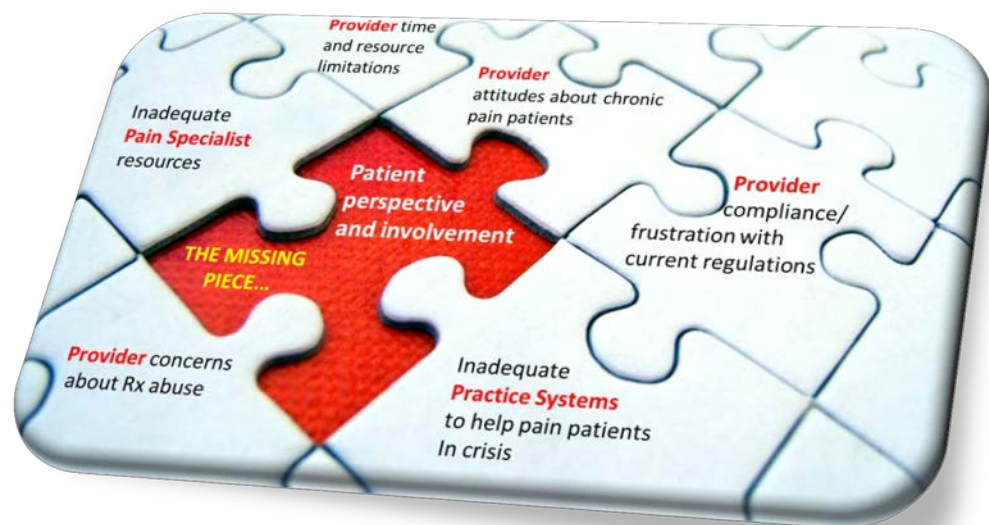


Partnering with Patients to Improve Management of Chronic Pain in Primary Care



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- I. OVERALL GOALS AND OBJECTIVES: The overall goal of this project is to improve management and outcomes for patients with chronic, nonmalignant pain (CNMP). The specific objectives include:**
- A.** *To coach three primary care practices through skill development and system changes needed to establish a longitudinal group visit program for patients living with (CNMP).*
 - B.** *To help CNMP patients to improve their own care by creating a Patient and Family Advisory Council (PFAC) to guide improvement and assist with self-management.*
 - C.** *To incorporate an integrative approach to chronic pain into group visits through use of consultants in psychology, nutrition, wellness coaching, physical therapy and pharmacy.*

II. TECHNICAL APPROACH

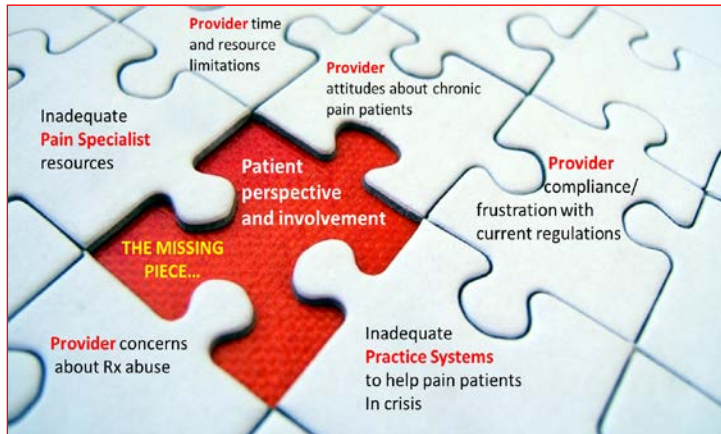
Current assessment of need in target area

Pain is one of the most challenging chronic conditions faced by both patients and providers. For several years there has been a heightened awareness of the need to improve pain management for our patients at the University of Cincinnati (UC) Academic Health Center (AHC). We have been actively assessing the quality of care provided to patients with CNMP in our Primary Care Network (PCN). The PCN includes 14 primary care practices, which saw over 50,000 patients in 2011. A study of three PCN practices in 2009 found 23% of office visits were with CNMP patients. This study and one conducted in two other PCN practices in 2012 identified practice gaps including: **1)** poor documentation of CNMP assessment and management; **2)** underuse of structured assessment instruments; **3)** limitations by the provider to assess and understand functional disability and emotional stress of CNMP patients due to CNMP; **4)** wide variations in prescribing medications for CNMP; and **5)** minimal coordination with specialists and other providers.

We are currently implementing practice improvement efforts that establish standardized care templates in the electronic medical record, provide evidence-based academic detailing, and mentor practices in quality improvement techniques. The focus of this work has been on improving systems of care from the perspective of practices and providers. To significantly change outcomes in chronic pain, however, there is also a critical need to better engage our patients as partners in improving health.

It has been recognized, both in the literature and in our practices, that the complexity of chronic pain results in patient and provider misperceptions, which are significant barriers to optimal management and patient satisfaction. A study of chronic pain patients managed by primary care providers found that patients feel disrespected, mistrusted, and suspected of drug-seeking.¹ As a result, patients are turning to other sources of information and management advice, and they are not sharing this information with their providers.² Some issues can be addressed through education, but there is an endemic issue for patients who feel that providers “can’t relate” to what they are experiencing, particularly with regard to issues of daily living and quality of life.

A recent study in our health system surveyed CNMP patients regarding their care. Patients noted significant anxiety when attempting to obtain refill prescriptions for their pain medications. Specifically, the process for getting refill prescriptions for opioids was poorly



defined and inconsistent. The anxiety from the patients' perspective translated into a high volume of phone calls, and contributed to provider and staff dissatisfaction with caring for CNMP patients. In a 2012 study of our providers, > 80% of respondents felt more stress caring for patients with CNMP than other patients, and < 40% felt they could truly help patients with CNMP, suggesting a significant breach in the

therapeutic relationship between providers and patients. This project is specifically designed to reconnect providers and CNMP patients as partners in the care process using three strategies that promote patient engagement and activation: group visits, a Patient/Family Advisory Council and an integrative approach to chronic pain management.

Group Visits: Group visits are an innovative delivery model designed to improve outcomes by better accessing the expertise of patients' experience for mutual support and group problem-solving. Group visits incorporate most components of individual visits, usually including private or semiprivate, one-on-one medical evaluations conducted by a provider at each visit, as well as interactive group sessions that promote patient engagement and emphasize patient self-management in areas such as medication adherence, complementary and integrative medicine, nutrition, exercise, and psychosocial contributors to health and illness. Use of group visits in complex chronic diseases such as cardiovascular disease, diabetes, and migraine have all supported improved outcomes, decreased resource utilization, and better patient-provider satisfaction.^{3,4,5,6,7,8,9,10,11,12,13,14} While little exists in the literature on the use of group visits in chronic pain, interventions developing social support systems, such as peer mentors or support groups,^{15,16,17} have been found to be effective and there is broad agreement that longitudinal, multimodal interventions and multidisciplinary coordination improve care and should be part of the treatment strategy for patients with chronic pain.^{18,19}

Encouraging experiences with group visits have been noted on a small scale within our practices. Several PCN practices and providers on our project team have conducted episodic group visits for conditions including diabetes and sickle cell disease, as well as some longitudinal group visits for well woman and well child care in a model called "Centering Parenting". The experience has found positive provider, staff and patient satisfaction, but it has taken considerable effort to establish the model. The logistics of group visits (i.e., space requirements, staffing, and simultaneous check-in/out) and skills needed for facilitation and managing group dynamics are significantly different than what is needed for individual care. This creates a need for new skill development and assistance during practice change. To successfully incorporate this new model of care, formal training, quality improvement coaching, and patient guidance for the process are needed.

Patient/Family Advisory Council (PFAC): With increasing evidence of the impact of patient engagement and activation on overall health,^{20,21,22} we recognize that the expertise of our

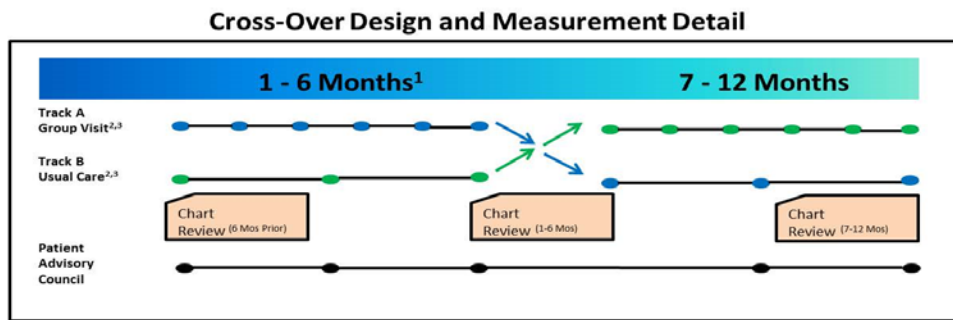
patients is an untapped resource to improve care in chronic pain. In addition to improving access to this expertise at the point of care, as through group visits, models which deliberately seek patient input into healthcare planning, (Patient/Family Advisory Boards) and incorporate patients as improvement team members, increase the likelihood that developed programs will meet patient needs.^{23,24} The use of Patient and Family Advisors in this capacity is a nationally-recognized strength of Cincinnati Children’s Hospital Medical Center and a new area of growth for the UC Medical Center, which recently launched its first Patient/Family Advisory Board.

Integrative Approach to Chronic Pain: An integrative approach to CNMP care incorporates the best of conventional medicine with the best of evidence-based complementary medicine approaches.²⁵ It also addresses patients’ concerns with function and helps to bridge silos created by patients seeking complementary therapies outside the realm of their traditional healthcare setting. There is ample evidence for non-pharmacological approaches to pain management (e.g., acupuncture, behavioral medicine, physical therapy); however, conventional treatment of CNMP often focuses exclusively on pharmacotherapy management. Our proposed innovative group model incorporates an interdisciplinary integrative health approach in which PCP visits are enhanced by integrative health specialists (e.g., yoga therapist, nutritionist) who are able to support skill development for patients and providers through facilitated group sessions.

Intervention Design and Methods

We are employing a randomized crossover design to assess the practical application and overall impact of group visits for chronic pain patients and providers. Patients will be recruited from each of three primary care practices and randomized to one of two arms of the design: **Arm 1: Six months of group visits followed by six months of usual care;** or **Arm 2: Six months of usual care followed by six months of group visits.** “Usual care” is defined as *the pain care currently provided to the patient*. For group visits, the groups will consist of 10-15 patients consistent with previous group visit models.⁴

Figure A: Research Study Design with Timing/Source of Data Collection



Legend:
 1. Cohorts switch tracks at six months. 2. At the beginning of each track, and at study’s completion, both cohorts complete: ORT (1 time only) PAM ,PHQ-9, GAD-7, BPI, PDI, SF-36, PSEQ. 3. At all other visits, both cohorts complete the PEG.

The crossover design (Figure A) has important methodological strengths including an active control group, patients serving as their own historical controls, and the opportunity for a quantitative assessment of the permanency of the group visit effect. Although the crossover design has an inherent limitation of some carry over effect in one treatment arm, our analysis plan will allow us to use utilization data from chart reviews to better clarify group visits’ impact pre-post across three distinct populations. Group visits, occurring monthly for six months, will

allow relationships to build among group members and patients to share successes and challenges for mutual support and problem-solving. The six visits will create an opportunity for providers and patients to address management issues (i.e., diagnostics, referrals, medication adjustments) while developing skills in integrative healing therapies and self-management. It will also help providers better appreciate patients' perspectives on living with chronic pain and how to best engage these patients in a therapeutic way. The six visit series has meritorious logistical considerations making it reproducible in most primary care clinics.

We will accomplish our objectives through the following activities:

- A. Coach three primary care practices through skill development and system changes needed to establish a longitudinal group visit program for patients living with CNMP.*

Practice Recruitment: We will recruit three NCQA-certified PCMH primary care practices committed to adopting an integrative health approach to chronic pain management using a longitudinal group visit model. Selected practices will have past improvement experience, adequate space and staffing for group visits, and commitment from the Practice Manager and a Provider Champion. Past experience with group visits or integrative health is not required.

Improvement Team Formation and Process: An Improvement Team will be convened at each site consisting of the Improvement Advisor, Data Manager, and Faculty Lead from our Project Team, as well as the Provider Champion, Staff Champion and two PFAC members from the practice site. Once IRB approval is received, the Improvement Team will participate in a Basic Training Program (described below) to develop skills needed to implement the group visit model. Following the training program, the Improvement Team will meet bi-weekly for the Improvement Advisor to guide the team in project planning and in conducting Plan-Do-Study-Act (PDSA) cycles to implement the group visit model. These PDSA cycles will be collected by the Project Team on a monthly basis. Run charts on functional pain assessment, self-management support and adherence to recommended care will be created from data collected at each group visit and reviewed with the Improvement Team.

Group Visit Model: The implementation of the group visit model will be guided at each practice site by the Improvement Advisor and Faculty Lead. The elements of the model to be described below will be available to all Improvement Team participants in a "Living with CNMP" Group Visit Binder that will be created by the Project Team during the initial planning period. During their bi-weekly meetings, the Improvement Team at each site will prepare a written "Visit Plan" by modifying a standard template (see Group Visit Template below) prior to each visit, and will complete a written "Debrief Sheet" within 24 hours following each visit to document learnings from the visit. With each site enrolling two cohorts with six group visits in each cohort, each practice site will have no more than one group visit each month as part of this project.

Patient Recruitment: Each practice will recruit 25-30 adult CNMP patients to the program, targeting primary care patients of each site's Provider Champion. Once consented to participate, each individual will be randomized into one of the two arms of the project. Using this strategy, only patients willing to participate in a group visit model will be enrolled, and all participants will have the opportunity to participate in group visits. This will assure that the patients in the comparison groups have not self-selected based on their desire or willingness to participate in a group visit experience.

Visit Plan: During their intervention period, each longitudinal cohort will participate in six monthly group visits. Each visit will last two hours with a standard template to be adapted at each site. All patients will complete HIPAA training and sign privacy statements as a requirement for participation. Other than this requirement, Group Rules will be developed by each cohort and posted in the room at each visit.

GROUP VISIT TEMPLATES

<p>Initial Visit Template: 8am – Arrival and registration 8:30am – Introductions and “Living Well” Circle Activity 8:45am – Group Rules Activity with HIPAA training 9:05am – Integrative Health Introduction, followed by Health Stations: Vitals and Pain Assessments; Brief Focused Individual Time; Integrative Health Coaching 10:15am – Discussion Board 10:25am – Closing Activity</p>	<p>Return Visit Template: 8am – Arrival and registration 8:30am – Health Stations: Vitals and Pain Assessments; Brief Focused Individual Time; Integrative Health Coaching 9:30am – Opener and “Living Well” Circle Activity 9:45am – Integrative Health Introduction and Coaching 10am – Discussion Board 10:25am – Closing Activity</p>
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Interactive Activities: At each visit, the Facilitator (usually the Provider Champion) will guide the group in Opener, “Living Well”, and Closer activities. These activities are designed to engage all patients in the group, support relationship formation among participants and to solicit valuable expertise from patients themselves on living with chronic pain.

Health Stations: During “Health Stations”, the group will work on developing Integrative Health skills while individual patients are seen briefly for vitals and pain assessments by the nurse/MA and for brief pain management-focused visits by the provider. All activities will take place within the group visit space or an immediately adjacent exam room to minimize time away from the group.

Discussion Board: Much of the learning in a group visit occurs from patient-patient interaction rather than provider to patient. The Discussion Board, a flip chart posted with markers, allows patient concerns and questions to direct a portion of each visit. At any point during the visit, patients or facilitators may add a topic to the Discussion Board for group sharing during the last 25-30min of the visit. Recognizing the shared challenges of living with chronic pain and problem-solving based on experience are important functions of group visits.

Basic Training Program: A Basic Training Program (BTP) will be planned for all Provider and Staff Champions, PFAC members and Project Team members prior to implementation of group visits. The purpose of the BTP is to develop skills in three domains essential to the success of the program: group visit facilitation, self-management support and evidence-based management of CNMP. Performance Improvement CME credit will be offered to all providers.

Group Visit Facilitation: At each site, the Provider Champion will facilitate the group with a co-Facilitator from our Project Team, ensuring program fidelity across the sites and ongoing skill development. Staff Champions and PFAC Members may also facilitate select activities during group visits. All Improvement Team members will require training in group facilitation skills. Training in group facilitation skills will be conducted by an external facilitator or member of our project team with advanced facilitation training.

Self-Management Support: All participants will be trained in “Achieving Communication and Care by Engaging Patients” (ACCEPT), an office-based self-management protocol based on motivational interviewing skills developed by Cincinnati Children’s Hospital Medical Center. Three of our Project Team members are Trainers in this method and will conduct this portion of

the BTP. ACCEPT training consists of 2-3 hours of on-line pre-work in advance of a two-hour live training conducted at the BTP, with additional skill development and skills “check-out” once the techniques are in use. Educational methods used during the in-person training will include role play, think-pair-share and critique of videoed interactions.

Evidence-Based Management of CNMP: This portion of the BTP will review evidence-based approaches to CNMP management including use of functional pain assessments, diagnostic criteria for common pain syndromes, and pharmacologic/non-pharmacologic treatments. We will include evidence-based integrative health approaches to CNMP management, presented by our integrative health specialists. It will provide a basic foundation in pain management, understanding of integrative health approaches, and relationship formation with consultants to all Improvement Team members.

B. To engage patients living with CNMP in improving their own care by creating a Patient and Family Advisory Council of patients and support people to guide improvement and assist with self-management support.

Recruitment: At each practice, at least two participating patients (and a support person of their choosing) will be recruited for inclusion in that site’s Improvement Team and the PFAC for the whole project. Patients will be compensated for their participation in these activities. The purpose of involving patients and family members is to maximize relevance and effectiveness of the group visit model and associated activities.

The Cincinnati Children’s Hospital Medical Center is nationally-recognized for commitment to continuous quality improvement, including its engagement of patients and families in the improvement process. We will engage a consultant from their PFAC to guide our recruitment, training and interaction with our Patient/Family Advisors.

Responsibilities: We anticipate that the Patient/Family Advisors will participate in the following activities: Improvement Team meetings; the Basic Training Program; group visits; self-management coaching; feedback to facilitators following each visit; and quarterly meetings of the PFAC for the whole project.

Self-management Support: Using the ACCEPT protocol, self-management support will be provided for patients at each visit, as part of the integrative health skill development during Health Stations (see Section C). Patient/Family Advisors will receive and assist in providing self-management support to fellow group members, supervised by the Facilitators. Their role in providing support will consist of modeling self-reflection and awareness of readiness for change and assisting fellow group members in forming Action Plans.

Patient/Family Advisory Council: The Patient/Family Advisory Council (PFAC) will consist of Patient/Family Advisors from each practice (up to a total of six patients and their support people) and will be led by the Improvement Advisor and a Co-PI. The Council will meet quarterly, providing the opportunity for enhanced role definition and support, feedback on the developing group visit model, and additional assessment of the impact of the groups on a subset of participants. Focus groups will be completed at the 3- and 9-month PFAC quarterly meetings. Semi-structured questions will guide program process improvement and assistance with self-management support. Qualitative data will be analyzed in an ongoing process to inform program development throughout the project.

- C. *To incorporate an integrative health approach to chronic pain into group visits through the incorporation of ancillary providers in behavioral medicine, nutrition/diet, health and wellness coaching, physical therapy, yoga therapy, acupuncture, and pharmacy.*

In order to expand treatment and management alternatives to both patients and providers, we will incorporate several integrative health strategies into this project. These integrative approaches to CNMP management will be integrated into the project through Improvement Team training, inclusion of integrative health specialists in primary care practices, and engaging in integrative health activities (e.g., yoga stretches for pain) during group visits.

Improvement Team Training: As part of the Basic Training Program, the integrative health faculty on our Project Team will provide an overview and evidence-base for the four areas of focus for the integrative health portion of the group visit curriculum: **1)** Mind-body techniques for relaxation led by a psychologist including breath-work, guided imagery, and progressive muscle relaxation/body scan; **2)** Physical activities such as stretching, yoga, and massage techniques, to address common sites of pain, led by a physical therapist and/or a yoga therapist, for self or partner; **3)** Dietary strategies to reduce pain led by a nutritionist/dietitian, involving healthy cooking demonstrations, nutritional assessment and planning, and anti-inflammatory principles; and **4)** Use of medications and supplements, including common medications/medications for pain, their indications, side effects and potential interactions, led by a pharmacist and an integrative health physician.

Connection of Integrative Health to Primary Care: Introduction of the faculty and key specialists will occur at the Basic Training Program and contact information, description of services and referral processes will be provided to all participating practices. The integrative health faculty (Drs. Cotton and Stevenson) and specialists will participate in Improvement Team meetings as relevant to the Visit Plans for each session. They will host a lunch-and-learn session at each of the participating practices on one of the four areas of focus described above.

Integrative Health: At each group visit, an integrative health specialist will briefly introduce a technique drawn from one of the four areas of focus. The Integrative Health Coaching portion of Health Stations will then provide time for skill development and coaching of patients by the specialist. The emphasis during this time will be on hands-on, active learning through activities such as cooking demonstrations, stretching routines, guided imageries, etc. Attention will be paid to teach modalities and skills that patients can easily replicate themselves at home or with the aid of a family member. Patients will be provided with resources related to the integrative health topic at each session to support their use of learned techniques at home. Facilitators will support each patient in developing a self-management goal at each group visit.

Evaluation Design

The overarching goal of this mixed methods research project is to successfully implement a longitudinal group visit model incorporating an integrative health approach to improve the care of patients with CNMP in primary care settings and assess its effectiveness. The evaluation for this project is primarily focused on assessing the impact of educational and systems interventions on the knowledge, attitudes and perceptions, of patients and providers regarding integrative health-focused longitudinal group visits for CNMP. Clinical outcomes, resource utilization and the practicality of integrating these interventions in primary care practices will also be assessed as described in Table 1.

Table 1: Overview of Data Sources and Data Collection Strategies

Outcome Metric	Data Sources	Data Collection	Data Analysis	Expected Improvement
Practice Adoption / System Changes of Group Visits for CNMP [Aim 1]	<ul style="list-style-type: none"> ▪ EMR Data Reports ▪ Semi-Structured Interviews ▪ Survey 	<ul style="list-style-type: none"> ▪ Practice pattern reports (i.e., diagnosis coding, telephone calls, opioid prescribing) will be developed in conjunction with providers and then generated for participating providers and practices ▪ Interviews conducted with key informants at each practice regarding implementation obstacles and solutions ▪ Practice Culture Inventory (short survey administered to all practice staff and providers at baseline and at the end of the project) 	<ul style="list-style-type: none"> ▪ Comparison of baseline report with project-end report ▪ Content analysis using qualitative software with transcribed and coded interview transcripts ▪ Comparison of baseline scores with project-end scores 	<ul style="list-style-type: none"> ▪ Identification of key implementation obstacles and individual practice solutions for incorporation into toolkit ▪ Increased skills for providing care through group visits and knowledge through patient-provider partnership ▪ Increased level of staff teamwork and clarity of roles.
Provider Knowledge, Attitudes, and Skill Development in Self-Management and Integrated Health Group Visits Facilitation for CNMP[Aim 1]	<ul style="list-style-type: none"> ▪ Survey of comfort with group visit model and integrative care ▪ Interviews 	<ul style="list-style-type: none"> ▪ Administered to all participating providers pre and post intervention ▪ Interviews conducted across practice sites with providers identified as key informants 	<ul style="list-style-type: none"> ▪ Comparison of baseline scores with project-end scores ▪ Content analysis using qualitative software with transcribed and coded interview transcripts 	<ul style="list-style-type: none"> ▪ 50% improvement in provider/learner knowledge and attitudes when compared to baseline
Creation of CNMP Patient Family Advisory Council (PFAC) [Aim 2]	<ul style="list-style-type: none"> ▪ Focus Groups 	<ul style="list-style-type: none"> ▪ Focus Groups conducted with all PFAC members at 3- and 9-months 	<ul style="list-style-type: none"> ▪ Content/thematic analysis with transcribed and coded interview transcripts 	<ul style="list-style-type: none"> ▪ Active advisory councils at each practice and identify key barriers / facilitators at the practice level.

Outcome Metric	Data Sources	Data Collection	Data Analysis	Expected Improvement
Patient Self-Management Efficacy for CNMP [Aim 3]	<ul style="list-style-type: none"> PSEQ (Pain Self Efficacy Questionnaire) & PAM (Patient Activation Measure) Focus Groups 	<ul style="list-style-type: none"> Administered to all patients at baseline, 6 and 12 months Conducted with patients pre and post intervention 	<ul style="list-style-type: none"> Comparison of baseline scores with mid-project and project-end scores Content analysis using qualitative software with transcribed and coded interview transcripts 	<ul style="list-style-type: none"> >50% improvement in patient reports of self-efficacy following group visit intervention Patients will report themes of increased satisfaction and engagement in shared decision making process
Patient Clinical Outcomes for CNMP [Aim 3]	<ul style="list-style-type: none"> Standardized tools to assess pain outcomes, mental health and pain related healthcare utilization Chart Reviews EMR Data Reports 	<ul style="list-style-type: none"> Administered to all patients pre, midpoint, and post intervention. Tools include Brief Pain Inventory (BPI), PHQ-9, GAD- 7, PEG (at every visit), SF-36, Pain Disability Index (PDI) Chart reviews pre, midpoint, and post intervention to examine utilization data EMR reports on health care utilization such as emergency room visits, and frequency of phone calls to practices pre, midpoint and post intervention 	<ul style="list-style-type: none"> Utilization of appropriate statistical tests comparing mean scores on standardized tools and health care utilization data at baseline and 6 and 12 months between the patients receiving the group visit intervention and those receiving usual care, as well as assessing individual changes Chart reviews and EMR reports will both be analyzed for presence/absence of assessments using a non-parametric alternative to repeated measures ANOVA; also by repeated measures ANOVA to examine changes to assessment measures 	<ul style="list-style-type: none"> Clinically significant reductions in symptom severity of depression and anxiety scores on self-report measures as well as increases in measures of functional status. Overall health care utilization for CNMP will drop 25% for patients receiving the intervention as measured by chart reviews of phone calls, ER visits, and opioid medication usage.

Providers: Semi-structured interviews will be completed with providers in the 3 clinics who will serve as key informants. We will identify these key informants from the pool of providers at each clinic location whose patients are participating in the group visits. Questions will focus on perceived benefits and burdens of the visits, the impact on patient’s overall health and utilization, and providers’ knowledge and attitudes regarding group visits and integrative health for CNMP.

Practice: Knowledge, attitudes and perceptions about group visits and integrative health for CNMP and implementation obstacles will be obtained via semi-structured interviews with key informants at each practice location. Additionally, providers and staff at participating clinics will complete the Practice Culture Inventory (PCI) at the beginning and end of the project to assess practice level changes as a result of the intervention. Finally, chart review data for overall healthcare utilization will also be used to examine any changes in practice patterns following the intervention.

Patients: Knowledge, attitudes and perceptions about group visits and integrative health for CNMP will be assessed qualitatively via focus groups with patients. At each clinic site, a focus group will be convened at the start of the group visit cycle and then again after the six group visits are completed. Quantitatively, we will examine pain-related outcomes (e.g., functional status, pain rating), mental health, and pain-related health utilization measures (e.g., phone calls, ER visits). The timing, as indicated in Figure A (page 3), and instruments (Table 2) were specifically chosen to ensure appropriate measurement of key outcome metrics while being sensitive to subject question burden. Comparisons between patients receiving the group visit intervention versus those patients treated with usual care during each of the six month interventions will be performed for the pre/post analyses.

Table 2: Patient Outcome Instruments

Outcome	Instrument	Measures	# of items	Study validated	Comments
Pain Related	Brief Pain Inventory (BPI)	Self report of pain severity, treatment, and impact of functioning	9	Yes	Primary Outcome
	Pain Disability Index (PDI)	Self report of pain related functional impairment	7	Yes	
	PEG	Self-report global assessment on pain intensity, emotional health, and function	3	Yes	Given to patients each visit
Mental Health	PHQ-9	Self report of depressive symptoms and suicidal ideation	9	Yes	
	GAD-7	Self report of anxiety symptoms	7	Yes	
Opioid	Opioid Risk Tool (ORT)	Identification of risk factors for opiate related aberrant behaviors	5	Yes	Completed by all patients at study outset
Self Efficacy / Attitudes / Perceptions	Patient Activation Measure (PAM)	Predicting general health and disease self management through stages of activation	22	Yes	
	Pain Self Efficacy Questionnaire (PSEQ)	Measuring one’s self efficacy with respect to pain management	10	Yes	

Statistical Analyses: The following considerations will apply to all analyses, both intent to treat and otherwise: Descriptive statistics will be presented, as appropriate. In all analyses, clinics will be treated as a random factor within which patients are nested, using a within-clinic covariance structure and a degrees of freedom method which will preserve denominator degrees of freedom based on numbers of patients. We will conduct both intent to treat analyses using all randomized patients and analyses restricted to only those patients completing a minimum number of visits. Should we have a reasonable distribution of numbers of visits attended by patients in the intervention condition, we will treat numbers of visits as a dose factor, using the treatment patients only. Most analyses will employ generalized mixed linear models estimated using SAS procedures *Mixed* or *Glimmix*, and assuming normal, binary, or Poisson distributions of the dependent variables. The alpha for each statistical test will be a two-tailed $p = .05$, unadjusted for multiple tests.

Because of our expectation that the intervention condition will produce lasting effects (carry-over), our statistical analysis methods will include changes and augmentations to the common crossover methods. Specifically: Carryover will be estimated via a treatment by phase interaction term, thus adjusting the treatment effect for carry-over. A separate analysis of persistent effects will use only the patients starting in the intervention condition, following them post-intervention during their control group phase. A simpler estimate of the intervention effect will be obtained by treating the first phase of the study as a randomized two group comparison, using patients' baseline values as covariates.

Power Considerations: We expect a minimum of 10 patients per group per clinic (a total of 30 in each arm) to qualify for inclusion to our main crossover statistical model. Using standard crossover analytic methods and assuming a .50 correlation between outcomes on each side of the crossover, we would have 80% power to detect a pre to post-intervention change of 40% to 50% of the unadjusted baseline standard deviation of a continuous outcome variable. An analysis comparing the two groups during the first phase only and assuming a similar correlation between baseline and outcome scores produces the same power for a difference between group means of 53% of the measure's unadjusted baseline standard deviation.

Scores on the BPI Short Form, which we will use to assess levels of pain, can be expected to have standard deviations of approximately 2.0 for pain levels and perhaps up to 3.0 for pain-related functional impairment (each on a scale of 1-10).²⁶ Thus our power figures suggest 80% power to detect differences of 0.8 to 1.06 points in pain levels between the two groups, and approximately 1.5 points in levels of functional impairment.

Target Audience Engagement: There are two primary target audiences in this project. The first target audience is the three primary care practices and the providers/staff providing care in these settings. The project includes detailed and intense contact with the practices and providers. The project team will meet regularly to review the progress and activities of each of the practices. Part of that review will be to discuss the level of engagement at each practice. The second target audience is the patients currently being treated for CNMP at the three practices. We will monitor participation via response rates for surveys, group visit attendance, appointments with providers, other health care utilization, and feedback from the PFAC.

Dissemination Plans: The dissemination plan for this project has both local and national components. The first component is to successfully implement longitudinal group visits for

CNMP and a PFAC in order to demonstrate feasibility for widespread adoption within the UC Health system. A Toolkit, containing training presentations, resources and materials such as the Group Visit Binder will be made available to practices within the PCN, and the project team will consult with individual practices interested in adopting the model. The second level of dissemination will occur nationally through professional publications and presentations. The project team is committed to at least three professional publications in peer reviewed journals and at least two regional or national meetings of primary care providers.

III. DETAILED WORK PLAN AND DELIVERABLES

This a two-year project with integrated deliverables that fall into three fundamental areas: **1)** implementing longitudinal group visits; **2)** creating the Patient/Family Advisory Council (PFAC); and **3)** incorporating an integrative health approach into chronic pain management. The first six to eight months will focus on receiving IRB approval, recruiting practices and Improvement Team members, developing resources and forming the PFAC. We will also use that time to gather baseline data and assess the systems changes that will be needed in the practices as we prepare for an 18-month implementation period. During the Implementation phase of the project, we will provide practices with a variety of interventions and practice-driven system changes to achieve the three project aims. Qualitative and quantitative data will be collected throughout this period. In the final six months of the project, we will help practices integrate changes for long-term impact as we analyze data, prepare manuscripts and develop wider plans for dissemination to other practices and systems.

Implementing Longitudinal Group Visits

- *Led by project faculty and the Improvement Advisor*
- *Interactive activities to engage all participants*
- *Strong focus on self-management and integrative health*
- *Small tests of change (PDSA) and metrics to guide effort*

Creating Patient and Family Advisory Council

- *Guide practice improvement efforts by providing a key, and often missing, perspective*
- *Member of Improvement Teams from the beginning*
- *Coach peers on self-management techniques*

Incorporating an Integrative Health Approach into Chronic Pain Management

- *Infuse the use of behavioral medicine, nutrition, wellness coaching, and physical activity into primary care management for CNMP*
- *Open robust referral pathways for integrative health specialty care*

Activity	Project Month	Responsible Person(s)	Anticipated Outcomes
Create and Submit IRB Protocol	1-3	Jill Boone Tiffany Diers Amy Short Chris White Tony Leonard Research Assistant	IRB approval/exemption
Recruit UCH Primary Care Practices and Champions	1-2	Tiffany Diers Amy Short	3 practices will commit to participate; each practice will identify a Provider Champion and Staff Champion
Develop Integrative Health Curriculum	1-3	Jill Boone Sian Cotton Tiffany Diers Stefanie Stevenson Chris White	Lesson plans, resources, and referral information for four key areas: mind-body techniques, physical activities, dietary, and medications/supplements
Develop Basic Training Curriculum	1-4	Jill Boone Sian Cotton Tiffany Diers Amy Short Chris White	Lesson plans for training participants in group facilitation skills, self-management (ACCEPT), evidence-based management of CNMP, and integrative health
Develop "Living with CNMP" Group Visit Binders	4-5	Jill Boone Tiffany Diers Amy Short Barbara Speer	A tool that Improvement Teams will use to guide implementation of the group visits; to include visit templates, draft debrief sheets, interactive activity materials and sections on self-management and integrative health
Develop focus group and semi-structured interview content to be Administered to Patients, Providers and Staff	4-6	Jill Boone Nancy Elder Chris White Sian Cotton Jack Kues	Surveys to measure the impact of group visits on both patients and providers/staff
Recruit for Group Visits	4-8	Jill Boone Amy Short Tiffany Diers Practice Champions	Each site will recruit 25-30 patients resulting in 10-13 matriculated patients for two cohorts
Recruitment of Patient and Family Advisory Council (PFAC)	5-6	Jill Boone Tiffany Diers Amy Short Practice Champions	At least two patients with CNMP will be recruited per practice site
Improvement Team Formation	5-6	Jill Boone Tiffany Diers Amy Short Barbara Speer Mary Beth Vonder Meulen Practice Champions Practice Staff PFAC	An Improvement Team will be formed at each site to include a Faculty Lead, the Improvement Advisor (Ms. Short), the Data Manager (Ms. Vonder Meulen), a Physician Champion from the practice, a Staff Champion from the practice, and two PFAC members

Activity	Project Month	Responsible Person(s)	Anticipated Outcomes
Basic Training Program for Participating Practices	7	Jill Boone Sian Cotton Tiffany Diers Nancy Elder Jack Kues Amy Short Barbara Speer Stefanie Stevenson Mary Beth Vonder Meulen Chris White	All practices will be represented at the Basic Training Program, including all Practice Champions and PFAC team members, to receive training in QI, group visit facilitation skills, self-management support (ACCEPT), evidence-based management of CNMP, and integrative health
Baseline Data Collection	6-9	Amy Short Mary Beth Vonder Meulen Practice Champions Chris White	Each practice will calculate a baseline for patient satisfaction, functional pain assessment, and adherence to evidence-based treatment guidelines
PFAC Meetings Commence	6-21	Jill Boone Tiffany Diers Amy Short Nancy Elder Mary Beth Vonder Meulen	Will meet quarterly; will provide feedback and support with group visits; additional meetings will occur before and after our intervention period.
QI Project Conducted at Each Practice	3-24	Jill Boone Tiffany Diers Amy Short Mary Beth Vonder Meulen Practice Champions PFAC	Biweekly Improvement Team meeting with Faculty Lead, Improvement Advisor and Data Manager to guide the team in project planning and conducting small tests of change (PDSA)
Integrative Health Lunch and Learn	7-8	Sian Cotton Stefanie Stevenson Chris White Practice Champions	One session in each practice for deeper learning and connection to key consultants, selected from among the following: mind-body techniques, physical activity, diet, or medications/supplements
Plan for Group Visits	7-9	Jill Boone Sian Cotton Tiffany Diers Amy Short Mary Beth Vonder Meulen Chris White Practice Champions PFAC	Site specific visit plan, group rules, interactive activities, health stations (ACCEPT/integrative health), and debrief sheet
Implement Group Visits	9-20	Jill Boone Tiffany Diers Amy Short Practice Champions PFAC	In each practice, one group visit will occur each month for 12 months, for a total of 36 group visits over a 12month period
Gather Evaluation Data	9-20	Amy Short Chris White Mary Beth Vonder Meulen	Run charts on patient satisfaction, functional pain assessment, self-management support, and adherence to evidence-based guidelines will be created and reviewed monthly

Activity	Project Month	Responsible Person(s)	Anticipated Outcomes
Analyze Data	9-20	Jill Boone Sian Cotton Tiffany Diers Nancy Elder Jack Kues Anthony Leonard Amy Short Chris White	<i>Analysis of process and outcome measures as described in evaluation design</i>
Interview PFAC members, Providers and Staff	22	Jill Boone Sian Cotton Nancy Elder Jack Kues	<i>Qualitative data to integrate into outcomes, to help analyze the impact of group visits</i>
Final Data Analysis	22	Jill Boone Sian Cotton Tiffany Diers Nancy Elder Jack Kues Anthony Leonard Amy Short Chris White	<i>Analysis of process and outcome measures as described in evaluation design</i>
Final Learning Session	23	Jill Boone Sian Cotton Tiffany Diers Jack Kues Amy Short Barbara Speer Mary Beth Vonder Meulen Chris White Practice Champions PFAC	<i>Presentation of QI project by Practice Champions; dissemination of final results and aggregate findings across practices</i>
Prepare Final Reports and Disseminate Outcomes and Best Practices	22-24	Jill Boone Sian Cotton Tiffany Diers Nancy Elder Jack Kues Anthony Leonard Amy Short Barbara Speer Mary Beth Vonder Meulen Chris White	<i>Timely submission of final report; submission of findings for presentation/publication to at least 3 scholarly venues</i>

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ORGANIZATIONAL DETAIL

I. Leadership and Organizational Capability:

Organizational Overview: The University of Cincinnati (UC) Academic Health Center (AHC) is a major source of medical education and care in Greater Cincinnati. The center has a distinguished reputation for training prominent health care professionals and providing leading-edge research and patient care and includes the colleges of medicine, nursing, pharmacy and allied health sciences. Select UCAHC groups will partner to provide the expertise, leadership, and systems to successfully complete this project, including: **UC Center for Continuous Professional Development** ❖ **Cincinnati Interprofessional Care Collaborative** ❖ **UC Health Center for Integrative Health and Wellness** ❖ **UC Health Primary Care Network (PCN)**.

The proposed chronic pain project will be implemented by the **Cincinnati Interprofessional Care Collaborative (CICC)**. The **CICC** is an interprofessional, multi-institutional team with representatives from all four colleges in the AHC, the UC College of Business, The Christ Hospital, Kroger Pharmacy, the Cincinnati VA Hospital, and UC Health (the UC Health System and physician practice plan). The specialties of this team include: family medicine, internal medicine/pediatrics, pharmacy research and resident training, community pharmacy practice, nursing, health services research, public health, health economics, medical education, quality improvement, and psychiatry/behavioral neuroscience.

CICC experience and expertise in chronic pain and quality improvement:

- [Chronic pain management in primary care](#) – Several research projects are in progress or have been completed with community primary care physicians to determine the prevalence of chronic pain in primary care practices and the nature of care provided to these patients, as well as to provide academic detailing in pain assessment and management.
- [Team-based management of pain episodes in sickle cell patients](#) – Two CICC members (and Project Leadership team members) currently lead a federally-funded initiative, the Ohio Valley Sickle Cell Network, to improve the health of people living with sickle cell disease as part of a national learning collaborative.
- [Survey of chronic pain management by primary care physicians](#) – A member of our team was responsible for survey development and data analysis for a national pain survey undertaken by a team of four organizations.
- [Pain management protocol development](#) – A pharmacist from our team was integrally involved in the UC Medical Center (UCMC) Pain Committee developing pain management protocols and providing pain education.
- [Quality Improvement and Transition of Care](#) – Our team QI expert previously worked on both hospital quality improvement and transitions of care programs for the UC Health system in collaboration with a community agency partner.

The UC Center for Integrative Health and Wellness treats people with a variety of medical and psychiatric conditions utilizing a holistic perspective focused on optimizing function and wellness. Treatments are multidisciplinary and may include elements of integrative physician consults, mind-body therapies, nutrition, health/wellness coaching, acupuncture, massage, and/or movement therapies.

The UC Health Primary Care Network (PCN) contains more than 50 primary care physicians located throughout Greater Cincinnati. It includes 14 internal medicine and family medicine primary care practices located throughout the Cincinnati area.