outcomes, we will restrict the study cohort. We will evaluate providers who go through Boot Camps, which will include the vast majority of PCPs and appropriate specialists (N=500). We will evaluate community-dwelling patients with non-cancer CP, who have a "post-Boot Camp" encounter with a provider. We will exclude patients receiving palliative/end-of-life care or hospice, those residing in long-term nursing facilities, or those with a diagnosis of a malignancy in the previous 12 months or surgery within the previous three months. We will also exclude patients who have no evidence of contact with the health system at least 12 months prior to the intervention. These eligibility criteria will be

applied to identify appropriate patients using coded data in the EHR, a process extensively used for research purposes at the PAMF Research Institute.

Data Collection and Extraction. Data will be collected via questionnaires and extracted from the EHR before and/or during the intervention. The date of the Boot Camp will be considered the start date of the intervention for providers, and the date of the first ambulatory encounter with a provider who has gone through the Boot Camp will be considered the index/start date of the intervention for patients. Data from surveys and the EHR will be linked and additional information on patient demographics (age, sex, and race), clinical characteristics (diagnoses and overall disease burden), prescribed medications, and health resource utilization will be extracted to create a de-identified dataset. Healthcare costs will be estimated from encounter diagnoses using a 150% adjustment of standard Medicare costs. We will also extract information from the EHR on providers, such as type of provider (PCP or specialist), practice location (PAMF Division), average volume of overall patients and patients with CP, average volume of prescriptions written and prescriptions written for opioids and other pain medication.

Analyses. Based on the intervals at which the data are collected, we will use four different analytic methods to measure the impact of the CPMR program: (i) trend analysis; (ii) pre/post analysis; (iii) interrupted time series analysis; and (iv) matched-control analysis (**Figure 4**). For all analyses, a P-value <0.05 will be considered statistically significant. Statistical analyses will be performed in STATA 13.0 (StataCorp; College Station, TX). Each method is described in detail below.

FIGURES 4. Analytic Approach. Vertical, red-dotted line separates time before and during intervention. Blue line (or dot) represents outcomes over time in group receiving intervention. Green line represents outcomes over time in matched-control group. Δ= change.



1. *Trend Analysis*. We will evaluate temporal trends in outcomes that are collected at the outset of the intervention and afterwards (i.e., outcomes related to program components that are implemented as part of the intervention), including documentation of referrals, SMA attendance, use of web-based content, documentation of opioid morphine equivalent dosing, use of pain contracts, opioid risk assessment, and patient-reported pain intensity and functional interference (as captured during SMA and natural clinical follow-up). We will use regression techniques to model each outcome conditional on the main predictor of interest (time in months) and other covariates (e.g., patient demographics and clinical characteristics). We ***hypothesize*** that, from the start of the intervention, there will be a significant increase over time in the number of documented referrals, attendance at SMAs, use of web-based content, documentation of opioid dosing, use of pain contracts, and opioid risk assessment; we expect that patient-reported functional status will improve, and that there may also be an improvement in patient-reported pain intensity.

2. *Pre/Post Analysis*. We will evaluate changes in provider satisfaction and engagement outcomes between the start and conclusion of the Boot Camps and simulated-SMAs and at three and six months follow-up. We will also evaluate patient satisfaction and engagement at the start and/or conclusion of the provider-delivered SMAs at three months follow-up. We will use regression techniques to model each outcome conditional on the main predictor of interest (at start/end and three months after SMA) and other covariates (as described above.) We ***hypothesize*** that three and six months after the Boot Camps/simulated-SMAs there will be a significant improvement in provider satisfaction, knowledge, and confidence in managing CP. We also expect an improvement in patient satisfaction with SMAs and confidence in self-managing pain, as well as a reduction in self-reported functional interference at three months follow-up. There may also be an improvement in self-reported pain intensity.

3. *Interrupted Time-Series Analysi*s. We will evaluate changes before and during the intervention for outcomes that can be extracted from the EHR (i.e., measures that are independent of the intervention), including, opioid prescribing rates, online messaging between patients and providers, and healthcare utilization and costs. We will use regression techniques to model each outcome conditional on the main predictor variables (time in months and before/during intervention) and other covariates (as described above). The difference in slope before and during the intervention will be evaluated by the inclusion of an interaction term (time*before/during). We ***hypothesize*** that there will be a significant change in the slope (i.e., trend over time) during the intervention, showing an increase use of online messaging, and a decrease in opioid prescribing and reduced healthcare utilization rates and costs.

4. *Matched-Control Analysis.* For outcomes that are amenable to time-series analyses, we will also perform a matched-control analysis to strengthen the validity of findings. We will use the non-PAMF Sutter Health population as our source of control providers and patients, as there are currently no ongoing CP initiatives in these regions. We will modify our plans if it appears that such initiatives will be undertaken. We will first select providers from non-PAMF sites with specialties, overall patient volume, and volume of patients with CP similar to PAMF physicians. Among the patients nested within these providers we will use propensity-score techniques to identify appropriately matched patients. Propensity scores will be estimated as the probability of being a PAMF CP patient with a provider who has "graduated" from Boot Camp, conditional on patient demographics, clinical characteristics (including pain diagnoses), and medications used. We will perform 1:1 nearest neighbor matching within 0.2 caliper widths of the pooled standard deviation of the logit of propensity scores. The matched-cohort analysis will be performed, as described above, to compare outcomes for similar patients and providers, who were not affected by the CPMR program. Regression techniques will be used as described above. We ***hypothesize*** that patients in the intervention group will perform better on all outcomes compared with matched-control patients.

For all analytic approaches, we will evaluate outcomes by various subgroups, including patient gender and race/ethnicity, and provider characteristics (e.g., providers with relatively high or low opioid prescribing rates prior to the intervention).

Expected Outcomes. Our *primary outcomes* of interest are (1) opioid prescribing rates and (2) provider compliance with CP management guidelines, including use of the pain/function assessment tool for all patients with CP; and appropriate opioid dosing and quantity dispensed, use of pain contracts, obtained informed consent, and opioid risk assessment for patients prescribed opioids. We believe that by achieving these primary outcomes, the other outcomes will follow (e.g., reduction in healthcare utilization and costs, and improved patient outcomes and patient and provider experience). We expect that opioid prescribing rates will decrease by 15% at 12 months after the initiation of the CPMR Program. While this is a modest, but meaningful decrease, we recognize that, for patients currently receiving opioids, prescription renewals may persist as there may be inertia with discontinuing chronic opioid therapy. We expect that 75% of providers who attend Boot Camps will be in full compliance with the aforementioned CP management guidelines at 12 months after program initiation, and that 95% of providers will have all opioid prescriptions at appropriate morphine equivalent dosing per Medical Board of California guidelines for safe opioid use.

Anticipated Challenges and Solutions. *(1) Expectations*. Providers and patients will need to adopt the new paradigm that CP may persist, while functional status and quality of life can improve. Many still believe that "good care" means more procedures and medicines. Through the Boot Camps/simulated SMAs and provider-delivered SMAs, respectively, providers and patients will receive information and support to change current expectations. (2) *Behavioral Health Coordination.* Care coordination for behavioral health services has many barriers, beginning with the current insurance structure that separates networks and payments for these services from the medical system. Strong firewalls exist that prevent community therapists from communicating freely with medical providers, and medical records are not unified. Treatment philosophies among traditional behavioral therapists support patient advocacy, without an understanding of why this is different for CP. For example, they may encourage patients to advocate for medication to treat their physical symptoms, which may undermine the shift in culture we are trying to achieve. To overcome this, we will develop internal communication pathways with PAMF behavioral health teams to coordinate therapeutic plans. A "smart text" in Epic will make the care plan visible to all. (3) *Boot Camp Attendance*. We believe that many providers are sufficiently frustrated with managing CP patients that they will attend. However, to ensure maximal attendance we will engage physician champions and PAMF Department Heads to encourage attendance for all providers that prescribe opioids. Importantly, we will track attendance and, if needed, we will make the Boot Camps mandatory for providers who write opioid prescriptions. (4) *SMA Attendance*. Our gap analysis revealed that attendance at CP SMAs has been relatively low. We believe that educating physicians on the value of SMAs, training them to deliver SMA content, and widening the reach of SMAs throughout all four PAMF Divisions will be instrumental in improving referrals to and patient use of SMAs. We will track referrals and attendance monthly, and will take corrective action if needed (including improved "marketing" of SMAs). (5) *Study Design*. This study has limitations typical of a non-randomized study design, particularly the potential for bias due unmeasured confounding. We have designed the evaluation to minimize biases that may be due to changes over time or differences between the intervention and the matched-control group. Nevertheless, we will acknowledge limitations and use caution when interpreting results.

C7. Detailed Work Plan and Timeline

The CPMR Program is in development and is supported by PAMF funds. This grant will be used to supplement consultancy fees for Dr. William Brose, which includes his involvement in developing content for and refining assessment tools for Boot Camps and physician-led SMAs. Funds will also support research staff, which will assist in implementing the program, oversee the evaluation, administer provider/patient questionnaires, extract data from the EHR, perform data analyses, and develop reports and publications, as outlined below.

CPMR Program Rollout. Information about Boot Camps and simulated-SMAs will be distributed to providers in August 2015. Physician champions are already engaged, and Department Heads will be notified to encourage their providers to attend. Boot Camps, one in each of the four PAMF Divisions, will be held between October and November 2015. Dr. Bronstein and Dr. Brose are finalizing content. Research staff will attend Boot Camps and simulated-SMAs to collect provider-reported survey data and will track provider attendance. The EHR will be used to determine if providers, who prescribe opioids, have not attended. Research staff will also follow-up with providers to complete surveys as three and six months from the time of Boot Camp.

Drs. Bronstein and Thai are currently developing the work flow and content for EHR resources. These builds/smart sets will be available in October 2015. Providers will be made aware of these resources and will be trained in their use at Boot Camps.

Initial provider-delivered SMA content will be finalized in October 2015, and will be available to patients as early as November 2015. SMA content will go through a rapid cycle improvement process. Finalized SMAs and web-content will be available in March 2016. Questionnaires will be administered to SMA participants by the Medical Assistant before and after the SMA session. The patients will be recruited to participant in a three-month follow-up questionnaire. The first 1,000 participants recruited will each receive a $25 gift card. Research staff will be responsible for follow-up with patients and collecting survey data.

Our PAMF psychiatrist, Dr. Singh, will direct our new pain psychologist in developing a psychological assessment triage process, and will create the SMAs for the skills building. Dr. Singh will direct the appropriate PAMF clinic staff to serve as “Navigators”. Due to the challenges associated with coordinating behavioral health, we anticipate that it will take some time to have the program fully implemented. We expect to have a working system by May 2016.

Research Activities. In collaboration with Dr. Bronstein (PI), the PAMF Research Institute will perform a robust evaluation of program implementation and impact. At the time of award notification, in August 2015, we will prepare and submit an application to our Sutter Health Institutional Review Board (IRB) to collect data from the EHR and to link these data with provider and patient questionnaires collected at Boot Camps and SMAs. These questionnaires will be collected as a part of routine medical practice and quality improvement purposes; we will request a waiver for signed consent to link these data. Follow-up patient surveys will be collected for research purposes, and signed consent will be required. We will aim to have IRB approval by October 1st 2015.

The administration and collection of survey data will occur concurrently with Boot Camps and SMAs, and at pre-specified follow-up, and will be performed by research staff, as described above. We anticipate that survey administration and collection will occur between October 2015 and December 2016.

To ensure the efficient and full implementation of the CPMR at PAMF, we will perform continual (monthly) measurements of opioid prescribing and provider compliance with CP management guidelines, as described in Section C6. Research staff will be responsible for generating monthly reports between November 2015 and December 2016.

A detailed analytic plan will be developed by the PI/Co-PIs to finalize processes for data linkage, extraction, validation, and analysis. The analytic plan will be completed by January 2016. Interim analysis will be conducted at six months from initial program implementation (April-May 2016). Analysis will include six-month endpoints for the primary outcomes, as well as processes and implementation measures. Main analysis will be conducted at 12 months from initial program implementation (Nov 2016-Jan 2017), and will include 12-month endpoints for all outcomes. We will prepare abstracts, presentations, and manuscripts based on study results between June 2016 and May 2017.

Dissemination. There are many opportunities to disseminate the findings on the implementation and impact of the CPMR program. Dr. Bronstein will present quarterly updates to PAMF leadership to keep them engaged and informed of the program's progress. As the program progresses, Dr. Bronstein will also present updates to Sutter Health leadership. This will help to promote the program and its system-wide implementation. We have planned for three meetings with Sutter Leadership (December 2015, August 2016, and February 2017). We also plan to submit abstracts to at least two scientific conferences: Pain Week (September 2016) and the Annual Scientific Meeting of the American Pain Society (May 2017). Publication of manuscripts will follow.

Deliverables. Throughout this study we plan to develop materials to share with CAPG/Pfizer, others in our organization, and scientific community, at large (as appropriate) (**Box 2**).

BOX 2. Project Deliverables	
Implementation Report	This document will contain metrics on program rollout, and will be shared with CAPG/Pfizer in March 2016
White Paper on Engaging Providers in Continual Learning	We will develop a white paper on lessons learned from engaging providers in Boot Camps and simulated-SMAs, with six-month data on process improvement outcomes. We anticipate completing this paper by July 2016, and will make it available to CAPG/Pfizer and PAMF/Sutter Health leadership.
Final Study Report	We will prepare a final study report that will include all outcome measures, which will be completed by February 2017. We will distribute the study report to CAPG/Pfizer and to PAMF/Sutter Health leadership.
Published Presentation and Manuscripts	We will compile all completed presentations (PDFs of posters, slide decks, manuscripts) and provide them to CAPG/Pfizer in October 2016 and May 2017.

*** ***Timeline*** and ***Schedule of Deliverables*** is provided in the supplemental grant material