Physician Coaching To Reduce Opioid-Related Harms.

PRINCIPAL INVESTIGATORS:

Andrew R. Quanbeck, PhD.
University of WI - Madison
Department: CHESS PROGRAM
1513 University Avenue, ME Bldg. Suite 4120
Madison, WI 53706
Phone 608.890.1016
Fax: 608.890.1438
Email: ARQUANBE@WISC.EDU

Randall Brown, M.D.
Department: Family Medicine
1100 Delaplaine Ct Room 3832
Madison, WI 53715
Phone: 608.263.6558, 608.263.3111
E-mail: randy.brown@fammed.wisc.edu

CO-INVESTIGATORS:

James M. Robinson, PhD.
Department: CTR for HLTH Systems Research & A
610 Walnut St. 1187 WARF Office Bldg
Madison, WI 53726
Phone: 608.263.4890
E-mail: jim@chsra.wisc.edu

Aleksandra Zgierska, M.D.
Department: Family Medicine
1100 Delaplaine Ct
Madison, WI 53715
Phone: 608.263.5679
E-mail: aleksandra.zgierska@fammed.wisc.edu

David H. Gustafson, PhD.
University of WI - Madison
Department: Industrial Engineering
1513 University Avenue, ME Bldg. Suite 4109
Madison, WI 53706
Phone 608.263.4882
Fax:608.265.3281 or 608.890.1438
Email: Dhgustaf@wisc.edu

CONSULTANTS:

Jane Ballantyne, M.D.
Department: Anesthesiology & Pain Medicine
1959 NE Pacific St. Suite BB#1421
Seattle, WA 98105
Phone: 206.616.9798
E-mail: jcb12@uw.edu

Paul Batalden, M.D.
Department: Community & Family Medicine
30 Lafayette St.
Lebanon, NH 03766
Phone: 603.653.3229
E-mail: paul.b.batalden@hitchcock.org

Roger Chou, M.D.
Department: Oregon Health & Science University
3181 SW Sam Jackson Park Rd
Portland, OR 97239
Phone: 503.494.4502
E-mail: chour@ohsu.edu

Perry Fine, M.D.
Department: Anesthesiology
30 North 1900 E Rm 3C444
Salt Lake, UT 84132
Phone: 801.585.0425
E-mail: perry.fine@hsc.utah.edu

Dennis McCarty, M.D.
Department: Oregon Health & Science University
3181 SW Sam Jackson Park Rd
Portland, OR 97239
Phone: 503.494.1177
E-mail: mccartyd@ohsu.edu

FUNDER: **National Institute of Health: National Institute on Drug Abuse**

PARTICIPATING INSTITUTIONS:

The Center for Health Enhancement System Studies (CHESS)
The University of Wisconsin Department of Family Medicine (DFM)
The University of Wisconsin School of Medicine and Public Health
The Center for Health Systems Research and Analysis (CHSRA)
The UW Institute for Clinical and Translational Research (ICTR)
The Wisconsin Research and Education Network (WREN)

TABLE OF CONTENTS

LIST OF APPENDICES

Abstract

This project addresses the urgent need to promote the adoption of evidence-based practices (EBPs) in healthcare by pilot-testing an innovative implementation strategy named NIATx-VOP (the **N**etwork for **I**mprovement of **A**ddiction **T**reatment approach to reducing **V**ariation in **O**pioid **P**rescribing). NIATx is an evidence-based quality improvement approach with roots in systems engineering that has been widely tested in addiction treatment. NIATx-VOP applies the NIATx approach to primary care with the aim of reducing variation in opioid prescribing. The proposed approach is intended to be a generalizable approach to EBP adoption, applied in this proposal to a specific problem and setting. The standard approach to improving medical practice involves experts producing clinical guidelines based on scientific evidence, and such a guideline has been developed for opioid prescribing for chronic non-cancer pain. Our implementation strategy consists of three innovations: (1) a process for translating clinical guidelines into a checklist-based implementation guide for clinicians, (2) a physician peer coaching model, and (3) implementation support using tools from systems engineering. This project will team the experts who developed the guideline for opioid prescribing with experts in implementation science and primary care to translate the guideline into an actionable, checklist-based implementation guide. If NIATx-VOP is effective in this pilot test, the study team will propose a randomized trial to test it against other approaches to EBP implementation. The long-term goal is to improve the adoption of EBPs in primary care by producing a generalizable model of change.

1. INTRODUCTION/BACKGROUND

Healthcare is notoriously slow to adopt evidence-based practices (EBPs). This proposal serves the long-term goal of developing a model for promoting the adoption of EBPs in primary care. The objective of this project is to develop and apply such a model to an urgent public health problem: the prescription opioid crisis. Over the past decades, opioids have been used increasingly to treat chronic non-cancer pain. This change in practice has been accompanied by alarming increases in prescription opioid misuse, addiction, and diversion. This work prepares for a subsequent randomized trial that will test the new model against other methods used to promote EBP adoption in primary care. The proposed model is called NIATx-VOP (the **N**etwork for **I**mprovement of **A**ddiction **T**reatment approach to reducing **V**ariation in **O**pioid **P**rescribing). NIATx-VOP is designed to improve adherence to clinical guidelines for opioid prescribing. NIATx-VOP builds upon NIATx, a proven method of quality improvement that applies systems engineering principles to addiction treatment. The prescription opioid crisis is a matter of substantial public health impact. Overdose deaths due to prescription pain medications now outrank motor vehicle accidents as the leading cause of accidental death in the United States. While this study does not assess patient-level health outcomes directly, it uses evidence-based tools from systems engineering to work with organizations in an effort to reduce variation in opioid prescribing rates and doses, and may contribute to improving the health of the public.

The primary aim of this implementation protocol is to pilot test NIATx-VOP in preparation for a large-scale randomized control trial designed to test NIATx-VOP against alternative approaches to EBP adoption in primary care, such as audit/feedback and academic detailing. NIATX-VOP integrates principles and approaches from systems engineering by (1) teaming clinical guideline writers with implementation specialists and primary care physicians to translate guidelines into a checklist-based implementation guide, (2) selecting, training, and deploying physician peer coaches to aid primary care clinics in implementing EBPs using evidence-based tools of systems engineering, and (3) focusing on process as a cause of variation in outcomes, since systemic adherence to guidelines should reduce variation. Although NIATx-VOP is rooted in established theory and empirical research, the approach has not been formally tested in primary care settings. This pilot study is intended to answer questions about the feasibility and preliminary effectiveness of the approach by studying adaptations that will make the approach work well in primary care. In the subsequent randomized trial, the study team intends to assess the relative costs and effects of NIATx-VOP, audit/feedback, and academic detailing to determine the most cost-effective approach for reducing variation in opioid prescribing rates between clinics, between providers within clinics, and in dosing levels for individual patients. Primary care was chosen as the target setting because, at a broad level, a strategy for improving the adoption of EBPs in primary care could apply to diverse patient outcomes and specifically because primary care physicians are the main prescribers of opioids (Volkow et al., 2009). If it suffices to change clinical practice simply to inform physicians of their opioid prescribing levels and how their prescribing compares to peers, then audit/feedback may be all that is required to reduce variation in opioid prescribing rates and doses. If education beyond audit/feedback is required for physicians to change clinical practice, then such education may be delivered relatively inexpensively by nurses or other healthcare professionals through academic detailing visits. However, evidence from prior empirical research and theory on organizational and individual change (Gustafson et al., 2013; McCarty et al., 2007; Hoffman et al., 2008) suggest that a more comprehensive strategy may be required to change clinical practice.

This proposal focuses on a specific clinical practice in need of change—prescription opioid prescribing. Opioid analgesics have been increasingly used to treat chronic non-cancer pain

(Boudreau et al., 2009), despite the lack of evidence of their effectiveness in improving long-term patient outcomes. In the past, physician education (1) encouraged physicians to listen to and treat patients' subjective pain complaints, (2) held that addiction was rare when pain medications were taken as prescribed, and (3) said that, if subjectively well-tolerated, opioids did not cause end-organ damage, and, hence, no ceiling existed for dose increases (Portenoy, 1996; Morgan, 1985; Bennett & Carr, 2002). This approach has been accompanied by alarming increases in prescription opioid misuse, addiction, and diversion (Paulozzi & Xi, 2008). Recent literature supports revising these previous teachings. Prescribing in daily doses exceeding the equivalent of 100-120mg of morphine equivalent daily dose (MEDD) is accompanied by increased risk of incident addiction and overdose (Edlund et al., 2010; Bohnert et al., 2011; Dunn et al., 2010). Additionally, patients at increased risk for misuse are more likely to receive opioid prescriptions and higher daily doses (Edlund et al., 2010; Weisner et al., 2009; Banta-Green et al., 2009).

An evidence based-guideline has been developed for opioid prescribing that advocates such procedures as screening for mental health and substance abuse issues; using "treatment agreements" to inform patients of the risks of taking opioids long-term; and urine drug testing (Chou et al., 2009). The increase in opioid overdoses and dependence in the past two decades has led to calls for change, and a number of providers and payers have made efforts to curb prescription-opioid-related harms (Trescott et al., 2011; McLellan & Turner, 2010). Group Health of Washington State, for instance, adopted a clinical guideline for opioid prescribing and embarked on a comprehensive campaign to monitor and limit opioid prescribing throughout the health system. A commentary on "facing up" to the opioid crisis in *BMJ* (Dhalla et al., 2011) advocated educational outreach programs modeled after pharmaceutical industry practices (e.g., office visits, presentations), conducted by independent healthcare professionals rather than pharmaceutical representatives. A growing consensus recognizes the need for change in opioid prescribing, and some examples of positive change can be found in the literature. However, these examples are sparse, and there are few (if any) approaches that have been systematically studied using experimental designs.. The literature on practice change in healthcare has repeatedly shown that system-level changes occur at a glacial pace in the U.S. healthcare system (Berwick, 2003). This proposal seeks to promote system-level change by pilot-testing an innovative implementation strategy that extends the pioneering systems engineering approach of NIATx to opioid prescribing.

For this proposal, the study team has convened a project advisory board that consists of three internationally recognized pain management experts from the original panel that developed the preeminent guideline for opioid prescribing in primary care (Jane Ballantyne M.D., from the University of Washington; Roger Chou M.D., of Oregon Health and Science University; and Perry Fine M.D., of the University of Utah). These pain management specialists will be joined on the advisory board by David Gustafson Ph.D. of the University of Wisconsin, and Dennis McCarty Ph.D. of Oregon Health and Science University, two internationally recognized experts on healthcare quality improvement who were joint PIs of the NIATx 200 study that is a precursor to this proposal. The final member of the advisory board is Paul Batalden M.D. of Dartmouth College, one of the world's leading experts on healthcare quality and coaching. This experienced group of pain management and implementation experts will work with primary care physicians from the community to comprise an advisory board that will help the research team translate the clinical guideline into a checklist-based implementation guide, and monitor and advise the research team throughout the implementation process.

2. OBJECTIVES

The coaching intervention to be used in this implementation study is modeled after a coaching protocol employed in previous research conducted by members of the research team. Coaching includes in-person site visits and phone/email communication. Four participating UW Health primary care clinics will be assigned a physician coach (who will be referred to in the clinics as a systems consultant) to work through the NIATX-VOP model over a 6-month active intervention period. The systems consultant will travel to each clinic for site visits at intervention months 1 and 2, and the round-table discussions at months 3 through 6 will be done via teleconference. There will also be inter-site teleconferences throughout the intervention, to be scheduled as requested by the sites. Another member of the study team who did not act as the Systems Consultant will visit the sites at month 6 to facilitate a focus group among the study participants.

During the month 1 visit, the systems consultant will present the latest research on balancing the benefits and risks of long-term opioid use to the clinical team and clinic managers. Clinical team members who wish to participate in the intervention activities will sign informed consent. This will be followed by a round-table discussion and walkthrough exercise where the systems consultant will join the consented clinic team in following administrative and clinical practices from the perspective of a patient with an opioid prescription for chronic, non-cancer pain. The systems consultant will also help the consented clinic team flowchart clinical and administrative workflows to determine the best course for study implementation.

During the month 2 visit, the systems consultant and consented clinic team members will have a round-table discussion to plan checklist implementation according to the workflow that was identified at month 1, and assess any individual, organizational or care systems barriers to implementation. The systems consultant and consented clinic team members will develop an implementation plan and schedule phone meetings with the consented clinic team for intervention months 3 through 6.

Throughout the 6 month active coaching intervention period, the systems consultant will help the consented clinic team implement ideas for change using Plan-Do-Study-Act change cycles (Deming, 1986). The systems consultant will maintain monthly email and phone contact with the consented clinic team after the initial site visit to monitor implementation progress, discuss implementation challenges, and offer advice. The purpose of these active coaching contacts between the consented clinic team and the systems consultants will be to facilitate guideline implementation. The systems consultant will also be available to discuss patient care issues (e.g., difficult cases) during monthly phone conferences, with all identifiable patient data removed before discussion of any issues related to patient care. The study team will also arrange inter-clinic teleconferences, to be scheduled throughout the intervention period as requested by the sites.

During month 6, a member of the study team who is not a systems consultant will coordinate a final site visit. At this visit, members of the clinical team who participated in the intervention will participate in a focus group. The purpose of the focus group is to collect data regarding the staff's experience with the intervention.

Clinician Participation

The study team will recruit up to 7 staff members from each of the 4 intervention clinics to sign informed consent forms and to complete round-table discussions at intervention months 1 and 2, monthly coaching sessions during months 3 through 6, and a focus group at month 6. All

study data will be collected by a member of the research team trained in human subjects' protection, and will not include identifiable patient information. The round-table discussions are designed to help the study team understand the incentives, scheduling, delivery methods, and other structures that will make NIATx-VOP useful for the providers who are participating in the study. Discussions will use open-ended questions and de-identified patient scenarios (e.g., approaching "difficult" patients; discussing the consequences of a breach of an opioid treatment agreement) designed to address: (1) Perceived organizational barriers and facilitators to following guidelines for opioid prescribing, (2) Clinician reactions to the implementation checklist and the plan for coaching, (3) Clinicians' personal experience prescribing opioids, and (4) Other educational opportunities about opioid prescribing that clinicians have been exposed to (Appendix C).

The inter-clinic teleconferences are designed for peer-to-peer interactions between the sites, and will address general areas of concern among the study subjects, including: (1) what changes each clinic is working on, (2) what activities are being done to facilitate those changes, (3) what changes have been successful, (4) what changes have not been successful, and (5) the methods that each clinic used to keep track of the progress of the changes.

Intervention month 6 is the end of the active coaching period, at which time participating providers will be debriefed, participate in a focus group, and offered a basic satisfaction survey (Appendix J).This focus group will assess fidelity to the planned intervention along three broad dimensions: (1) amount of the intervention received, (2) adherence to the protocol, and (3) quality of intervention delivery (Appendix C). This focus group will be semi-structured, and will be based on open-ended questions such as: (1) What kinds of process changes were associated with improvement, (2) What factors helped providers and clinics make changes, (3) What were the barriers to improvement, and how were they addressed, and (4) When the intervention didn't work well, what was different (Appendix C)? Data collected in the month 6 focus groups will help the research team to refine the approach for future studies by determining the individual and organizational conditions necessary to promote effectiveness.

3. SELECTION OF CLINICS AND SUBJECTS

The study will be conducted over a 12 month period. All research study personnel will complete training to protect confidential information and conduct research with human subjects in a safe and respectful manner. All subject information will be maintained in strict compliance with Human Subjects laws and regulations. The UW CHESS Research team will not have access to medical records.

Clinic Identification and Recruitment

The study team will recruit 4 intervention and 4 control clinics, for a total of 8 clinics for data analysis. Recruitment will focus on primary care clinics that are part of the University of Wisconsin Medical Foundation (n=20). Clinics offering resident training will be excluded (n=7). One clinic will be excluded from consideration because one of the systems consultants has an active clinical practice there (n=1). The remaining 12 clinics will first be grouped into two categories (community vs. regional) and then ordered by the number of patients with long term opioid prescriptions (defined as 10+ orders in previous 12 months). Within these two categories, the clinics will be paired based on number of patients with long term opioid prescriptions. One pair of clinics will be recruited from the regional group (2 clinics out of 4) and 3 pairs will be recruited from the community group (6 clinics out of 9). Within each pairing, the study team will randomly select one clinic to approach first and invite them to be the intervention clinic. If the

first clinic in the pairing agrees to participate, they will be assigned as the intervention clinic for the pair and the second clinic in the pair will be assigned to control. If the first clinic approached declines to participate, the second clinic in the pair will be invited to serve as the intervention clinic. If the second clinic agrees to participate, they will be assigned to the intervention and the first clinic will be assigned to control. If both clinics decline to participate, an alternate pair of clinics will be selected within each category (there are 3 alternates among the community clinics, 2 alternate clinics in the regional clinics) based on the number of patients with 10+ opioid prescriptions until one of the alternate clinics agrees to participate. After such agreement is secured, the alternate clinic will be assigned to the intervention and the first clinic approached in the pairing will be assigned to control.

Recruitment will be done by the PIs, Drs. Brown and Quanbeck via email and phone (Appendix D and Appendix G). Recruitment activities will be directed toward the Medical Director and/or Clinic Manager at the intervention clinics. Intervention clinics will be assigned a study physician (either Dr. Brown or Dr. Zgierska) to act as the systems consultant. The systems consultant will provide monthly guidance to their assigned clinics throughout the intervention phase of the study (months 1 through 6). The study team will not conduct any study activities at the control clinics. The study team will analyze a de-identified dataset of electronic health records from both the intervention and control clinics to assess the effectiveness of the intervention. The study team selected this set of clinics to enable systematic monitoring of opioid prescribing rates and other clinical data through a clinical data warehouse housed by the Department of Family Medicine and Community Health.

This research is aimed at improving clinical practice related to opioid prescribing, and falls ultimately under the context of increasing patient safety (the clinical guideline being used is primarily geared towards reducing the risk of overdose death). As such, the study team believes the risks to clinician subjects and individual patients are minimal, and the intervention will ultimately improve patient safety. One potential risk of participation is that staff members could feel pressure to participate in the study. Opioid prescribing is a potentially controversial topic that is receiving increasing public attention. Physicians and other prescribers may be uncomfortable discussing their prescribing practices and may resist attempts to change clinical practice. To mitigate any perceived pressure to participate in the study, the systems consultant will make it clear, through written materials and oral instructions, that staff participation in the research is completely voluntary. The systems consultant will explain that the research studies the feasibility of implementing a comprehensive system for adopting clinical guidelines for opioid prescribing, and that the research might discover, for instance, that the system fails to be adopted. Reasons for implementation failure are as important to note and understand as reasons for success. Other measures taken to lessen risk include the following: (1).The primary unit of analysis will be the clinic; no staff members will ever be identified in presentations or publications. (2) Individual prescribers will not be identified in study databases. The systems consultant will not have knowledge of individual prescribing levels. Measures of variation in provider-to-provider prescribing levels will only be assessed at a summary level (e.g., standard deviation, minimum, maximum, etc.); (3) The systems consultant will emphasize the idea that opioid prescribing guidelines have lacked an evidence base to guide practice to date, and that the current implementation study is intended to provide preliminary evidence to improve opioid prescribing practices.

For logistical reasons, qualitative data collected during round-table discussions and teleconferences with clinic staff will be identifiable for the researcher conducting the discussion. Discussions will be conducted by researchers who are trained in protecting patient confidentiality. Qualitative data collected in round-table discussions will not include respondents

names. A code number assigned to each participant will be attached prior to storing in the project dataset. In this way, the study team can ensure that the study team members present during the discussions will be the only people who can identify the interviewees' responses. Research staff members that have access to the data for analysis purposes will not have access to subject names supplying qualitative data.

4. REGISTRATION PROCEDURES

Up to 7 clinicians at each of the 4 intervention sites will be recruited to participate in intervention activities. After they have received permission from the clinic Medical Director, Drs. Brown or Zgierska will meet with potential clinician subjects present the study at a clinic provider staff meeting to gauge the clinicians' interest in participating in the study. They will explain the study objectives and subject participation expectations during this meeting. Drs. Brown or Zgierska will also assure the providers that there is no obligation to participate in the study and that their decision is voluntary and that their clinical practice will in no way be effected by their choice to participate or not. The clinicians will be told they do not have to decide about participation during this meeting; they can take their time to think about it and contact the research team at a later time. They will also be told they can drop from study participation at any time. Drs. Brown or Zgierska will be available at any time to answer questions about the study. Participating clinicians will be asked to participate in two round-table discussions, one focus group, and 4 coaching sessions. During these activities, participants will be asked about their impressions and experience with the coaching intervention, whether the intervention helped or did not help their clinical practice, and any suggestions to improve the approach. No personal health information will be collected during the interviews, focus group or coaching sessions. The focus group will be audio recorded so that responses can be transcribed after all groups are complete. Participants will not be identified on the recording or transcription.

Drs. Brown or Zgierska will send email invitations (Appendix D) to those clinicians not able to attend the meetings related to coaching. Drs. Brown or Zgierska will conduct the monthly coaching meetings via teleconference to participating providers. Providers who are unable to attend these coaching meetings will be followed up with one-on-one.

Informed Consent

As an organization-level implementation research study, clinic staff members are the primary research subjects. Though patient care may ultimately be affected by this project, this is a quality improvement research study and individual patients will not be directly involved. Patients are not the primary human subjects for this study. Identifiable patient and staff data will not be available to the CHESS research team. All patient data will be de-identified by a designated UWMF staff whose primary role is the management of patient data (Wen-Jan Tuan). A waiver of patient consent will be requested from the IRB since the intervention is delivered to clinicians rather than patients. A waiver of informed consent at the clinician level is also requested in order to analyze prescribing patterns among clinicians at control sites and non-consented clinicians at intervention sites.

After the clinical staff have expressed interested in the study and scheduled the month 1 round-table discussion, Drs. Brown and/or Zgierska will meet with the potential clinician subjects to give them the clinician consent form. This document will include: (1) the nature and purpose of the study, (2) the types of data which will be collected, (3) what will be given to study participants, (4) the measures taken to ensure confidentiality of data collected and HIPAA regulations privacy protection, (5) and the timeline of the study. Potential clinician subjects will

be clearly informed that their decision to join or not join the study is voluntary and that they may drop out of the study at any time. All face-to-face contacts with clinician subjects will take place either in the clinician's subject's office or a private room in the clinic at a convenient time for the clinician subject (Appendix B).

5. TREATMENT PLAN

It is anticipated that approximately 28 clinician subjects at4 UWMF primary care clinics will participate (4 clinics as intervention sites, 4 clinics as control sites). Clinician subjects will be provided 6 months of monthly coaching support meetings (intervention months 1 through 6), and a focus group at intervention month 6. Only clinicians at intervention sites will be offered the opportunity to participate in coaching meetings, focus groups, and inter-clinic teleconferences.

6. MEASUREMENT OF EFFECT

This proposal uses the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) model as an organizing evaluation framework (Glasgow et al., 1999) to examine the quality, speed, and impact of implementing NIATx-VOP. RE-AIM is a comprehensive evaluation framework that assesses implementation in five dimensions. While RE-AIM has been used to evaluate many disease management and public health interventions, a review of its use found varying degrees of fidelity (Gaglio & Glasgow, 2012). Specific measures for each RE-AIM dimension are presented in **Table 1.**

Table 1: RE-AIM measures

Domain	Measure
Reach	Number and percentage of patients served by eligible clinics, Characteristics of participating patients vs. general patient population, and Structured interview with Family Medicine director to qualitatively assess recruitment process
Effectiveness	Percentage of opioid patients completing urine drug screens prior to and during the study intervention, Overall rate of opioid prescribing (percent of patients with a chronic pain diagnosis receiving daily opioids) by clinic and provider, Number and percentage of chronic pain patients screened for mental health/substance use problems, Overall rate of opioid/benzodiazepene co-prescribing, Number and percentage of patients signing pain management agreements, Number and percentage of opioid prescriptions above 120 mg daily morphine equivalent, Number and percentage of providers who drop out of study at 3 months, and Focus group with participants to assess satisfaction, effectiveness, and subgroup differences
Adoption	Number of clinics excluded, Number of clinics that participate, Characteristics of participating clinics vs. non-participants, Number and percentage of staff excluded, Number and percentage of staff who participate, and Characteristics of participating staff vs. non-participants
Implementation	Hours of coaching delivered/received per provider, Adaptations made to coaching protocol during intervention period, Cost of coaching intervention, and Focus group with participants to assess consistency of coaching intervention

Maintenance	Number and percentage of patients taking daily opioids who complete urine drug screens (6 month followup), Overall rate of opioid prescribing by clinic and provider (6 month followup), Number and percentage of patients screened for mental health/substance use problems (6 month followup), Overall rate of opioid/benzodiazepene co-prescribing (6 month followup), Number and percentage of patients signing pain management agreements (6 month followup), Number and percentage of providers who drop out of study (6 month followup), and Focus group with clinicians who made substantial changes

Source: Re-aim.org; Measuring the Use of the RE-AIM Model Dimension Items Checklist

7. STATISTICAL CONSIDERATION

Research Design

The clinic will serve as the primary unit of analysis. UW Health primary care clinics will be recruited for participation in the intervention and data collection activities. Due to issues with provider turn-over and generalizability to typical primary care settings, clinics where physicians-in-training engage in patient care will be excluded. To be eligible, potential clinics must have more than one provider in the clinic with opioid prescribing privileges. From the group of eligible clinics, 8 will be randomly selected for data analysis and 4 will be randomly assigned the coaching intervention. Their Medical Directors and/or Clinic Managers will be contacted via email for scheduling of an initial study meeting as previously described.

Relevant comparisons with four comparison clinics (not receiving the study intervention nor participating in qualitative data collection) for study measures will be made in two ways. First, historical data are available for many study measures, permitting time-series analysis of repeated measures to detect changes in a clinic over time (pre-intervention vs. post-intervention). Second, intervention clinics can be compared to paired control clinics by accessing study measures through a system-wide data warehouse in the Department of Family Medicine and Community Health (DFMCH). A data analyst in the DFMCH (Wen-Jan Tuan, who has contact with PHI as a part of his daily responsibilities) will prepare a de-identified dataset (i.e. without information that identifies individual patients or providers), encrypt the limited dataset, and securely transit the dataset to the project statistician for analysis purposes. Our cohort design provides a preliminary test of the feasibility and effectiveness of NIATx-VOP required before designing the larger RCT that will ultimately be conducted.

Quantitative data collection and analysis

The study team will access many RE-AIM measures through a data warehouse (UW Clarity Data Warehouse) maintained in the University of Wisconsin's Department of Family Medicine and Community Health (for example, reach data such as number and percentage of patients excluded; effectiveness and maintenance data such as overall rate of opioid prescribing by provider, opioid/benzodiazepine co-prescribing rates, number of urine drug screens; etc.).

The quantitative analysis of data from the electronic health record will focus primarily on average daily opioid dose for chronic pain patients at the clinic level [morphine equivalent daily dose (MEDD)]. Changes in outcomes will be assessed through repeated monthly observations assessed retrospectively post-intervention. Data will be collected throughout the three years of the study as follows: Months 1 – 12: Pre-Intervention period; Months 13 – 24: Intervention

period; Months 25 – 33: Post-Intervention period. Opioid drug utilization data will be augmented by other process and outcome measures outlined in Table 1 and in Appendix I, which specifies the data elements that will be analyzed from the electronic health record.

The study team will analyze a de-identified dataset from the EHRs for evaluation purposes. The study team has systems in place to ensure protection of patient-level data. The database administrator (Wen-Jan Tuan) will be the only member of the research team who will have any level of access to personally identifiable personal health information in the underlying EHR. The research team will not have access to any individual patient data or PHI. Mr. Tuan is trained in human subjects' protection and has over 20 years of experience working in information technology, including 8 years in health informatics. Mr. Tuan will use SAS to extract and analyze data from the Clarity database (a data warehouse, which in turns gets its data from the EHR). Staff identities will also be protected; identifying information (such as staff names) will be replaced with code numbers. Other variables assessed at the setting or staff level (e.g., characteristics of participating clinics vs. non-participants) can be accessed through administrative databases maintained by the University of Wisconsin's Department of Family Medicine.

Qualitative data collected at the staff levels will be stored in a SQL Server database housed at the University of Wisconsin's Center for Health Enhancement Systems Studies (CHESS) for analysis purposes. Password-protected accounts will be granted by the CHESS database administrator (Mr. Matthew Wright) to provide access to study data at appropriate levels for selected members of the research team. Any publication that results from the study data will not include the names of clinics or staff members where data were collected (e.g. Data were collected from university affiliated primary care clinics in the Midwest). All other results will be presented in anonymous aggregated form.

Statistical model

To isolate and measure the intervention effect on each measure of interest, a mixed-effect model will be applied to the data. The model will contain a fixed effect for a shared common linear trend; the sensitivity of the results will be tested to other non-linear trends. Fixed effects will be included for the impact of the intervention on the measure of interest. Since the intervention activities will be skewed toward the beginning of the intervention period, an increasing cumulative effect will be modeled that allows the rate of increase to change during the period. That is, analysis will use a piecewise linear function of the intervention duration with "knots" at the start and midway through the 12-month period. At the end of the intervention period, a second linear progression will be run to capture any continuing effect or any regression back to pre-intervention response levels. Other fixed effects will be included for observed characteristics of providers that may have a significant impact on the response variable (for example, patient/physician ratio). Random effects will be included to allow for correlation among repeated observations within the same clinic, provider, or patient. Auto-correlated model error terms will be included to allow for additional correlation among observations from the same patient in adjacent months. Appropriate transformations of the response variable (e.g., logarithms, square roots, etc.) will be considered to avoid negative fitted values and to better match the frequency of outlying values.

The resulting mean effect models will have the following form: Let Y_{ijkt} = observed response variable in month t, for patient k of provider j in clinic i; let X_{ijkt} = be a vector of fixed effect covariates corresponding to Y_{ijkt} aside from the intervention effects; let t_i be the first intervention month for clinic i. This value will be considered to be infinite for the control clinics; let u_i , v_j and

w_k be random effects (unobserved) corresponding to clinic i, provider j and patient k, respectively. It is assumed that these effects are independently distributed with zero means and variances to be estimated from the data; let e_{ijkt} be the model error term (noise). It is also assumed that these values are independent of the random effects, but may be auto-correlated. The mean value is zero and the variance-covariance parameters can be estimated from the data.

Then, $Y_{ijkt} = \alpha + X'_{ijkt}\,\beta + \gamma\, t + \delta_1 \min(6, \max(0, t-t_i+1)) + \delta_2 \min(6, \max(0, t-t_i-5)) + \lambda \max(0, t-t_i-11) + u_i + v_j + w_k + e_{ijkt}$. With this construction, α is the intercept, β is the vector of fixed effect covariate coefficients, γ is the common time trend, δ_1 is the monthly increment to the intervention effect during the first six months of the intervention period, δ_2 is the monthly increment to the intervention effect during the second six months of the intervention period, $6\delta_1+6\delta_2$ is the cumulative intervention effect, and λ is the monthly post-intervention increment. In addition to modeling mean response values, the frequency of values above prescribed levels will be modeled in order to assess the impact of the intervention on outlier frequency. For example, if Y_{ijkt} is the quantity of opioids prescribed in month t for patient k of provider j in clinic i, then a model would be fit directly to Y_{ijkt} (or an appropriate transformation of Y_{ijkt}) to assess the intervention impact on expected opioid utilization. Alternatively, if $Z_{ijkt} = I(Y_{ijkt} \geq 100\text{mg})$, an indicator that signals whether opioid use for the month equals or exceeds 100mg MEDD. Modeling Z_{ijkt} with a mixed effect logistic regression model would identify the intervention effect on the frequency of high opioid utilization months.

Cost analysis

Methods and instruments used for cost data collection in the NIATx 200 study (Gustafson et al., 2013) will be adapted for use in the current study. Systems consultants will keep detailed logs of contacts with clinics (based on an online tracking system developed for NIATx 200) to assess staff participation during the intervention and fidelity to the protocol. The systems consultants will document the date and duration of each contact they have with clinic staff members, role of the staff member, and a summary of the topics discussed. The cost of the intervention is estimated by assessing time spent by systems consultants and clinicians during the implementation phase (using coaching logs), multiplying by appropriate wage rates based on averages publicly available through the Wisconsin Department of Workforce Development, and adding any non-personnel costs, such as travel to site visits, the cost of teleconferencing services for follow-up calls, etc.

Qualitative data collection and analysis

The quantitative analysis will be complemented by qualitative analysis in assessing the feasibility and preliminary effectiveness of NIATx-VOP. Participating clinician subjects at each participating site will participate in round-table discussions. Written consent will be obtained from the participant before the first discussion, and both discussions will be scheduled during a time and place of the participant's choice. The first objective in the qualitative data analysis is to conduct a formative evaluation that will inform the implementation model. Stakeholder feedback will be gathered during pre-intervention interviews with up to 7 clinicians in each of the 4 intervention clinics. These will be round-table discussions using open-ended questions and patient scenarios (e.g., approaching "difficult" patients; discussing the consequences of a breach of an opioid treatment agreement) designed to learn about: (1) Perceived organizational barriers and facilitators to following guidelines for opioid prescribing, (2) Clinician reactions to the implementation checklist and the plan for coaching, (3) Clinicians' personal experience prescribing opioids, and (4) Other educational opportunities about opioid prescribing that

clinicians have been exposed to (Appendix C).

The second objective in the qualitative data analysis is to assess the coaching process and fidelity to the intended intervention. To that end, a second round of interviews will take place in month 24. Fidelity will be defined along three broad dimensions: (1) amount of the intervention received (i.e., "dose"), (2) adherence to the protocol, and (3) quality of intervention delivery (Proctor et al., 2011). Assessing the dose of intervention received will rely on quantitative data (the number of coaching hours delivered to clinic staff) obtained through coaching logs. For adherence, the planned protocol will be reviewed with clinicians and document adaptations made to the protocol at each site. Quality of the intervention delivery will be assessed by asking clinicians to reflect on their experience with coaching, and the effect it had on their attitudes about opioid prescribing.

The third objective is to compare the experience of providers and clinics that changed substantially vs. those who did not, thereby integrating the qualitative and quantitative data sources. Consented providers at each of the four intervention clinics will be invited to participate in a supplemental focus group at the end of the intervention period (month 6), which will explore questions such as: (1) What kinds of process changes were associated with improvement, (2) What factors helped providers and clinics make changes, (3) What were the barriers to improvement, and how were they addressed, and (4) When the intervention didn't work well, what was different (Appendix C)? The investigators will consult with Dr. Nora Jacobson, an experienced qualitative researcher from the University of Wisconsin's Institute for Clinical and Translational Research, to carry out the qualitative data collection and analysis. A researcher in consultation with Dr. Jacobson will conduct the focus group. Data collected during the focus group will be recorded and transcribed by the researcher. If any names are used during the course of the focus group session, these will not be transcribed. The researcher and Dr. Quanbeck will independently code each transcript before meeting to discuss and resolve any significant coding inconsistencies. Qualitative data will be managed using NVivo.

The study team will continue to track effectiveness measures during the follow-up sustainability period using data from the electronic health record (e.g., opioid prescribing rate by clinician, number of treatment agreements signed) to assess the long-term effect of NIATx-VOP on clinical practice. The protocol will be determined to be feasible if four intervention clinics are successfully enrolled, and all four participate in coaching training, monthly coaching meetings for a 6-month period, interviews, and focus groups. With eight clinics reporting data (four intervention clinics and four control clinics), baseline estimates of means and standard deviations will be obtained for RE-AIM outcomes, and estimates of treatment effect sizes.

8. RECORDS TO BE KEPT

- Clinician subject intake
- Subject demographics
- Clinic demographics
- Qualitative interview data
- Focus groups data
- Provider consent form
- De-identified patient EHR data
- Systems Consultant Coaching Log

9. PATIENT CONSENT AND PEER JUDGMENT

Potential staff participants will be provided with a consent form that includes information on the study. Staff members will be informed of: (1) the nature and purpose of the study, (2) the types of data which will be collected, (3) what will be given to study participants, (4) the measures taken to ensure confidentiality of data collected and HIPAA regulations privacy protection, (5) the timeline of the study, and (6) potential conflicts of interest for members of the research team.

Staff participants who sign the informed consent form and take part in coaching meetings will be offered up to 6 category 1 continuing medical education credits through the American Academy of Family Physicians.

It is anticipated that recruitment for this study will begin in October2015, pending receipt of IRB approval. The revised provider consent form is included with this submission (Appendix B).

10. INCLUSION OF WOMEN AND MINORITIES

Women and minorities are not specifically being targeted for participation. The study team expects to be able to recruit women and minorities in participating clinics.

The study team anticipates recruiting approximately 28 clinician subjects to participate in qualitative interviews and focus groups. The exact demographic characteristics of the participants are unknown. However, the University of Wisconsin's Department of Family Medicine and Community Health was able to provide information on staff sex for the 13 clinics that are potentially being recruited: among 88 staff members, there were 44 males and 44 females, participation by women is anticipated.

11. INCLUSION OF CHILDREN

Children will not be included in this study. The intended participants are adults who are professional employees, such as clinicians, of the clinics being studied.

12. REFERENCES

Banta-Green CJ, Merrill JO, Doyle SR, Boudreau DM, Calsyn DA. Opioid use behaviors, mental health and pain—Development of a typology of chronic pain patients. *Drug Alcohol Depend.* 2009 Sep 1;104(1-2):34-42.

Bennett DS, Carr DB. Opiophobia as a barrier to the treatment of pain. *J Pain Palliat Care Pharmacother.* 2002;16(1):105-109.

Berwick DM. Disseminating innovations in health care. *JAMA*. 2003 Apr 16;289(15):1969-1975.

Bohnert AS, Valenstein M, Bair MJ, Ganoczy D, McCarthy JF, Ilgen MA, Blow FC. Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA.* 2011 Apr 6;305(13):1315-1321.

Boudreau D, Von Korff M, Rutter CM, Saunders K, Ray GT, Sullivan MD, Campbell CI, Merrill JO, Silverberg MJ, Banta-Green C, Weisner C. Trends in long-term opioid therapy for chronic non-cancer pain. *Pharmacoepidemiol Drug Saf.* 2009 Dec;18(12):1166-1175.

Chou R, Fanciullo GJ, Fine PG, Adler JA, Ballantyne JC, Davies P, Donovan MI, Fishbain DA, Foley KM, Fudin J, Gilson AM, Kelter A, Mauskop A, O'Connor PG, Passik SD, Pasternak GW, Portenoy RK, Rich BA, Roberts RG, Todd KH, Miaskowski C; American Pain Society-American Academy of Pain Medicine Opioids Guidelines Panel. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. *J Pain*. 2009 Feb;10(2):113-130.

Deming WE. Out of the Crisis. Cambridge (MA): Massachusetts Institute of Technology, Center for Advanced Engineering Studies; 1986.

Dhalla IA, Persaud N, Juurlink DN. Facing up to the prescription opioid crisis. BMJ. 2011;343:d5142.

Dunn KM, Saunders KW, Rutter CM, Banta-Green CJ, Merrill JO, Sullivan MD, Weisner CM, Silverberg MJ, Campbell CI, Psaty BM, Von Korff M. Opioid prescriptions for chronic pain and overdose: A cohort study. Ann Intern Med. 2010;152(2):85-92.

Dunn KM, Saunders KW, Rutter CM, Banta-Green CJ, Merrill JO, Sullivan MD, Weisner CM, Silverberg MJ, Campbell CI, Psaty BM, Von Korff M. Opioid prescriptions for chronic pain and overdose: A cohort study. Ann Intern Med. 2010;152(2):85-92.
Edlund MJ, Martin BC, Devries A, Fan MY, Braden JB, Sullivan MD. Trends in use of opioids for chronic noncancer pain among individuals with mental health and substance use disorders: The TROUP Study. Clin J Pain. 2010 Jan;26(1):1-8.

Edlund MJ, Martin BC, Fan MY, Devries A, Braden JB, Sullivan MD. Risks for opioid abuse and dependence among recipients of chronic opioid therapy: Results from the TROUP Study. Drug Alcohol Depend. 2010 Nov 1;112(1-2):90-98.

Gaglio B, Glasgow RE. Evaluation approaches for dissemination and implementation research. In Brownson RC, Colditz GA, Proctor EK, eds. *Dissemination and Implementation Research in Health: Translating Science to Practice.* New York (NY): Oxford University Press; 2012;327-356.

Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: The RE-AIM framework. Am J Public Health. 1999;89(9):1322-1327.

Gustafson DH, Quanbeck AR, Robinson JM, Ford JH 2nd, Pulvermacher A, French MT, McConnell KJ, Batalden PB, Hoffman KA, McCarty D. Which elements of improvement collaboratives are most effective? A cluster-randomized trial. *Addiction*. 14 Jan 2013 [Epub ahead of print]. [NIHMSID: NIHMS436746]

Hoffman KA, Ford II JH, Choi D, Gustafson DH, McCarty D. Replication and sustainability of improved access and retention within the Network for the Improvement of Addiction Treatment. *Drug Alcohol Depend*. 2008 Nov;98(1-2):63-69. [PMCID: PMC2607248]

McCarty D, Gustafson DH, Wisdom JP, Ford J, Choi D, Molfenter T, Capoccia V, Cotter F. The Network for the Improvement of Addiction Treatment (NIATx): Enhancing access and retention. Drug Alcohol Depend. 2007;88(2-3):138-145. [PMCID: PMC1896099]

McLellan AT, Turner BJ. Chronic noncancer pain management and opioid overdose: Time to change prescribing practices. Ann Intern Med. 2010 Jan 19;152(2):123-124.

Morgan JP. American opiophobia. *Adv Alcohol Subst Abuse.* 1985 Sep 1;5(1-2):163-172.

Paulozzi LJ, Xi Y. Recent changes in drug poisoning mortality in the United States by urban-rural status and by drug type. Pharmacoepidemiol Drug Saf. 2008 Oct;17(10):997-1005.

Portenoy RK. Opioid therapy for chronic nonmalignant pain: A review of the critical issues. J Pain Symptom Manage. 1996;11(4):203-217.

Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, Griffey R, & Hensley M. Outcomes for implementation research: Conceptual distinctions, measurement challenges, and research agenda. Adm. Policy in Ment Health. 2011; 38(2): 65-76.

Trescott CE, Beck RM, Seelig MD, Von Korff MR. Group Health's initiative to avert opioid misuse and overdose among patients with chronic noncancer pain. Health Aff. (Millwood). 2011 Aug 1;30(8):1420-1424.

Volkow ND, McLellan TA, Cotto JH, Karithanom M, Weiss SRB. Characteristics of opioid prescriptions in 2009. JAMA. 2011 Apr 6;305(13):1299-1301.

Weisner CM, Campbell CI, Ray GT, Saunders K, Merrill JO, Banta-Green C, Sullivan MD, Silverberg MJ, Mertens JR, Boudreau D, Von Korff M. Trends in prescribed opioid therapy for non-cancer pain for individuals with prior substance use disorders. Pain. 2009 Oct;145(3):287-293.