

Prescription Opioid Management in Chronic Pain Patients: A Patient-Centered Activation Intervention

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ABSTRACT

Patients with chronic pain (PWCP) typically have multiple chronic conditions, and many points of contact with the health system. They can feel disempowered, and experience fragmented care and poor outcomes. PWCP report concerns about under-treatment of pain, difficulties in obtaining medication, and stigma. Prescription opioids are a very common, and controversial, pain treatment. PWCP often lack the skills and knowledge to talk to their physicians about their pain and opioid use, and to navigate the health care system. The study compared the effectiveness of an innovative behavioral Patient Activation plus Usual Care (PA+UC) intervention to Usual Care (UC) only on patient-centered outcomes among PWCP. With our stakeholder group of patient, clinical, and operational advisors, we conducted a pragmatic, randomized trial to examine the effectiveness of a group-based PA intervention in two large primary care clinics in an integrated health system. We randomized 376 PWCP to either the PA+UC arm or UC only arm. The curriculum covers patient activation and empowerment, how to talk to doctors about prescription opioid use, and self-management of chronic pain, including how to navigate the health care system and online patient portal. We developed the study questions, intervention curriculum, outcome measures, and dissemination plan with our stakeholder groups. We examined effects over 12 months using follow-up patient interviews combined with electronic health records (EHR) and a mixed effects modeling approach. Patient outcomes included patient-reported activation, quality of life, prescription opioid use, pain severity and function, patient-provider communication, patient satisfaction, self-care, including use of health information technology, and service utilization.

RESEARCH QUESTION

Will a primary care-based behavioral intervention for patient activation and engagement and self-management, for patients with chronic pain who are taking opioid pain medication, result in better patient outcomes than Usual Care?

AIMS

Aim 1: Refine and finalize a patient-driven intervention curriculum and patient-centered outcomes, developed with a stakeholder group.

Aim 2: Compare the effectiveness of Patient Activation + Usual Care (PA+UC) versus Usual Care (UC) on patient-centered outcomes.

Will patients in the PA+UC arm:

- a. Have greater improvement in patient activation, patient satisfaction, pain and function scores, quality of life and provider communication over time?
- b. Be more likely to engage in self-management strategies?
- c. Be more likely to actively use primary care, and decrease use of acute care services?

Aim 3: To compare the effectiveness of PA+UC versus UC on prescription opioid use. Will patients in the PA+UC arm be more likely to reach their goal for prescription opioid use and/or decrease their use over time?

SIGNIFICANCE

Chronic non-cancer pain is widespread and debilitating, often involving multiple chronic health conditions, and is a burden on patients, their families, and health systems. The Institute of Medicine's 2011 report, "Relieving Pain in America" estimated that roughly 100 million adult Americans suffer from chronic pain, a number which only stands to increase due to an aging population and increasing chronic disease. It is one of the most common complaints presenting in primary care, and costs the U.S. between \$560-635 billion annually in health care and lost productivity. We focused on chronic non-cancer pain, since clinical considerations differ for individuals with a terminal condition.

Patients with chronic pain (PWCP) can have considerable work and social disability, compromised quality of life, loss of function, and isolation from family and friends. PWCP suffer from social stigma as well, and frequently from depression. The impact on patients' family members and community is also considerable, as we learned in our prior surveys and recent qualitative work with PWCP.

Prescription opioids are the most common medication used to treat pain, and their use has increased dramatically in recent years. However, long-term use, or chronic opioid therapy (COT), remains controversial; and evidence supporting COT for long-term pain and functional outcomes is mixed. There is considerable evidence and concern over associated harms. Increases in adverse events such as opioid abuse, falls, overdose and deaths associated with COT has led to what has been called a prescription opioid epidemic. The overdose rate in 2008 was nearly four times the rate in 1999, with 14,800 prescription opioid overdose deaths. Hospitalizations for prescription opioid poisoning doubled from 1999 to 2006. From 2004 to 2009, emergency room visits involving prescription opioids nearly doubled. From 1999 to 2009, drug abuse treatment admissions rates for non-heroin opiates grew over 400%. In 2010, 11.1% of persons age 18-25 used prescription opioids non-medically, and 1.4% were prescription opioid dependent. Patients may be unaware of long-term risks.

Federal agencies and health systems are responding to the increased rates of mortality and overdose with new initiatives related to opioid prescribing. The Food and Drug Administration (FDA) has issued Risk Evaluation and Mitigation Strategies (REMS) for training and education materials for prescribers of

long-acting opioids, and for manufacturers to obtain new drug approvals. Hydrocodone (e.g. Vicodin) has recently been reclassified as a Schedule II medication, and the FDA recently ordered new patient information labels on prescription bottles. Health systems have also initiated programs to reduce opioid prescribing, and dosages. For example, Group Health Cooperative (now Kaiser Permanente Washington) implemented an initiative to standardize prescribing practices and lower dosages to reduce risks associated with opioid use. It was a multi-faceted, primary care approach, designed with input from a variety of departments including “leaders in primary care, physical and rehabilitation medicine, clinical improvement, pharmacy, legal affairs, and other relevant departments to define new care processes that could be implemented”. Although ultimately intended to improve patient safety, it is not clear how patient-centered these types of initiatives are.

There is a unique tension in the experience of patients and providers with prescription opioids. Providers are reluctant to prescribe them because they are concerned both about scrutiny of their prescribing practices, about patients abusing them and other adverse events, and also feel frustration with this population. PWCP are often viewed as among the most difficult patients, because clinicians often feel they do not know how to help them. Patients, on the other hand, often have poor pain control, are afraid of losing access to their medication, and can find it difficult to talk with their provider. They do not want to be seen as the “difficult patient.” They often experience stigma from using prescription opioids, and feel they are treated with mistrust. They also may not feel “heard” by their physicians, and feel they are just being prescribed a pill. It is often easy to lose sight of the fact that patients and providers have the same goal: to reduce pain, and improve the functioning and quality of life of the patient.

Whom to talk with and how to get care is confusing for patients, particularly those with chronic illness. If they have more than one provider, they may not know which one is appropriate. In a pilot study of complex patients with multiple conditions, we found that those with pain frequently seek care at the emergency room. Health information technology (IT) can make it easier to communicate with and navigate the health system, but we have found pain patients often have not taken advantage of these resources, (e.g., not registering to email their physician). As part of Centers for Medicare and Medicaid Services (CMS) Stage 2 “meaningful use criteria”, web-based patient portals will be available to most health plans and federally qualified health centers (FQHC), but patients may need help to engage in use of these tools.

METHODS

This was a randomized clinical trial in Adult Medicine, which compared a behavioral patient activation and pain self-management intervention to usual care for chronic pain patients using opioid pain medication.

Study Site and Patients. The study was located at the Santa Clara and San Jose Medical Centers of Kaiser Permanente Northern California, and led by a research team from the Kaiser Permanente Northern California Division of Research. The team included strong clinical research partnerships with the Chiefs

of Medicine at each site, Dr. Sheryl Sun at Santa Clara and Dr. Michael Matsumoto at San Jose. The study sites were large primary care medical centers reflecting the diversity of the service area.

Study Design. The design was a pragmatic, randomized controlled trial with the patient as the unit of randomization. Eligible patients were those who used prescription opioids for a minimum of 3 days a week for the past 3+ months. We compared patient reported outcomes (see below) as well as health services use and prescription opioid use for those in the intervention arm to those who received usual care only (comparator group). We choose “usual care only” as the comparator group to best inform the intervention’s potential to enhance current practice. Usual care was determined by patients’ individual providers, according to practice guidelines related to specific conditions.

Data Sources. Patient-centered outcomes are reported from patient survey data at baseline, 6 and 12 months post recruitment. Pain is an individual experience, affected by individual factors, and patients and providers often have different definitions of treatment success. We assessed multiple domains to capture the patient experience. The EHR was the data source for patient clinical characteristics, patient portal use, prescription opioid use, and health services utilization.

Primary Outcome Measures

Patient Activation. Measured by Patient Activation Measure (PAM), a 13-item instrument for measuring patient beliefs, knowledge and confidence for engaging in a wide range of health behaviors.

Self-Efficacy. The Pain Self-Efficacy Questionnaire (PSEQ) is an established 10-item measure of pain self-efficacy that is widely used in clinical settings to assess confidence in one's ability to work and lead a normal life despite pain.

Quality of Life. Measured by two dimensions of the PROMIS Global Health Scale- Physical Health and Mental Health.

Depression. Measured by the Patient Health Questionnaire-9 (PHQ-9), one of the most commonly used validated screening tools used to measure depression severity.

Pain Coping. Pain coping strategies and measures of functioning were assessed with the Chronic Pain Coping Inventory -42.

Pain Severity and Functional Status. Measured with the Patient-Reported Outcome Measurement Information System 29-item Health Profile (PROMIS-29) instrument. PROMIS is a system of highly reliable, precise and easy to implement measures of patient-reported outcomes in physical and mental health and social well-being, which can be used as primary or secondary endpoints in clinical studies of treatment effectiveness. The single pain-intensity item is used in raw form. We also assessed the respondent’s satisfaction with his/her overall sex life using the PROMIS Global Satisfaction with Sex Life. In addition, the survey asks questions about source and quality of pain (not part of the PROMIS-29).

Patient Satisfaction. Measured by patients' overall satisfaction with their overall health care, and their primary care doctor on a scale of "0" to "10," where "0" is the worst possible care and "10" is the best possible care.

Patient Provider Communication. Measured by the Communication Assessment Tool (CAT), a 14-item instrument, the CAT asks respondents to rate different dimensions of the communication and interpersonal skills of their physician using a 5-point rating scale. The Perceived Efficacy in Patient-Physician Interactions Questionnaire (PEPPI) was used to measure patients' self-efficacy in obtaining medical information and attention to their medical concerns from physicians.

Prescription Opioid Use. Pharmacy data on opioid dispensations were extracted and summarized from the EHR. We asked about patients' long-term goals for prescription opioid use among 4 categories: stay the same, increase, decrease, and stopping. Progress toward goals was assessed at 6 and 12 month follow-ups.

Pain Management. The survey asks questions about non-pharmaceutical pain management strategies.

Opioid Misuse. The Screener and Opioid Assessment for Patients in Pain (SOAPP) and Current Opioid Misuse Measure (COMM) were used to identify aberrant behaviors related to long-term opioid treatment.

Other (non-opioid) Substance Use. Drug, alcohol and tobacco use were collected from patient survey data.

Health Care Utilization and Engagement. Primary care services (number of non-urgent outpatient visits) and acute care services (number of emergency room visits and inpatient stays) within KPNC were extracted from the EHR. Questions on services received outside KPNC were included in the patient survey. Use of Kaiser's patient portal and health education programs were extracted from EHR and assessed by self-report.

Patient Activation Group Intervention Sessions Curriculum. The intervention consists of 4 group sessions, one meeting per week, led by a licensed psychologist trained in pain management.

Session 1: "Taking a Leading Role". This session focused on empowering patients to take a leading role in their pain management and overall healthcare. It provides patients with information about how pain manifests in the brain and the body via the Gate Control Theory of Pain, the long-term risks and side effects of prescription opioid use and how neuroplasticity can cause pain to become chronic in nature and render pain medications less effective, ineffective, or possibly even harmful over time. Patients were introduced to why mind, body, and behavioral methods of pain control are part of a comprehensive pain management package.

Session 2: "Lifestyle and Balance". This session discussed importance of healthy behaviors (e.g. exercise, sleep, caffeine, nutrition, alcohol, tobacco, and emotional health), and how they are related to chronic pain. This session provided interactive education on the stress response of the autonomic nervous system and how pain activates the stress response, thereby providing rationale for why learning how to

reduce sympathetic nervous system activity is crucial for a comprehensive pain management package. Patients had an opportunity to learn and practice several new pain management skills.

Session 3: “Navigating the health care system”. This session’s goal was to meet patients’ individual needs via active use of the KP online portal via smart phones or computers. The session included hands-on practice navigating kp.org, exploring Kaiser’s healthy lifestyle resources, as well as resources outside of KP.

Session 4: “Partnership and Prevention”. The last session focused on increasing patients’ confidence in discussing pain and self-management strategies with their primary care team, with a focus on assertive communication strategies.

SAMPLE SIZE

To power our main patient outcomes, we planned to recruit 324 patients. With a conservative sample retention rate of 80%, we estimated a final sample size of approximately 260 patients at the 12 month follow-up, which would provide power of .80 or higher for the proposed analyses. We surpassed our enrollment goal and our final sample size was 376. With a 90% retention rate, our final sample size of patients at the 12 month follow up was 342, allowing sufficient sample to power to test all research hypotheses.

We illustrate power calculations for hypothesis testing based on our original proposed estimates, using worst case scenarios for each type of model used in the research aims, and assuming a Type 1 error rate of $\alpha=.05$. As an example of a continuous outcome, we consider the difference in activation scores between the Patient Activation (PA) + Usual Care (UC) and UC only groups. The cross-sectional analyses modeled by multivariate regression analyses will have a power of .80 to detect a conventionally small effect size of 0.07 with 12 independent covariates including the treatment group indicator, with a sample size of 260. We then examine the longitudinal analyses modeled by linear mixed-effects models. Assuming the worst case scenario of a correlation between the three repeated measures (baseline, 6 and 12 month questionnaires) to be 0.3 (analyses of prior studies indicate correlations of < 0.3), the power to detect a 24% difference in standard deviation units will be .80 with a sample size of 230. As an example of power calculation for a binary response, we present statistical power for the likelihood of portal use between the PA+UC and UC groups. We will first examine the cross-sectional analyses modeled by multivariate logistic regression models. Based on results from an internally funded pilot study of complex patients, we expect an overall rate of portal use of 61%. The test of significance for an odds ratio of 2.5 for the coefficient of the indicator variable for treatment group (=1 if PA+UC, 0=UC), will have a power of .80 with a sample size of 166. In longitudinal analyses modeled by mixed-effects logistic models, using 3 repeated measures, for a worst case correlation of 30% between successive measurements, we will be able to detect a 12% difference between the PA+UC and UC groups with a power of .80 and sample size of 126 patients in each arm ($n=252$). Given that our final sample size exceeded our original estimate, we have adequate power to examine main study questions.

CONFIDENTIALITY

In accordance with long-standing policy, all data collected as part of this study is being held in strict confidence. Only study staff has access to the data collected as part of the study, and all employees who come in contact with these records sign an agreement to maintain confidentiality. All study participant materials are stored electronically on a password protected, secure Kaiser Permanente Division of Research server. A Certificate of Confidentiality from NIH was obtained for the study.

All names are removed from research records; no identifying information is used in any report or publication that is produced from this study. Data will only be presented in the aggregate.

PARTICIPATION RECRUITMENT

Inclusion and Exclusion Criteria. Our target population was all eligible adult primary care patients receiving care at the Santa Clara or San Jose Medical Centers, who were regularly taking prescription opioids at time of enrollment.

Inclusion criteria. (1) adult patients aged 18+ who received primary care at one of the study clinics and used prescription opioids for pain at least three days per week over the previous three months.

Exclusion criteria. Potential participants were excluded if they: (1) had any serious comorbidity other than their pain (e.g., terminal illness, active cancer, severe mental health issues such as psychosis), or any condition that would impair their ability to engage with the intervention; (2) were currently being treated in a pain clinic; (3) were in chemical dependency treatment; (4) had stopped or were planning to stop taking opioids before the intervention started; (5) had a relative or close friend participating in the study; or (6) did not read or understand English.

Recruitment. We used a multi-method approach to recruitment found to be very successful in previous studies. It included the following methods of making potential participants aware of the opportunity to participate in the study:

Identification via EHR. We identified potentially eligible patients through the EHR. With the approval of the patients' primary care physician, we sent eligible patients an IRB-approved recruitment letter with an invitation to participate. After 10 days, the research staff telephoned patients to determine if they were interested in participating in the study. Using an IRB-approved telephone screening script, the research staff screened and recruited eligible patients based on the study inclusion criteria.

KPNC clinician referral. Providers received instruction regarding the study and identification of eligible patients, as well as a referral script. Providers explained the study to potentially eligible patients, and provided a flyer to the patients so that they could contact study staff if interested.

Patients who were interested in the study, but not yet willing or interested in being contacted directly, were given a "Participant Information Sheet", which contained contact information for the Principal Investigator and research staff.

Self-referral. Fliers advertising the study were available in the clinic lobby. Interested patients could respond to the information on the study flier by calling a designated study phone number. The research

staff telephoned interested patients, using an IRB-approved telephone screening script, conducted a brief screening survey and invited eligible patients to participate.

Informed consent and baseline appointment. For patients who were eligible and agreed to participate, the research staff scheduled a one-hour, in-person appointment at the medical center at the patient's convenience. At the appointment, the research staff explained the study, invited the patient to participate, and obtained informed consent, using an IRB-approved recruiting script. Informed consent included access to patient medical records for research, including pharmacy and utilization of medical, mental health and chemical dependency services. The Research Associate answered all questions by the patient about the study, and reviewed the study consent form with the patients. If the participant stated that they understood the purpose of the study, and agreed to participate, the participant's signature was obtained. The research staff also clearly explained the HIPAA authorization form, and obtained the participant's signature.

After signing the consent form, the patient was asked to complete the online baseline survey, using a study laptop. The survey took about 45-60 minutes to complete.

Randomization. Randomization was conducted independently, using a block randomization approach and a SAS random-number generator. Assignments were pre-determined and placed in sealed opaque envelopes. As each eligible patient provided informed consent, the research staff opened an envelope to identify the treatment group to which the patient was assigned. Assignments were concealed from study staff until opened in front of patient.

Participants assigned to the intervention arm were required to attend their first session within 3 months of completing the baseline survey. In situations where this was difficult, participants were offered the option to re-do the baseline survey or forgo the group sessions and proceed with the remainder of the study (the 6 and 12 month follow up telephone interviews), which aligned with the planned intent-to-treat analysis of the study.

Follow-up appointments. Patients were interviewed by telephone at 6 and 12 months post intake. Trained DOR interviewers conducted follow up interviews (approximately 45 minutes) using standardized scripts and procedures. For patients who were difficult to reach by phone, we sent contact letters to let them know we were trying to reach them, and provided a telephone number to contact us. The Kaiser EHR was utilized for locating updated contact information. Multiple attempts were made to contact patients over 4-6 week time period.

COMPENSATION

Patients were offered \$50 Target gift cards for completion of the baseline assessment to compensate them for their time. Patients were offered \$50 Target gift cards for completion of the 6-month and 12-month telephone assessment (\$150 possible total for all assessments).

VULNERABLE POPULATIONS

We did not specifically exclude patients identified as vulnerable populations (e.g. educationally or economically disadvantaged patients). This was a low-risk behavioral study that did not include the use of any pharmaceuticals prescribed by the study. Participation in the study was completely voluntary, and patients could refuse. It was possible that some KP employees could be recruited. However, there was no coercion to participate and participation in the study had no impact on employment status or treatment.

RISKS AND BENEFITS

This study entailed no physical procedures and imparted no physical risk. However, because materials for the study entailed disclosure about sensitive information, there were risks to confidentiality. Participants may have felt uncomfortable disclosing information about their chronic pain. In addition, it was expected that some individuals could receive a more effective treatment than others. Specifically, those assigned to the usual care group condition may not have experienced as much improvement in study outcomes as those assigned the experimental behavioral health intervention.

The experimental treatment in this study was a behavioral health intervention and was considered a low-risk treatment method. The intervention was conducted at the same treatment location where patients received usual care. Dr. Campbell and Dr. Weisner carefully monitored delivery of the intervention and took steps to ensure participant safety. Finally, all participants (participants in both treatment arms) received the same ongoing medical care in the KPNC health plan they would have received if they were not part of the study.

Safety monitoring plan and reporting mechanisms. In addition to the data security measures discussed, we utilized an Independent Safety Monitor (ISM) who periodically examined aggregate reports of adverse events generated by the primary data analyst. Risk to patients was extremely low relative to biomedical randomized controlled trials. The ISM did not have any personal or professional interest in the outcome of the trial.

The role of the ISM was to (1) monitor and evaluate the safety of study participants, (2) monitor the performance of the study, and (3) assure that the data safety and monitoring plan, including the reporting of any adverse events (AEs) and serious adverse events (SAEs) was adhered to.

We did not anticipate any injuries in the course of the study. For any potential injury, patients were eligible for services based on their usual KPNC health plan coverage. The PIs monitored the safety and efficacy of the study by compiling a data and safety monitoring report twice yearly and submitting it for review to the ISM. The report included a summary of all serious and non-serious adverse events, relationship to the intervention and recommendation for action.

Study-specific potential adverse events. There were no physical procedures to patients and risk of study-specific adverse events was very low. The study team members were trained to identify adverse

reactions. A study participant could be withdrawn from the study intervention if the investigator determined that it was the best decision in order to protect the safety of the member

Procedures in case of clinical escalation during the study follow-up period. Participants in the study had resources available to them through primary care as well as specialty care clinics within KPNC. All study participants were members of the KPNC health plan and were able to access services directly. Study interviewers were well trained and had KPNC and public telephone numbers and resources available in order to effectively link participants with clinical and emergency services if such need became apparent during course of the study. The investigators took all necessary steps to ensure patient safety, ensuring that participants received clinical attention and that participants were quickly evaluated by a provider in primary care, if these steps were needed. All participants received ongoing usual clinical care from primary care services.

QUALITATIVE INTERVIEWS

Over the course of the study, we interviewed 13 primary care physicians about their experience caring for patients on prescription opioids. Through a series of open-ended questions, we solicited feedback on the current prescribing environment and how it has affected providers' relationships with patients, and the quality of care provided. The interviews were conducted by the study research clinician. All interviews were conducted during lunch hours at the primary care clinic, and were recorded. Audio files were transcribed, and summaries were drafted of each interview. Data will be used to supplement main quantitative findings.

STAKEHOLDER ENGAGEMENT

We engaged an extensive panel of patient and clinical stakeholders in all aspects of the research from formulation of research questions and study aims, development of recruitment, and data collection materials, refinement of the intervention curriculum, monitoring study progress, interpretation of study findings, and development of presentations and manuscripts. The stakeholder panel included clinical and operational leaders with significant professional experience in treating pain with prescription opioids. There were seven KPNC clinicians with expertise in primary care (**Sheryl Sun, MD**), psychiatry (**Mason Turner, MD**), addiction medicine (**Murtuza Ghadiali, MD**), emergency medicine (**Steve Offerman, MD**), psychology/chronic pain (**Karen Peters, PhD**), pharmacy (**George Shea, R.Ph, MBA**), and anesthesiology and pain management (**Andrea Rubinstein, MD**). We also had two family practice physicians specializing in chronic pain treatment from Contra Costa Medical Center (CCMC), **Ken Saffier, MD** and **Karen Burt-Imara, MD**, and a psychiatrist/bioethics researcher from academia (**Mark Sullivan MD**). Lastly our stakeholder panel was complemented by the director of a nationally renowned chronic pain advocacy organization, American Chronic Pain Association, **Penney Cowan**.

There were four patient stakeholders, two from within Kaiser and two from Contra Costa Medical Center (CCMC), a local Federally Qualified Health Center (FQHC). The two Kaiser patients, **Ben Gonzalez** and **Georgie Hunter**, were invited to participate as stakeholders while attending the KP Santa Clara Pain

Management Rehabilitation Program (PMRP). The two FQHC patients, **Kristie Mathews** and **Sylvia Turner**, were recruited from the Pain and Wellness Group at the CCMC.

Patient and clinical stakeholders met separately for the first year, and subsequently as one group. Training was provided to clinical stakeholders and research staff on the principles of patient engagement and patient-centered outcomes research. Meetings were held quarterly and there was regular communication via email, and phone.

RESEARCH TEAM

Cynthia Campbell, PhD, MPH, Principal Investigator (PI). Dr. Campbell was responsible for the scientific and technical aspect of the grant activities at the Kaiser Permanente, Northern California (KPNC) Division of Research (DOR). She led the overall direction of the project, including ensuring that the project stayed patient centered through the close participation of the multidisciplinary patient and stakeholder advisory groups. Additionally, she was responsible for the development of the data collection tools, curriculum development, protocol implementation at the clinic, analytic plan, data extraction and analysis, manuscript preparation, and dissemination of study findings to the professional community through presentations, manuscripts, and working with state and national workgroups.

Constance Weisner, DrPH, LCSW, Principal Investigator. Dr. Weisner was responsible for the scientific and administrative direction of the study, in coordination with Dr. Campbell at DOR. Her responsibilities included finalizing the study design and data collection tools, partnering with Dr. Campbell to work with the stakeholder groups, monitoring the data collection and analysis, interpreting study data, preparing manuscripts, and disseminate findings.

Andrea Rubinstein, MD, Co-Investigator. Dr. Rubinstein was responsible for bringing clinical knowledge of chronic pain etiology and symptomology in addition to expertise regarding prescription opioid use and other pain management practices, guidelines and protocols. She was an active member of the study team focusing on clinical issues regarding chronic pain management, KPNC clinical policy, a member of the stakeholder group, and contributed to the finalization of study tools, data interpretation, and writing manuscripts and disseminating study results

Catherine Marino, PsyD, functions as the **Behavioral Health Clinician.** She was responsible for executing the clinical activities required in the patient activation study arm, which consisted of four group sessions. She is a licensed clinical psychologists with specialization in pain management and patient activation (such as stages of change model, motivational interviewing, and cognitive behavioral therapy). Dr. Marino has a highly successful track record working with patients with complex and chronic conditions in primary care, chemical dependency, and psychiatry.

Monique Does, MPH, worked closely with Dr. Campbell as the **Project Manager.** She was a resource for the scientific leadership, clinical staff, and study participants. She managed the training and assisted clinical staff with study methodology and ensured the baseline, 6-month, and 12-month questionnaires were translated into efficient data collection tools. She built relationships with clinicians and staff, acted

as a liaison between the clinics and the research team, provided technical and hands-on assistance, assessment and feedback, coaching, and team-building. She was the primary contact for the patient and clinical stakeholders, and was responsible for engaging the stakeholders throughout the research process. In addition to these operational necessities, she ensured that the IRB requirements were current; she provided support for the weekly study team meetings, the stakeholder group meetings, and assisted in tracking methodology decisions made during the course of the study.

Nancy Charvat-Aguilar, MPH, Research Assistant, partnered with the Behavioral Health Clinician during the first two years of the project to ensure the recruitment, baseline, 6-month and 12-month interviews were completed. Specifically, she assisted in recruitment and informed consent activities and helped to pilot interview instruments and create and maintain participant databases.

Andrea Kline-Simon, MS , Data Analyst. Ms. Kline-Simon's primary roles were defining study population, identifying potentially eligible candidates in the EHR, finalizing data collection protocols, developing an analytic plan, and helping to develop the patient tracking system. Andrea also provided consultation on recruitment and data collection issues, and assisted with monitoring adverse events, running enrollment reports and drafting manuscripts for publication.

Sara Adams, MPH, Data Analyst. Ms. Adams primary responsibilities on the study were compiling final study results, and drafting methods and results for final research report and manuscripts. She cleaned survey data, retrieved relevant data from EHR and compiled final data tables. She created summary statistics for outcome variables, and compared differences between treatment groups on outcome measures at 6 and 12 months. She ran cross-sectional multivariate models to examine relationships between the outcomes and the two treatment arms at the 6-month and 12-month follow-ups, and used a repeated measures mixed effects framework to examine differences in outcomes by treatment arm over time.