

Abstract

Chronic pain and prescription opioid use disorders intersect in a public health crisis that is dealt with daily in individual clinician exam rooms. Clinicians often lack appropriate tools, knowledge and resources to safely treat the pain and avoid opioid misuse and diversion. Interstate Postgraduate Medical Association (IPMA), the University of Wisconsin School of Medicine and Public Health Department of Family Medicine (UW DFM) and its program, the Wisconsin Research and Education Network (WREN) propose *Improving Responsible Opioid Prescribing for Individuals with Chronic Pain*. This collaborative of primary care clinics, clinicians, researchers, and educators will conduct a system-based improvement project incorporating evidence-based practices for chronic pain management and opioid prescribing that can ultimately lead to improved clinical outcomes of primary care patients with chronic pain who are treated with prescription opioids.

The **primary goal** of this proposal is to **change clinician behavior** as manifested by the incorporation by primary care clinicians of evidence-based opioid prescribing practices in chronic non-cancer pain (Table 1).

Table 1. Project Objectives & Measures

Outcome Objectives	Evaluation Component Among Patients Treated with Long-Term Opioids for Chronic Non-Cancer Pain
<i>Primary:</i> Increased patient-clinician education and discussion surrounding issues relevant to long-term opioid therapy	Increased percentage of patients with signed Opioid Treatment Agreement
<i>Secondary:</i> Increased assessment of the risk associated with long-term opioid therapy	Increased percentage of patients who were assessed with a opioid therapy-related risk assessment tool; decreased percentage of patients co-prescribed opioids and benzodiazepines
Improved monitoring for prescription medication misuse or abuse	Increased percentage of patients assessed with urine drug testing; increased frequency of clinician log-in to the Prescription Drug Monitoring Program (PDMP)

Definitions

Chronic Pain Patients: Based on the existing definitions within the UW DFM, chronic pain patients will be defined as adults age 18 and over who have been prescribed opioids for non-cancer pain for at least 90 days.

Academic Detailing: An on-site 60-90 minute educational meeting between a content expert and the clinicians and staff from the enrolled clinics wishing to improve the quality of care provided for their chronic pain patients.

Clinicians: Clinicians will be defined as healthcare professionals who have prescribing privileges for controlled substances, including physicians, advanced practice nurses, and physician assistants.

Practice Facilitation: Practice facilitation is an evidence-based method of assisting practices in changing the process of care. External facilitators assist practices in implementing their prioritized goals, changing practice workflow, and improving patient outcomes.

Prescription Drug Monitoring Program: PDMP is a state-wide, state-run database developed to improve patient care and safety, and to reduce the abuse and diversion of controlled prescription drugs. It contains information on the filled prescriptions for controlled substances, as submitted by pharmacies and other dispensing facilities. Wisconsin has a PDMP but does not have mandatory usage laws. Use is recommended to clinicians as a routine part of the management of opioid therapy.

Shared Decision Making (SDM): SDM refers to a dialog between the clinician and patient through all phases of the decision-making process resulting in a treatment choice that incorporates the clinical evidence as well as the personal values and preferences of the patient.

Spaced Education: Spaced education refers to brief, straightforward, and easily accessible educational tools delivered via the web or mobile devices. Instant feedback allows learners to self-assess or validate their current knowledge or practice.

Stepped-Wedge Design: The stepped-wedge design is a randomized controlled trial design where all participants (clinical practices in this proposal) start as control sites and then are randomly assigned to sequentially receive the intervention until all become the intervention site.

Overall Goal & Objectives

The **primary goal** of this proposal is to **change clinician behavior** as manifested by the incorporation by primary care clinicians of evidence-based opioid prescribing practices in chronic non-cancer pain. As presented in Table 1, *Improving Responsible Opioid Prescribing for Individuals with Chronic Pain* proposes specific measurable, patient-centered outcomes.

- Primary outcome among opioid-treated patients with chronic pain–
Percentage of patients with a signed opioid treatment agreement
- Secondary outcomes among opioid-treated patients with chronic pain–
Percentage of patients assessed with an opioid risk assessment tool
Percentage of patients co-prescribed a benzodiazepine medication
Percentage of patients assessed with urine drug testing
Frequency of clinician’s access to the Prescription Drug Monitoring Program

To achieve our objectives, we will use spaced education, academic detailing and practice facilitation to:

- Implement the standardized “safe opioid prescribing” tools incorporated into the existing electronic health record systems in the UW DFM primary care clinics;
- Educate clinicians on these tools and the clinical evidence supporting their use in practice;

- Educate clinicians on incorporating SDM techniques including informed consent and establishing goals of therapy into the treatment of their chronic pain patients;
- Improve the management of chronic pain patients via collaborative agreements, based on the SDM principles, between patients and their clinicians.

Through the proposed education and interventions, we aim to promote responsible prescribing of opioids and, ultimately, reduce adverse events associated with opioid therapy and engage patients in their chronic pain care.

Technical Approach

IPMA and the clinical practice partners will recruit clinics to participate in this randomized controlled trial (*stepped-wedge design*) of an educational intervention for primary care clinicians. The desired outcome is to change clinician behavior so that patient care and, ultimately, safety and outcomes, are improved.

UW DFM primary care clinics and health system is currently in the process of incorporating evidence-based practice tools (e.g., risk assessment, medication agreement, drug testing) into the EPIC electronic health record (EHR). The UW system does not plan to extend clinician education on the use of these tools beyond a brief “how to use it” session. We believe that effective implementation of these best practices requires more extensive education and practice facilitation for clinicians so that patients with chronic pain will enjoy the benefits of better care. The clinicians will need methods and skills to have a conversation with their patients about the use of these tools and their potential benefits to maximize the effectiveness of and patient satisfaction with chronic pain treatment. Clinicians will need to educate patients that effective chronic pain management consists of a multimodal approach, with pharmacotherapy constituting only one element.

This project will leverage the work that has been underway at UW where the University of Wisconsin Medical Foundation Chronic Pain Initiative quality improvement (QI) efforts have focused on optimizing care in chronic pain and safety of opioid prescribing. This group has worked to build extensive clinician “safe-prescribing” processes that will be incorporated into the EPIC-based EHRs. The standardized processes that have been developed and will be incorporated include:

- Diagnosis, Intractability, Risk, Efficacy (DIRE) tool
- Opioid treatment agreement (recommended but underutilized)
- Urine drug testing (recommended but underutilized)
- Clinician access to the PDMP (recommended but underutilized)
- Chronic pain patient management protocol

It is well recognized that provision of tools in the absence of effective education and practice redesign is unlikely to promote substantial long-term change. The requested funding will enable clinician education and measurement of the effectiveness of spaced education, academic detailing and practice facilitation as adjuncts to the minimal educational initiatives planned as part of the “routine” EHR rollout within the UW clinics.

Clinician Education – The educational intervention, delivered to all of the intervention clinics as we move through the phases of intervention through the following methods: knowledge, academic detailing and practice facilitation.

Knowledge. IPMA and the lead physicians will develop a knowledge-based program through on-line spaced education. Spaced education employs a new and innovative approach to continuing medical education with research evidence demonstrating improved knowledge retention after two years compared to traditional educational methods.¹ Spaced education delivers a “question of the day” via e-mail to an individual clinician and requires a mastery of knowledge before the clinician is allowed to complete the activity and receive credit. Two spaced education modules will be made available to all clinicians and staff participating in this QI initiative: 1) A teaching module to increase clinical knowledge regarding evidence-based management of chronic non-cancer pain and appropriate opioid prescribing in primary care settings, including information on how to access and use the relevant tools within the EHR system. 2) An SDM training module for clinicians and their staff on how to engage patients in SDM and discussion about chronic pain management, and to elicit patient preferences and goals; this module will also incorporate patient education resources. Clinicians will receive one *AMA PRA Category 1 Credit*TM for each completed spaced education module.

Academic detailing. On-site academic detailing (clinician-to-clinician + staff lecture and discussion) will follow the spaced education as the sites gain the “interventional” status. Aleksandra Zgierska, MD, PhD will serve as the content expert. These in-person educational meetings will focus on: 1) the “safe opioid prescribing” tools, 2) familiarizing clinicians and staff with available patient education resources, and 3) reviewing value and use of patient treatment agreements. The goal of these sessions is to create an agenda for change and a “to-do” list generated by each practice that will serve as input to practice facilitation.

Practice facilitation. Following the academic detailing sessions, participating clinics will receive ongoing assistance and the ability to receive practice improvement credit through practice facilitation sessions. These sessions, led by trained WREN research coordinators, will focus on overcoming barriers to implementing the chronic pain and opioid prescribing tools, including urine drug testing lab options and use of the PDMP resources. Clinicians will be able to receive performance improvement credit for their QI work.

Patient Education – Patients with chronic pain treated with opioids will benefit from this initiative as clinicians strive to educate patients on the best treatment of chronic pain and safer use of opioid medications. Patient-specific educational materials on the use of opioid treatment agreements, risk assessment, recognizing side effects and potential hazards, and understanding urine drug testing will be developed. These materials will present information in a format allowing patients to understand and share in the decision for their chronic pain management. We will contract with Emmi Solutions to host and use a patient decision multimedia tool on chronic pain management.

¹ B. Price Kerfoot, Learning Benefits of On-Line Spaced Education Persist for 2 Years, *The Journal of Urology*, 181, 6, p 2671–2673, June 2009

The program, *Pain Management: Opioids for Chronic Pain Management* is being developed to address the following:

- Help patients understand how to use opioid medications the right way
- Describe chronic pain, both persistent and intermittent
- Explain what opioids are, the risks, and the basics of how to take them safely
- Explain how tolerance develops and the problems it causes
- Describe how much pain relief they can expect
- Describe what kind of pain is usually not responsive to opioids
- Discuss alternatives to opioids especially if opioid therapy does not relieve pain or improve function
- Discuss opioid treatment agreements

Use of EHR for Decision Support: Data are an integral component in this initiative. In order to fully execute the project, including monitoring outcomes, we will offer participation only to primary care clinics at UW DFM that use the EPIC EHRs containing the chronic pain management elements described earlier. The experience of WREN has been that different healthcare organizations have different capabilities and processes for making rapid software changes for decision support. These limitations can limit timing and use of EHRs in projects and clinical studies. Because UW clinics have the pain tools and documents in the final stages of development and in the planning for roll-out in EPIC in 3rd quarter 2015, we are well timed to work within this system and implement this study.

Current Assessment of Need in Target Area

Quantitative Baseline Data Summary and Project Starting Point

The most recent statistics show that about 70% of the opioid-analgesic overdose deaths in 2011 involved prescription-based opioids such as hydrocodone, morphine or oxycodone. This number has dramatically increased in recent years, rising from 2,749 deaths in 1999 to 11,693 deaths in 2011.² Prescription drug overdose rates are on the rise throughout the United States with the greatest increase seen in individuals prescribed both opioids and benzodiazepines. Wisconsin faces severe prescription drug-related problems. According to the Centers for Disease Control and Prevention, Wisconsin has a high rate of prescriptions for opioid analgesics at 76 prescriptions per 100 people in 2012 ([CDC Morbidity and Mortality Weekly Report](#))³. Wisconsin has the 34th highest drug overdose mortality rate in the United States, with 10.9 per 100,000 suffering drug overdose fatalities, according to a new report, [Prescription Drug Abuse, Strategies to Stop the Epidemic](#). The number of drug overdose deaths - a majority of which are from prescription drugs - in Wisconsin doubled since 1999 when the rate was 4 per 100,000. Nationally, rates have doubled in 29 states since 1999, quadrupled in four of these states and tripled in 10 more⁴.

² Drug Poisoning Deaths Involving Opioid Analgesics: United States, 1999 – 2011, NCHS Data Brief #166, Sept 2014.

³ Vital Signs: Variation Among States in Prescribing of Opioid Pain Relievers and Benzodiazepines — United States, 2012, MMWR, July 4, 2014,

⁴ Prescription Drug Abuse, Strategies to Stop the Epidemic, Trust for American's Health

EPIC EHR audits from UW primary care clinics confirm that chronic opioid use is prevalent among UW outpatients and evidence-based management of these patients remains suboptimal. According to UW Health EHR data, 21.2% of 275,668 adult outpatients seen in the past year were prescribed an opioid. One-third of those prescribed an opioid appeared to be long-term users (7% of all UW adult outpatients). Yet only 59% of these long-term users had a treatment agreement documented and 50% were co-prescribed benzodiazepines.

Primary Audience

The primary audience includes family and general internal medicine clinicians, clinic administrators and other healthcare professionals who are involved in the treatment of patients with chronic pain. We will reach a subset of the UW DFM clinics during the educational intervention but, if successful, the tools and web-based educational items will later be electronically available throughout the entire EHR systems, and results disseminated throughout the entire UW clinic system. Ultimately, patients will benefit the most if optimized chronic pain management translates into improved clinical outcomes and safety, and a reduction in adverse events associated with opioid therapy.

Project Design and Methods

The project's educational design will promote building of innovative activities focused on evidence-based pain management into clinically integrated networks. This 2.5 year project will use a Stepped Wedge Randomized Design with quarterly enrollment of participating clinics (see Timeline for details).

A total of nine similar-size primary care clinics will be recruited throughout the UW DFM from among teaching clinics and community clinics in urban, suburban and rural areas. Based on our preliminary data from the UW Health EHR analysis and using conservative estimates for the average adult clinic population (5,000 per clinic) and the proportion of adult patients receiving long-term opioids (3%), we estimate to have greater than 80% power to detect a 20% relative increase in use of a pain medication agreement (primary outcome), assuming that the baseline use is 59%. This power calculation was derived from a traditional cluster randomized trial (CRT) methodology with an intra-class correlation coefficient of 1.5%, yielding 84% power with greater than 95% confidence. A stepped-wedge study design will allow each participating clinic to serve as a control clinic pre-intervention and a study clinic post-intervention, contributing to the fact that stepped wedge designs are more powerful than comparable traditional CRTs.⁵ Therefore our study will be more than adequately powered to detect what we consider to be a clinically significant effect of a 20% improvement.

Use of a stepped-wedge design, coupled with outcome measures that can be measured via EHR data will allow an efficient, rigorous and controlled evaluation of the effectiveness of the proposed intervention that, if proven successful, can be rapidly disseminated across the entire UW health systems. Because EHR audits are efficient, we will also evaluate the selected outcomes in non-project comparison clinics (defined as other primary care clinics in the UW system that were not

⁵ Woertman W, de Hoop E, Moerbeek M, et al. Stepped wedge designs could reduce the required sample size in cluster randomized trials. *Journal of Clinical Epidemiology* 66 (2013) 752-758

selected into the educational intervention), providing even greater power to assess the effectiveness of the educational intervention by controlling for temporal trends in the larger health system.

Table 2. Intervention Timeline Overview

UW DFM clinic	Quarter 2-3	Quarter 4	Quarter 5	Quarter 6
1	Control	Intervention	Intervention	Intervention
2	Control	Intervention	Intervention	Intervention
3	Control	Intervention	Intervention	Intervention
4	Control	Control	Intervention	Intervention
5	Control	Control	Intervention	Intervention
6	Control	Control	Intervention	Intervention
7	Control	Control	Control	Intervention
8	Control	Control	Control	Intervention
9	Control	Control	Control	Intervention

Evaluation Design

Our objectives are to increase the use of evidence-based recommendations for the management of chronic pain patients through changing clinician behavior. We will conduct pre- and post-intervention assessments of the care provided using EHR-available metrics. Our evaluation components and sources are presented in Table 3.

Table 3. Evaluation Design

Evaluation Component	Source of Data	Variable
Opioid risk tool (DIRE)	EHR	Documented screening using the DIRE tool
Opioid Treatment Agreement	EHR	Presence of treatment agreement
Urine Drug Test	EHR	Time since last test (days)
Co-prescription of opioids and benzodiazepines	EHR	Presence of active prescriptions for both opioids and benzodiazepines in the medication record
PDMP Use by Prescriber	PDMP*	Pre-post use Frequency of prescriber log-in into the PDMP database; new PDMP system registration by a prescriber
Covariates: practice type and clinician characteristics	EHR	Practice size Clinician Make-up (MD, DO, PA, NP) Practice Type

*According to the [National Alliance for Model State Drug Laws](#), Wisconsin allows disclosure of data for statistical, research or educational purposes.

Quantifiable change expected. We will expect to see a **20%** relative increase in the use of patient-clinician opioid treatment agreements, opioid risk assessment tools, and urine drug testing. Because changes in pharmacological treatment are often taking place over a longer period of time, we expect a 10% decrease in co-prescribing of opioids and contra-indicated benzodiazepines at 6 months after the onset of the intervention at each clinic.

Clinician engagement. Clinician engagement will be directly assessed through the variables listed in Table 3 with the assumption that pre-post changes are a result of clinician engagement and use of the pain tools. Direct measurement will also occur via participating-clinician completion rates of the spaced education curriculum, evaluation of knowledge pre- then post-completion, practice facilitation sessions and related activities, and registration and use of the PDMP.

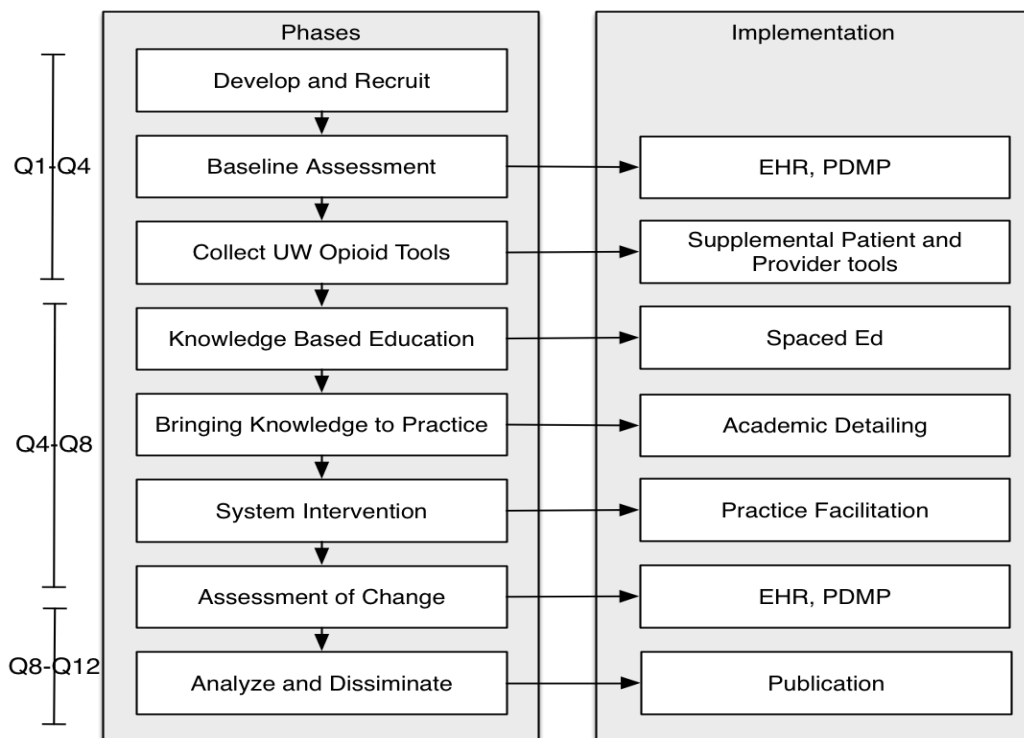
Outcomes Dissemination. All of the project materials will be located on the publicly-accessible UW DFM website so that all clinics, patients and interested people, regardless of geographical location, will have easy access to these materials. We will report results in peer-reviewed professional journals, the PBRNs' annual meeting, and other local and national professional meetings. Results will be shared through the national PBRN listserv focusing on sustainability and spread. Importantly, any demonstration of effectiveness within UW health systems has the potential to motivate the system to adopt these educational intervention system-wide, thus promoting improved patient care.

Detailed Workplan and Deliverables Schedule

Narrative

Project award date notification is expected in December 2014 with project commencement in January 2015. The 30 month project timeline is presented below. Quarters 1 – 2 include IRB approvals, clinic site enrollment, education activity planning, and evaluation planning. Clinic enrollment will begin in Q4 and all sites will have an initial assessment, including EHR review and baseline knowledge assessment. In Q5, academic detailing and practice facilitation sessions will begin and continue through Q7. Post-intervention assessment will begin in the initial study clinics six months post-intervention, also in Q7. Subsequently, wave 2 and wave 3 of interventional clinics will have their post-intervention assessment in Q8 and Q9. Q 8 – 10 will also incorporate data analysis, wrap up, reporting, manuscript preparation, and outcomes dissemination. Figure 1 provides the project workflow.

Figure 1. Project Workflow



Project Management

UW: Dr. David Hahn will serve as the Principal Investigator and will be responsible for overseeing this project with shared responsibilities across all partners. Dr. Aleksandra Zgierska will serve as co-PI, providing content expertise in development of all educational interventions, data queries, and in-person programming. Dr. Paul Smith will serve as a collaborator, providing expertise in stepped-wedge design, practice facilitation, and patient education development. UW DFM’s WREN project manager will provide oversight of most intervention tasks undertaken by WREN Research Coordinators, including:

- Initiate and update IRB applications
- Practice site and clinician recruitment
- Protocol training
- Scheduling of academic detailing and practice facilitation visits
- Oversight of practice facilitation staff
- Data collection procedures,
- Regulatory compliance

WREN Research Coordinators will perform all practice facilitation activities, data reporting, and participate in content and manuscript development. UW DFM database and information technology specialists will be employed to assist with EHR extraction and analysis and web page development.

IPMA: IPMA’s project manager will:

- Coordinate overall project management;
- Manage budget and subcontracts;
- Host regular meetings to ensure we meet our deliverable schedule;
- Assist project managers with on-site training and materials preparation;
- Oversee the spaced-education activities;
- Certify educational content for CME and CEU credit; and
- Have primary responsibility for outcome reporting.

Workplan Schedule

The following diagram provides a summary presentation of our planned work over the course of the two year project. The deliverables chart in Table 4 provides a timeline of major deliverables and the responsibility assigned to this deliverable.

Table 4. Deliverables Chart

	Timeframe to Completion	Responsibility
Planning and Development		
Notification of Award	December 2014	Pfizer
Official Start Date	January 15, 2015	Pfizer
Contracting and Milestone Development	January – Feb 2015	IPMA
IRB application for exemption	Feb - April 2015	UW
Recruit Clinics and Clinicians	April - August 2015	UW
Develop Spaced Education Modules	April – July 2015	All partners
EPIC EHR system roll-out of safe prescribing tools and protocol	September 2015	UW
Finalize Educational Intervention and Planning for Academic Intervention and Practice Facilitation	July -November 2015	IPMA & UW
Finalize clinical recruitment and participation schedule	Sept – Nov 2015	UW & IPMA
Analysis of pre-intervention data		
Perform baseline outcome data analysis & result summary (data from the EHR of participating clinics; PDMP data on its utilization by participating clinicians)	Sept – January 2015	UW
Intervention		
Start spaced-ed for 1st wave clinicians	December 2015	IPMA
1st Round of Interventions	Feb-April 2016	UW
Start spaced-ed for 2nd wave clinicians	March 2016	IPMA
2nd Round of Interventions	April-June 2016	UW
Start spaced-ed for 3rd wave clinicians	May 2016	IPMA
3rd Round of Interventions	June-August 2016	UW

	Timeframe to Completion	Responsibility
Clinician knowledge change assessment	August-October 2016	IPMA
Analysis of post-intervention change in metrics, using the EHR and PDMP data	August-October 2016	UW
Outcomes reporting to funder	November 2016	IPMA
Dissemination and Sustainability		
Regional and National PBRN Meetings- prelim results	June-November 2016	WREN
Manuscript development	November 2016-February 2017	UW, WREN, IPMA
Results and materials distributed via national PBRN listserv	February 2017	WREN
National PBRN meeting – final results	November 2017	WREN
AAFP Scientific Assembly	October 2017	WREN
Other professional conferences	2017-2018	UW & IPMA
Publications (JCEHP)	TBD	IPMA

Organizational Detail

Leadership and Organizational Capability:

UW DFM, including the WREN program, and IPMA are joining forces to address responsible opioid prescribing for individuals with chronic pain. Our successful partnership brings together our collaborative and individual experiences.

University of Wisconsin Department of Family Medicine (UW DFM), including the Wisconsin Research & Education Network (WREN)

UW DFM includes over 200 faculty with 21 clinic locations throughout the state of Wisconsin. Research areas of focus include alcohol and substance abuse, complementary/integrative medicine, translational research, nutrition and obesity prevention, and upper respiratory diseases. WREN, a program of UW DFM, is one of the oldest practice-based research network (PBRNs) in the country. WREN promotes and conducts research in partnership with primary care clinicians and communities in both UW DFM clinics and clinics external from the UW system. WREN has staff in place around the state and pre-existing relationships with more than 86 practices and 203 clinicians throughout Wisconsin. WREN has participated in or supported more than 65 research projects since its inception, including 12 federally funded grants or contracts. Research topics have included cancer screening, prevention of heart disease, health literacy, complexity of ambulatory primary care, transition from hospital to ambulatory care, treatment of asthma, diabetes, and depression. WREN Regional Research Coordinators (RRCs) use practice facilitation as a method to effectively translate research findings and clinical guidelines into practice. David Hahn, MD, MS will oversee the UW DFM and WREN commitment to this project. Fellow DFM faculty clinicians Aleksandra Zgierska, MD, PhD and Paul Smith, MD will serve as co-PI (content expert) and collaborator, respectively.

IPMA – Interstate Postgraduate Medical Association

Since its foundation in 1916, Interstate Postgraduate Medical Association of North America has continuously maintained its original goal of physician education that positively impacts patient care. As a not-for-profit 501(c)(3) educational association, IPMA's stated mission is the dissemination of medical knowledge and the improvement of physicians' ability to prevent, detect and treat disease. A diverse array of educational activities and initiatives apply evidence-based adult learning strategies to transform practice, ultimately improving patient health. Mary Ales, IPMA Executive Director will oversee IPMA's commitment to this project.

Each educational initiative is carefully designed to effectively change clinician practice, impact clinician performance, and ultimately improve patient and community health. IPMA's diverse educational offerings include comprehensive needs assessments that identify learner gaps and educational needs; an annual Primary Care Update conference that delivers practical, clinically focused education; and cutting-edge performance improvement initiatives that incorporate self-directed learning to advance clinical practice. IPMA has developed educational tools and curriculum for clinicians in perimenopause, menopause, and management of VMS symptoms. Central to these resources has been applying patient focused decision making grounded in evidence-based data. IPMA is proud to hold accreditation with commendation from the Accreditation Council for Continuing Medical Education (ACCME).

Emmi Solutions, LLC (“Emmi”) is the leading SaaS (Software-as-a-Service) provider of interactive patient engagement and empowerment programs designed to **improve clinical and financial outcomes** for healthcare providers and payers. A true patient engagement industry pioneer, Emmi is tackling some of the most complex business issues facing healthcare providers and payers today in an effort to reduce costs, increase revenue, and improve clinical outcomes and quality. Emmi is a complete and integrated multi-modal patient engagement platform that leverages Web, mobile, email, video, IVR and print. Emmi can engage patients in any setting and on almost any third-party device (desktop, smartphone, tablet, mobile phone, etc.), allowing it to target, prescribe and deliver efficacious, high value-add solutions at discrete points of care – when and where they are needed most and are most likely to yield the greatest overall benefit to patients. Accordingly, Emmi goes beyond simply engaging patients and is focused on delivering and measuring efficacious programs at a granular individual patient level.

Key Staff Capacity

UW DFM and WREN

David L Hahn, M.D., M.S. [Dr. Hahn](#) leads the Wisconsin Research & Education Network (WREN), a program of the Department of Family Medicine at the University of Wisconsin School of Medicine and Public Health (UW SMPH). WREN provides research and educational opportunities for primary care physicians and other healthcare providers. Dr. Hahn was one of the founding members of WREN and was named Director on November 1, 2012 after retiring from a full career in family practice. He will be the UW SMPH Principal Investigator (PI). Dr. Hahn’s expertise will be utilized to recruit clinics as participants in this project, including conducting face-to-face recruiting visits at potential practice locations, and consulting with information technology staff to pull data through electronic health record (EHR) analysis. He will also provide technical oversight and content expertise.

Aleksandra Zgierska, M.D., Ph.D. Dr. Zgierska is an Assistant Professor in the Department of Family Medicine at UW SMPH. She is board-certified in family medicine and addiction medicine. Her research interests and clinical expertise center around improving safety of opioid therapy, and optimizing care and outcomes in chronic pain and opioid addiction. She will serve as co-PI, overseeing content development, and performing the expert academic instruction to participating clinics. Dr. Zgierska will also inform the EHR queries, given her knowledge of health services research-related methodology, and primary and specialty care clinical operations, especially in relation to the management of chronic pain, addiction and opioid therapy.

Paul Smith, M.D. Dr. Smith is a Professor in the Department of Family Medicine at UW SMPH. He has been instrumental in providing oversight for a stepped-wedge design study undertaken by the same partner group, which is serving as a project orientation and descriptive model for the current proposal. He will serve as a collaborator on this project, contributing his expertise in family practice care and planning, practice facilitation and stepped-wedge project design and implementation.

Regina Vidaver, Ph.D. Dr. Vidaver serves as Program Manager for WREN. In this role, she supervises staff and manages all administrative elements for WREN, including budgeting and



PRACTICE-CHANGING CME

INTERSTATE POSTGRADUATE MEDICAL ASSOCIATION

October 14, 2014

Robert E. Kristofco MSW FACME
Grants Officer, Medical Education Director
Women's Health and Pain Initiatives
Independent Grants for Learning & Change
External Medical Communications
Pfizer, Inc.
235 East 42nd Street 685/14/62
New York, NY 10017

Re: Letter of Commitment

Dear Mr. Kristofco:

Interstate Postgraduate Medical Association of North American, a physician led, nonprofit educational organization that provides independent continuing medical education is pleased to serve as the lead applicant for the Pfizer request for proposal titled: *Improving Responsible Opioid Prescribing for Individuals with Chronic Pain* in response to Grant # 16213567, Improving Chronic Pain Outcomes. Together with our partners at the University of Wisconsin – Department of Family Medicine and Wisconsin Research and Education Network and the Duke Division of Community Health we present our full proposal.

IPMA is prepared to serve as the lead applicant and administrator for this project. The attached documentation includes our proposal and budget for this two year project. The appropriate personnel involved in this project are prepared to assure that funds provided will be allocated for this project only.

Sincerely,

Robert A. Lee, MD
Vice Chair
Interstate Postgraduate Medical Association of North America



David L. Hahn, MD MS
Director, Wisconsin Research & Education Network
Department of Family Medicine
UW School of Medicine and Public Health

October 10, 2014

Dear Dr. Hahn,

On behalf of the UW Department of Family Medicine (DFM) I enthusiastically support your project "Improving Responsible Opioid Prescribing for Individuals with Chronic Pain." This grant proposal embodies what I see as the leading edge of pragmatic primary care research: (1) using "big data" from EHRs to identify practice gaps and opportunities, (2) engaging clinics in practice improvements via practice-based research networks and (3) again using "big data" from EHRs to efficiently measure outcomes on large numbers of individuals.

The local DFM clinics eligible to participate in this project consist of four teaching clinics and 14 community clinics, which collectively care for over 100,000 adult outpatients. Many of these clinics have participated in previous WREN projects and I am confident that you will have no difficulty recruiting 6 of these sites to participate in your stepped-wedge educational, facilitated intervention.

The DFM has a long history of using EPIC EHR data to assess care practices. Pertinent to this grant is Dr. Zgierska's prior EHR audits on chronic opioid prescribing in DFM clinics. I believe you have demonstrated the need for this project, and I have complete confidence in the feasibility of your proposed EHR outcome monitoring plan to assess the effectiveness of your intervention.

As DFM Research Director I wholeheartedly endorse your efforts and stand ready to assist you in any way I can.

Sincerely,

A handwritten signature in black ink, appearing to read "Lawrence P Hanrahan".

Lawrence P Hanrahan PhD MS
Research Director, Department of Family Medicine
Principal Investigator, UW E-Health PHINEX Project
School of Medicine and Public Health
University of Wisconsin-Madison



OFFICE OF RESEARCH AND SPONSORED PROGRAMS

UW Reference # MSN180985

**Pfizer, Inc
Interstate Postgraduate Medical Association**

David Hahn

**Improving Responsible Opioid Prescribing for Individuals with
Chronic Pain**

This proposal has been administratively approved on behalf of the Board of Regents of the University of Wisconsin System and is submitted for your consideration. Please keep our office advised as developments occur with regard to this application.

The appropriate programmatic and administrative personnel of each institution involved in this application are aware of the sponsor's grant policy and are prepared to establish the necessary inter-institutional agreement(s) consistent with that policy.

All costs cited conform to established institutional policies and procedures. Our DHHS Negotiated Rate Agreement can be found at <http://www.rsp.wisc.edu/rates/rates.pdf>. Website: <http://www.rsp.wisc.edu/>

A final agreement is contingent upon the successful negotiation of terms and conditions acceptable to the University of Wisconsin-Madison.

We ask that you use the University's above-referenced proposal number in any future correspondence.

Questions regarding administrative matters should be directed to:

PreAward Services by email: preaward@rsp.wisc.edu or by phone: (608) 262-3822.

Questions regarding the technical nature of this application should be directed to:

The Principal Investigator.

A handwritten signature in cursive script that reads "Brenda Egan".

Brenda Egan, Interim Managing Officer, PreAward Services

10/14/14

October 13, 2014

David L. Hahn, MD, MS
Director, Wisconsin Research and Education Network (WREN)
Department of Family Medicine
University of Wisconsin School of Medicine and Public Health
Madison, Wisconsin
Via Email

Dear Dr. Hahn:

This letter serves to outline the work currently underway at UW Health to improve the management and outcomes of our patients receiving chronic opiate therapy. This work is being coordinated by the UW Health Center for Clinical Knowledge Management. In addition to a description of the work underway, our time line for developing, piloting, and implementing this work system-wide is also included. I hope that this work will align with your research interests and plans.

These opiate care projects are being guided by an interdisciplinary team of primary care providers, and focus on the establishment of a uniform and safe process for the evaluation, documentation, monitoring and oversight of chronic opioid therapy in adult patients with non-cancer pain. We are working toward the following objectives:

- **Establishing a new opiate management policy:** A well-defined policy with principles governing the activities health care providers and patients are expected to follow does not currently exist. The development and implementation of this policy will: set and enforce standards around the medication refill process with including refill quantities and processes for both acute and chronic pain; will include the use of diagnostic tools to determine a patient's opiate risk factor and individual pain assessment; will inform an individualized plan of care that will be updated on a regular basis; will determine standards and workflows for urine drug screening; will support a medication agreement reviewed and signed by both the patient and primary care physicians; and will detail an escalation process for agreement violations.
- **Implementing a new medication agreement ("Contract"):** To this point multiple documents have existed for the same purpose but inconsistencies in content existed. The main purpose is to define expectations of treatment for both patients and prescribers. One agreement with specific expectations supported by the Opiate Management Policy (one pharmacy, one prescribing provider, etc.) will be implemented.
- **Refining our process for urine drug screening:** Randomized screening is scheduled for a minimum of one time each year. At this time individual clinics are approaching and carrying out testing inconsistently with the initiative goal to find congruency in workflows. A specific order panel that includes automatic reflective testing has been designed by Clinical Laboratory experts. Decision support surrounding appropriate testing to order and interpretation of results has been developed to assist clinicians.
- **Implementing new tools in our electronic health record (EHR):** Population Management Tools (built into and managed in the electronic health record). The development of a patient registry that lists all patients meeting the predetermined criteria will better help define the population included in this initiative and will ensure no patients get lost in the system. An accompanying reporting workbench population from the registry used for identifying patients needing care will act as the driving dashboard for clinicians at all levels to work proactively to tell the patient story and manage their care. The reporting workbench will

David L. Hahn, MD, MS
October 13, 2014

allow for better outreach with this population. Patient assessment smart text will allow clinicians to easily capture pain assessment and opiate risk factors.

- **Implementing controlled substance abuser policy and patient identification functionality:** Currently a policy and workflow for substance abusers exists but is not consistently used. Updating and implementing this policy throughout all of primary care will ensure all noted abusers are being held to the same standard. An indicator on the patient header within the EHR will alert physicians appropriately.

Our current plan is to complete development of these tasks within the next 2-3 months, with pilot activities to begin at that time. After a pilot period of approximately six months, we plan to be able to implement all tools system-wide around July 2015. As with most quality improvement work, these timelines are subject to change as we continue to learn the best ways to care for these challenging patients.

As mentioned above, I hope that this work will align with your research plans. If you need any additional information, please do not hesitate to call me at 608-262-7537.

Sincerely,

A handwritten signature in black ink, appearing to read "Lee Vermeulen". The signature is fluid and cursive, with the first name "Lee" being more prominent and the last name "Vermeulen" following in a similar style.

Lee Vermeulen, R.Ph., M.S., FCCP
Director, UW Health Center for Clinical Knowledge Management
Clinical Professor, UW- Madison School of Pharmacy