Managing Pain:
Opioids as Part of the Solution, Not the Problem

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I. OVERALL AIM AND OBJECTIVES

Chronic nonmalignant pain (CNMP) is particularly common in primary care settings with prevalence estimated anywhere from 5% to 50%, depending on the source [1-6]. In alignment with the Patient Centered Medical Home (PCMH) and Chronic Care Model [7], many experts and clinicians agree that CNMP requires a multi-modal, interdisciplinary approach to achieve maximum benefit for patients. CNMP, however, differs from many other chronic diseases cared for by primary care providers (PCPs) because of the availability of chronic opioids as a treatment option. PCPs must consider addiction, drug diversion, overdose, and legal and regulatory factors in their patient assessment and treatment decision making.[9, 10] For many providers, decisions about the use and management of chronic opioids remain one of the most difficult aspects of caring for patients with CNMP. [11, 12] **The goal of this project is to improve quality of care for primary care patients with CNMP in the UCHealth Primary Care Network (PCN) via the implementation of practice and system wide changes.**

Specifically, this project aims to:

1. *Improve the assessment and associated documentation of all components of pain (pain severity, functional disability and psychological distress) in all patients with CNMP, and opioid addiction and misuse risk and opioid use monitoring in patients with CNMP on chronic opioid therapy.*
2. *Improve the appropriate prescribing of analgesic and adjuvant medications for CNMP, including opioids.*
3. *Improve the appropriate use of, referral to and communication with pain management providers, physical therapy, mental health providers and complementary and alternative medicine (CAM) providers*

The PCN consists of 14 primary care practices (family medicine, general internal medicine and internal medicine/pediatrics) affiliated with UCHealth, the clinical arm of the University of Cincinnati. These practices include two urban residency training sites and 12 urban and suburban locations, including several practices that provide services to Medicaid and underserved populations. These practices saw 50,000 patients in 2011. Chronic pain is a significant problem in these practices; in 2009, a pilot study in 3 PCN practices found that 23% of office visits were with patients with chronic nonmalignant pain (CNMP). By improving the quality of care provided to these patients with CNMP, this project will make a significant difference in the lives of hundreds of patients. By assisting practices to make sustainable changes in their systems of chronic pain assessment and management, this project will improve the lives of even more patients in the coming years.

II. CURRENT ASSESSMENT OF NEED IN TARGET AREA

In the past 3 years, we have actively assessed the quality of care provided to patients with CNMP. The Cincinnati Area Research and Improvement Group (CARInG) practice based research network (PBRN) is a regional PBRN whose goal is to improve the care of patients and the work experience in primary care through a partnership of clinicians, medical office staff, patients and researchers. The primary care practices of UCHealth (PCN) are member practices of the CARInG Network, and several of these practices were involved in two initial studies that provide data confirming three main gaps that we will address in our project:

- Documentation of all aspects of CNMP assessment and management are poor, with little use of structured instruments;
- The prescribing of analgesic and adjuvant medications for CNMP, including opioids is haphazard;
- Coordination of care with specialists and other providers is minimal.

1) Documentation of all aspects of CNMP assessment and management are poor, with little use of structured instruments:

A 2009 CARInG study of 8 practices in the Cincinnati area (including 3 PCN practices) documented care for 137 patients with CNMP. We found that only 68% of patients had at least one assessment of pain severity in their chart, 41% an assessment of functional disability and 32% an assessment of emotional distress. Very few of these assessments used a structured instrument (13% of pain severity assessments, 9% of disability and 23% of emotional distress). Forty-seven percent of patients were on chronic opioids. For these 64 patients, 25% had a urine drug screen in their chart and 21% had an opioid contract.[12]

In a 2012 study of 3 practices (including 2 PCN practices), reviews of charts of 138 patients with chronic pain found that pain severity was documented at least once in 91%, functional disability in 58% and emotional distress in 33% of patient charts. However, the use of structured instruments still lagged, with only 58%, 8% and 12% of assessments for pain severity, functional disability and emotional distress, respectively, using any type of structured instrument. Only the tool used for assessing emotional distress (the patient health questionnaire 9 (PHQ9) was a validated instrument. For the 40% (55 patients) who were on chronic narcotics, 46% had an opioid contract, 39% a statewide prescribing registry report (OARRS) and 40% a urine drug screen in the chart. Only 42% of charts documented any kind of questioning or use of instruments to assess for misuse, abuse or diversion of opioids.

2) Prescribing of analgesic and adjuvant medications for CNMP, including opioids is haphazard

In the 2009 study, 100% of the 137 patients were on medications; the most commonly used were opioids (47% currently using), non-steroidal anti-inflammatory drugs (NSAIDS) (40% using), and muscle relaxers (32% using). Individual patients were currently using between 1 and 8 medications each for pain. In the 2012 study, detail about types of opioids was obtained, and 40% of patients with CNMP were on short acting opioids only and 5% were on both short and long acting opioids. None took only long acting opioids.

3) Coordination of care with specialists and other providers is minimal

In 2009, of the 137 patients with CNMP, 51% were referred to a specialist physician for a second opinion, 21% to a pain management specialist and 35% for physical therapy. A smaller number received mental health counseling (9%), or saw a chiropractor, (9%) massage therapist (3%) or acupuncturist (2%). In the 2012 study, 65% of patients were referred to a specialist physician and 21% to a pain management specialist. However, in both studies, the chart documentation was usually unclear as to the purpose of the referral and the communication between the primary care provider and the specialists was minimal.

In 2012, we also surveyed primary care physicians, resident physicians and nursing staff (nurses and medical assistants) at 3 practices (2 PCN) about their confidence in providing quality care for patients. Forty physicians and residents returned surveys. Most physicians were fairly or extremely confident they could diagnose and manage co-existing depression (80%) and manage chronic opioid side effects (68%), but fewer physicians were that confident they could accurately assess functional disability (38%), determine opioid abuse potential (50%) or even accurately assess pain severity (50%). Twenty-seven nursing staff returned surveys. Most nursing staff were fairly or extremely confident they could engage with providers and share their nursing impressions with providers (82%), but fewer were as confident in their ability to assess for opioid side effects during medication reconciliation (40%) or help assess functional disability (40%). However, 80% of the nursing staff agreed that providers considered them an important part of the team caring for patients with CNMP, and 83% of providers agreed that nursing staff we an important part of that team.

Together, these data demonstrate the great need within primary care practices for better systems of care for patients with CNMP. Without better systems supporting these providers and their staffs, improved care for patients with CNMP will be fleeting. Luckily, many of the practices are ready to move forward in improving their care. In our small study in 2012, both nursing staff and providers saw the importance of teamwork in CNMP care. By 2012, six PCN practices had achieved NCQA patient-centered medical home (PCMH) certification, and several other practices were in the process of applying for certification. These practices are ready to expand their team based practice models to complex chronic problems like chronic pain. Other PCN practices may find this project the stimulus to move them towards this important certification step.

III. TECHNICAL APPROACH, INTERVENTION DESIGN AND METHODS

We will achieve our 3 objectives through the following activities:

*At **ALL** PCN practices:*

1. Develop practice and PCN based registries of patients with CNMP to allow for data collection, reporting, feedback and quality improvement activities.
2. Implement EHR-based chronic pain assessment and management templates across ALL the PCN practices.

*At a **SUBSET** of 4 PCN practices:*

3. Perform the following academic detailing and educational sessions:
    a. Coordination of care with, and local resources for, pain management, physical therapy, mental health and CAM modalities for CNMP;
    b. Appropriate use of analgesic and adjuvant medications, including opioids;
    c. Legal requirements and evidence-based guidelines for the prescribing of chronic opioids for CNMP.
4. Implement practice-specific PDSA cycles with chronic pain system improvement strategies on the 3 areas of academic detailing. These will include:
        i. Assessment of provider and staff beliefs, attitudes and self-efficacy regarding CNMP care to help guide selection of PDSA strategy;

ii. Collection of patient and practice outcomes;
iii. Kick-off learning session for all providers and staff to review PDSA
iv. Assistance from a practice facilitator specializing in practice-based research/quality improvement, to implement practice change strategy.

With the experience of the CARInG PBRN in performing practice-based research and quality improvement, the experience of UC staff in facilitating primary care quality improvement, and the support of the leadership of the PCN and the medical directors at the individual PCN practices, we are well situated to succeed in implementing and evaluating this project. Our approach has two types of activities that promote improved care of patients with CNMP. (See table below) The first two activities will be performed and made available to all PCN practices. The next four activities will involve active assistance to practices in order to produce system changes and will occur in four purposefully selected practices – a residency practice, a practice which includes Medicaid/underserved patients, and two additional PCMH-certified practices. These practices will be selected to assess how system changes are implemented in a variety of practices styles and locations.

Technical approach activities	**4 actively assisted PCN practices**	**10 remaining PCN practices**
Registry of practice patients with CNMP made available to providers	Yes	Yes
Validated assessment and management instruments added to EPIC CNMP EHR template and available to all providers	Yes	Yes
Academic detailing and educational sessions to providers and staff	Yes	No
Assessment of provider and staff beliefs, attitudes and self-efficacy regarding CNMP care to help guide selection of PDSA strategy	Yes	No*
Collection of practice and patient outcomes with feedback provided to practice providers and staff	Yes	No*
Assistance from practice-based research/quality improvement facilitator with practice QI project	Yes	No

For evaluation purposes only, surveys and outcomes will be collected from these practices

As outlined in the Evaluation Design section below, we will compare changes in several process and patient outcomes between the two groups of practices in order to assess the potential added benefit of facilitated system changes for CNMP care. At the end of this project, materials developed for the actively assisted practices will be made available to all the practices, and limited practice facilitation assistance will also be made available, through membership in the CARInG Network.

The following describes the methods and the activities for each of the interventions. Each planned intervention is based on evidence-based guidelines (when available), and the medical

literature. In areas where this is no evidence to guide our interventions, we have incorporated additional data collection and analysis into our plan

1. **Develop practice and PCN-based registries of patients with CNMP to allow for data collection, reporting, feedback and quality improvement activities.**

Since few providers are using structured instruments to identify and assess patients with CNMP, developing patient registries will require input from health IT, project leadership and CNMP consultants. We will work together to develop an IT protocol that incorporates diagnosis codes, prescribing data and selected components that may include visit frequency, referral patterns and laboratory testing that we will test via planned chart reviews to determine what components identify the most patients who have chronic pain while limiting the misidentification of patients without chronic pain.

2. **Implement EHR-based chronic pain assessment and management templates across ALL the PCN practices**

For practices to use structured instruments to assess and manage CNMP, the instruments must be readily available to clinicians and patients. Currently, our EPIC EHR has no chronic pain template. We will create an advisory group consisting of 3 medical directors of PCN practices, a pain management specialist, a pharmacist, a quality improvement specialist and a UCHealth EPIC programmer to review and help customize a group of valid tools that will be placed within a chronic pain template in the EPIC EHR, and which will be easily accessible to primary care providers (PCPs) and their staffs. Since PCPs have limited time for each patient encounter, we will provide instruments that can be completed with patients by nursing staff, and also tools which can be printed and handed to patients to complete on their own. Potential instruments the advisory group will consider for inclusion in the template include:

Purpose	Potential instrument
Initial assessment of patients with CNMP	Brief Pain Inventory (short form) Short form McGill pain questionnaire S-LANSS questionnaire for neuropathic pain
Ongoing assessment of patients with CNMP	PEG 3 question assessment PADT Pain assessment and documentation tool
Opioid risk and appropriateness	ORT Opioid Risk Tool SOAPP Screener and opioid assessment for patients with pain DIRE score patient selection for chronic opioid analgesia
Ongoing Opioid Use	COMM Current Opioid Misuse Measure
Depression and anxiety screens	PHQ9 Patient Health Questionnaire 9 GAD7 Generalized Anxiety Disorder 7
Drug and alcohol misuse and abuse	AUDIT-C 3 question alcohol screen CAGE and CADE-AID problem drug and alcohol screen

3. **At the subset of 4 PCN practices, perform the following academic detailing and educational sessions:**

A. Coordination of care with, and local resources for, pain management, physical therapy, mental health and CAM modalities for CNMP;

B. Appropriate use of analgesic and adjuvant medications, including opioids;
C. Legal requirements and evidence-based guidelines for the prescribing of chronic opioids for CNMP.

A: Care coordination and referrals are an important part of the PCMH and the Chronic Care Model. All guidelines note that CNMP is a complex biopsychosocial problem, and that care with a multidisciplinary team improves pain outcomes. Our initial assessments identified inconsistent referrals and communication, but the medical literature does not yet contain evidence on how best to structure coordination, communication and referrals around patients with CNMP. Therefore, our first step will be a qualitative study of these patterns in our community of PCPS and non-primary care partners in order to identify local best practices for referrals, communication and coordination. Under the leadership of the Investigator, an experienced qualitative researcher, we will perform individual interviews and focus groups with the following individuals:

- *Primary care providers in PCN offices/nursing and administrative staff in PCN offices*
- *Pain management specialists/nursing and administrative staff in pain offices*
- *Physical therapists/administrative staff in PT offices*
- *Mental health counselors and psychiatrists/administrative staff in mental health offices*

Since providers have difficult schedules, we will interview them individually, but will hold several focus groups for nursing and administrative staff. We anticipate interviewing five PCPs and six care partners. Interview questions will include open-ended questions around successful referrals and communications, main barriers to communication, successful coordination of care and barriers to coordination. Analysis will be performed with a goal of producing key factors necessary for successful referrals and communication, including timing of referrals, bidirectional communication, expectations and outcomes. This will guide the academic detailing session, and also guide the chart reviews planned for the evaluation.

Working with our consultants in pain management, physical therapy, integrative medicine and mental health, we will design four academic detailing sessions for PCN providers and staff. Each session will include written and digital information to be left with providers and staff and will focus on important, practical information presented in a manner that addresses the needs identified from the qualitative study. At the end of each session, those at the PCN offices should understand better the role of each type of care partner in CNMP, the type of services offered by the care partner for CNMP, indications for referrals, and practicalities about how to refer to these care partners in the our region.

B) Since 100% of patients with CNMP receive medications, a better understanding of medications and their appropriate use is imperative. The Investigator will arrange both in-person training and digital online resources for nursing staff performing medication reconciliation and for providers making prescribing decisions. In addition to conducting an academic detailing session at each practice, she will work with the QI specialist and practice facilitator to develop and assist with potential PDSA cycles around better medication prescribing and reconciliation for system improvement detailed below.

C) Regulatory changes in many states, including Ohio, mandate providers and their staffs to fulfill a number of requirements for patients on chronic opioid therapy. In our 2012 pilot study, we found that only 35% of patients met the requirements of the 2011 law, and that even fewer (5%) met risk stratification, patient selection, informed consent and monitoring recommendations from the 2009 clinical guidelines for the use of chronic opioid therapy in chronic non-cancer pain by the American Pain Society-American Academy of Pain Medicine Opioids Guideline Panel.[13] We will develop an academic detailing session at each practice and will work with the QI specialist and practice facilitator to assist with the development of PDSA cycles around regulatory and guideline compliance for chronic opioid therapy for system improvement detailed below.

4. **Implement practice-based PDSA cycles with chronic pain system improvement strategies at the subset of practices based on the 3 areas of academic detailing. These will include:**
   i. Assessment of provider and staff beliefs, attitudes and self-efficacy regarding CNMP care to help guide selection of PDSA strategy;
   ii. Collection of patient and practice outcomes;
   iii. Kick-off learning session for all providers and staff to review PDSA
   iv. Assistance from a practice facilitator specializing in practice based research/quality improvement, to implement practice change strategy.

Using Deming's Model for Improvement as a theoretical foundation[14], we will use improvement science to design strategies for improving the assessment and management of patients with CNMP. We will adapt our 2012 survey of provider and staff beliefs, attitudes and self-efficacy regarding CNMP care and use it to help assess needs at each practice. Then, at each practice, a team of key stakeholders will be convened to define the aims and scope of the project for their practice. Then, using the patient registry, we collect both baseline and later data to validate the efficacy of interventions. We will also resurvey providers and staff to assess changes in their beliefs, attitudes and self-efficacy, as well as their opinions regarding other project components. Key drivers and possible interventions will be developed based on baseline results. Next steps include using quality improvement tools to prioritize interventions which will be tested on a small scale using Plan-Do-Study-Act (PDSA) cycles. Learnings from these small experiments will be folded into the following PDSA cycles, each building upon the other to ramp towards best practices that are validated by improvements in the baseline measurements. As effective interventions are identified in this manner, the scale of testing will be increased and further improved until they are ultimately implemented as the standard procedure. Metrics will be kept and monitored at the practice site to ensure sustained improvement.

IV. EVALUATION DESIGN

The evaluation of this project will utilize both qualitative and quantitative methods to assess the impact on professional practice and patient care. We will examine both outcomes (summative) and project implementation (formative) aspects of the program. Our target audience is primary care practices and includes physicians and other staff. However, our systems-based approach to practice change includes other parts of the delivery system that

impact practice and the care of patients being prescribed opioids for chronic pain. These include our HIT system, pain specialists, and other providers offering therapies for chronic pain patients (e.g., PT and CAM). The table below provides an overview of the evaluation plan for each of our three project aims. As appropriate, we will compare both before and after outcomes and outcomes between the four actively assisted practices (experimental group) and the ten passively assisted practices (control group).

Evaluation Focus	Improve assessment	Improve prescribing	Improve coordination
Practice gap metrics/ measures	• Documented use of standardized tools (described earlier in the proposal) in EHR. • Clinical notes in chart that reference tools and indicate management decisions based on tool results • Survey providers about the value and ease of use of EHR-embedded tools and understanding of how to use the results • Improvement in pain scores in patient charts using standardized tools	• Adherence to prescribing guidelines, including maximum opioid dosing • More frequent and complete medication reconciliation • Greater comfort and self-efficacy by prescribers and staff regarding prescribing and caring for CNMPs. • More effective use of all medications and adjunctive therapies	• Number and quality of referrals to outside specialists (pain specialists, PT, CAM) • Interviews/focus groups will be conducted to assess referral patterns and decisions • Specialists will be surveyed to gain their assessment of the quantity and quality of referrals • Provider/staff surveys assessing perception of care coordination
Sources of data	• Baseline and at end of study use standardized instruments for CNMP assessment via IT data report and a chart review of a sample of patients with CNMP. • Actual patient pain scores found in instruments at baseline, midpoint and end of study • Surveys will be midpoint and at end and will be conducted electronically.	• Chart review of CNMPs at baseline and quarterly thereafter • Physician/staff comfort/self- efficacy measures at baseline mid-project and post-project.	• Chart reviews of PCPs and specialists to assess referral patterns at baseline and throughout the project • Surveys of PCPs and specialists • Examination of referral communication (e.g., letters, reports, etc.) • Patient surveys will be conducted to assess their perception of coordination of care.
Data collection and analysis	• Baseline data will be collected prior to any interventions • We will aggregate data by month and report rates of use (number of uses/number of	• Via chart reviews, we will monitor a sample of patients in each practice and for each prescriber in the practice. Data related to their assessment, treatment	• Numbers and types of referrals will be assessed at baseline and monthly throughout the project. Statistical analyses will primarily compare pre-post changes, but also

	opportunities for use) • Analysis will focus primarily on rate comparisons over time but will also compare experimental active assistance practices and control passive assistance practices at baseline and project end	and outcomes will be assessed. • Baseline evaluations will assess the quality of opioid prescribing for CNMP patients per guidelines • Additional evaluations will be conducted at mid-project and at project end. • Statistical comparisons will be made for each time period and between the 2 groups of practices • Prescriber and staff comfort/self-efficacy will be compared in the experimental group at baseline, mid-project, and project end	between the 2 groups of practices • Qualitative data (surveys and /or interviews) will be conducted at baseline, mid-project, and post-project. Transcripts of interviews will be analyzed with qualitative analysis software. Survey data will be compared pre-post • Social network analysis will examine types and strength of referral patterns
Methods of control	• Primarily a pre-post intervention design with internal controls by practice, number of CNMPs seen/month • Control group will have access to EHR-based tools but will not receive the active assistance and educational intervention. Comparison between these 2 groups will be at baseline and project end.	• Primarily a pre-post design with some comparisons between experimental practices and control practices • Internally, we will control for practice sites and new/existing patients.	• Primarily a pre-post design with internal controls by practice and number of CNMPs seen/month • We will also examine the impact of insurance type and geographic location on referrals.
Impact on practice (translation)	• The education and systems interventions will be built around QI PDSA cycles. The level of participation by practitioners will be monitored as well as the quality and outcomes of the QI activities to accomplish the 3 project aims. • At a systems-level the primary interventions will be the development of patient registries and EHR-embedded tools and resources. We will monitor the level of participation of practitioners and staff as well as the quality, and use of, the products and resources		
Target audience/ Dissemination	• Primary care providers, offices, and systems are the focal audience for this project. A secondary audience are CME/CPD providers and quality improvement professionals • This project is designed to meet the rigors of clinical research design as a small, practice based study. We will be developing manuscripts for submission to journals in primary care (Family and Internal Medicine), health professions education, and quality improvement. As a secondary dissemination strategy, the team will submit abstracts to national meetings in primary care and health professions education.		

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Detailed Work Plan and Deliverables Schedule

This a two-year project with integrated deliverables that fall into three fundamental areas: 1) Practice Engagement, 2) Systems Changes, and 3) Outcomes assessment/research. The first six to eight months will focus on developing systems (eg. patient registries) and tools/resources. We will also use that time to recruit practices and gather baseline data 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.

Practice Engagement

- Recruitment and development of 4 pilot and 10 control practices
- Development of specialty services for better integration with pilot practices
- Outcome-focused interventions
    - Academic detailing
    - Quality Improvement projects
    - Performance feedback

Systems Changes

- Creation of a patient registry
- EPIC-embedded tools and resources for pain management

Outcomes Evaluation and Research

- Baseline data (chart reviews, interviews, and surveys)
- Practice change assessment (experimental and control practices)
- Patient impact (chart/registry review and patient surveys)
- Scalability (to other conditions, other practices, and other systems)
- Dissemination (Publications and presentations)

Activity	Project Month	Responsible Person(s)	Anticipated Outcomes
Create and submit IRB protocol	*1-2*		*IRB approval/exemption*
Recruit UCH primary care practices and Champions	*1-2*		*3-4 practices will commit to participate; each practice will identify a Provider Champion and Staff Champion*
Conduct initial provider/staff surveys	*3-4*		*>80% of surveys distributed will be returned*
Conduct interviews with primary care and referral partners	*3-6*		*Develop recommendations for enhanced referral communication*
Design EHR template in collaboration with consultants and providers	*3-6*		*EPIC-compatible EHR template for chronic pain management ready for trial*

Establish registry of chronic pain patients for each partnering practice	*3-6*		*Registry of population of focus to anchor data collection for improvement activities*
Develop data process to include chart review and automated data reporting	*4-6*		*Templates for chart reviews; functioning process for twice monthly automated EHR reporting*
Conduct first chart review	*5-6*		*50 chart reviews will be conducted on the population of focus at each practice site*
Analysis of survey and initial chart reviews	*5-7*		*Analysis of process and outcome measures as described in Evaluation Design; comparison of participating practices versus other PCN sites*
Kick-off Learning Session for participating practices	*8*		*All practices will be represented at the Kick-off event, including all Provider and Staff Champions*
QI Project conducted at each practice	*8-20*		*Biweekly contacts with analysis of run charts to guide improvement; key driver diagrams created for each site with associated PDSA cycles and ramps*
Academic detailing at each practice	*8-20*		*Three sessions at each practice based on preference and need*
Mid-point survey of providers, staff, patients	*14-15*		*>80% of surveys will be returned; analysis of results within one month of receipt*
Mid-point Learning Session at each practice site	*16*		*All practices and Champions will participate; dissemination of mid-point survey results, key driver diagrams/PDSA cycles*
Final chart review and survey of providers and staff ; survey of specialists regarding referral communication; patient satisfaction surveys	*20-21*		*50 chart reviews will be conducted at each practice site; >80% of surveys will be returned; analysis of process and outcome measures as described in Evaluation Design; Comparison of participating practices with other PCN practices*
Final Learning Session open to all PCN practices	*23*		*Presentation of QI Project by each pair of Practice Champions; dissemination of final chart review and survey results and aggregate findings across practices;*
Prepare final reports and disseminate learnings	*22-24*		*Timely submission of final report; Submission of findings for presentation/publication to at least 3 scholarly venues*