HHS Public Access

Author manuscript

J Am Pharm Assoc (2003). Author manuscript; available in PMC 2019 July 01.

Published in final edited form as:

J Am Pharm Assoc (2003). 2018 ; 58(4): 395–403. doi:10.1016/j.japh.2018.03.005.

A Community Pharmacy Intervention for Opioid Medication Misuse: A Pilot Randomized Clinical Trial

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Abstract

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Conflicts of interest: The authors have nothing to disclose.

Objective—Community pharmacy continues to play a crucial role in the national response to the opioid epidemic. The purpose of this article is to describe the protocol for a pilot study that is examining the feasibility and acceptability of the Motivational Intervention-Medication Therapy Management (MI-MTM) model. This study also examines the preliminary clinical effect of MI-MTM for improving opioid medication misuse and patient activation in self-management of health conditions that increase risk for misuse.

Design—MI-MTM is a pharmacy-based integrated care model made up of 4 evidence-based practices, including: medication therapy management; brief motivational intervention; patient navigation, and naloxone training and referral. To test MI-MTM in comparison to Standard Medication Counseling (SMC), we are conducting a 2 group randomized single-blinded controlled trial with assessments at 3 time points.

Setting and Participants—The study is being conducted within a western Pennsylvania university-based community pharmacy with 46 patients with opioid misuse (MI-MTM=23, SMC=23).

Outcomes measures—Feasibility will be measured by capturing patient completion rate of MI-MTM sessions. Acceptability will be measured by administering satisfaction surveys regarding pharmacist and patient navigator services. Acceptability will also be captured by conducting intensive qualitative interviews. Preliminary effect of the intervention on misuse will be measured using the Prescription Opioid Misuse Index and the Opioid Compliance Checklist. Activation in self-management will be measured using the Patient Activation Measure.

Results—This project is currently recruiting and results are forthcoming.

Conclusion—This study is the first in the US to implement an evidence-based integrated behavioral intervention into the community pharmacy setting to address opioid medication misuse among pharmacy patients. The results of this study will provide necessary foundational data that allows further testing of this intervention model in a larger trial.

Background

Nearly 12.5 million individuals in 2015 in the US reported misuse of opioid pain-relievers in the past year,[1] with approximately 36% obtaining opioid medications for misuse through filling medications from a prescriber.[1] Medical claims analyses show up to 24% of patients within chronic pain conditions have behaviors indicative of opioid medication misuse.[2] Opioid medication misuse behaviors include early refills, taking medications at higher doses or more frequently than prescribed, doctor shopping, and using medications to deal with problems or for psychoactive effects.[2,3] Individuals who misuse prescription opioids are likely to have comorbid mental and behavioral health disorders[2,4–6] as well as physical health concerns, such as pain and poor general health.[5,7] Administrative claims analyses show a more than two-fold increased likelihood for opioid medication overdose among those who misuse.[8]

These data underscore the urgent need for expansion of misuse identification, intervention services, and linkage with care across the health care continuum. Patients engaged in misuse who have these complex chronic health conditions may benefit from interventions that

address two critical areas. First, interventions must target medication misuse behaviors. Second, interventions also must target aiding patients to navigate and access health and social service systems in order to successfully engage in and adhere to care for conditions that may be associated with increased misuse risk.[9,10]

Community Pharmacy Opportunity for Intervention

Community pharmacy settings play an important role in addressing the opioid epidemic. Community pharmacies are among primary sources where patients legally fill opioid prescriptions that are often misused.[11,12] Approximately 36% of patients in the US who reported misuse of opioid medications in 2015 obtained them through filling medications from a prescriber.[1] Community pharmacies present a potentially abundant resource for addressing the opioid epidemic nationally. Specifically, there are more than 60,000 community pharmacies that employ more than 170,000 pharmacists in the US.[13] The pharmacist is one of the most accessible healthcare professions in the country, with nearly 93% of Americans living within 5 miles of a pharmacy.[14] Further, pharmacists are also ranked among the top 2 most trusted professionals in the US,[15] with research showing patients are willing to receive behavioral health information from these professionals.[16] Data from the membership of the National Community Pharmacists Association show that more than 40% of community pharmacies have private counseling rooms where pharmacists can discretely provide care to patients and maintain confidentiality.[17]

Our previous research has documented that there is significant pharmacist interest in engaging patients who misuse opioid medications, [18,19] and that patients can be identified for misuse in this setting.[20] Specifically, our previous research of 333 adult non-cancer patients filling opioid pain medications in 4 rural/urban community pharmacies showed opioid medication misuse among 15.1% of patients.[20] These data also documented those positive for misuse have high rates of concomitant health problems that increase chances for misuse, which include depression (49%), post-traumatic stress disorder (PTSD; 37.5%), hazardous alcohol use (31.3%), illicit drug use (22.5%), and levels of poor general health (89.6%) and severe pain surpassing US norms (91.8%). A total of 98% of patients with misuse had ≥1 of these concomitant health conditions.

Objectives

Altogether, given the: (1) critical need to expand the response to the opioid epidemic; (2) the high potential value of expanding the response by increasing the role of community pharmacy; and (3) the promising empirical foundation for delivering a community pharmacy-based intervention for opioid medication misuse; this article describes the intervention, methods of evaluation, and practice implications of a clinical study that is testing the feasibility, acceptability, and preliminary clinical effect of the Motivational Intervention-Medication Therapy Management Model (MI-MTM; Clinical trial registration: NCT03149718). To our knowledge, this study is the first in the US to implement an evidence-based integrated behavioral intervention into the community pharmacy setting to address opioid medication misuse among pharmacy patients.

Methods

The design for this project is a one community pharmacy site single-blinded 2 group randomized controlled trial (RCT). Staff members conducting data collection will be blinded to intervention condition. This design was the optimal choice given that we were interested in testing MI-MTM in comparison to standard care, and a RCT enables control for threats to internal validity. Patients in this project are being recruited at a western Pennsylvania university-based community pharmacy setting. We selected this pharmacy as recruitment site for this study because: (1) it is located in a region of Pennsylvania with the second highest rate of opioid misuse (4.21%);[21] (2) while it is affiliated with large medical center with extensive resources, it maintains a patient and community-centered focus, thus characterizing both chain and independent pharmacies; (3) it serves medically complex patients who regularly fill/refill prescriptions, and (4) typical of many community pharmacies, it has a private counseling room. The pharmacy cares for patients from the region, university staff/faculty, and local community.

Misuse Screening

As patients present at the pharmacy to pick up their opioid pain medications, the study pharmacist is informed by staff of a potentially eligible patient. The study pharmacist approaches the patient at the counter and inquiries about interest in taking a brief electronic tablet-based health screen (<5 minutes) with the opportunity of compensation if the patient qualifies, enrolls, and participates in the study. Patients are asked on the tablet to verify they are English speaking, ≥18 years, and not receiving cancer treatment. We specifically elected to exclude patients with cancer as this is a common exclusion in opioid misuse research[2,4,8] given that appropriate/inappropriate opioid utilization among these patients is not well-understood or described in the field. Patients meeting these criteria continue misuse screening.

Opioid medication misuse is determined by a positive screen score of ≥2 on the Prescription Opioid Misuse Index (POMI; see outcomes section for validity/reliability[22]). We selected this measure for misuse given its strong empirical support, [22] and compared to other measures, it is both brief and is publicly available at no cost—which may support its potential future utilization in practice. Furthermore, this measure also is a conceptual base for a similar claims-based indicator of misuse, [2] which likewise has robust validity [2,23] and can be valuable for system-level monitoring of misuse behaviors. Table 1 displays the specific individual items that comprise the POMI, which captures behaviors such as seeking early refills, taking medications at higher doses or more frequently than prescribed, doctor shopping, and using medication to deal with problems or for psychoactive effects.[2,3] A self-report screening was selected (opposed to biochemical screening) because: (1) self-report is less invasive for patients than biochemical tests (e.g., urine, blood); (2) self-report measures are easily completed as patients wait for medications to be filled; (3) self-report screening is in-line with current screenings in general medical settings, and (4) our previous research has shown a non-trivial portion of patients will self-report misuse.[24]

Inclusion/Exclusion Criteria and Intervention

Patients with positive opioid misuse are eligible to be included in this study. Exclusion criteria and rationale are detailed in Table 2. Patients are excluded from participation based on pregnancy, a psychotic/manic episode in the last 30 days, filling buprenorphine only, inability to provide contact information, and planning to move residences within the next 3 months. Patients filling opioid medications for short-term pain are not excluded. In the planning phase of the study, we did not anticipate patients with acute conditions would qualify for misuse given the short duration of their opioid exposure. However, if these patients qualify for misuse, it is important to examine if MI-MTM benefits them. Patients excluded are given educational information about medication misuse, and research staff members assist them to seek additional care if desired. However, we do not exclude patients with severe substance use problems (e.g., daily illicit use) given that MI-MTM has the capacity to refer and assist patients to engage in treatment. Patients who screen positive for misuse that are interested and consent to participate are given a baseline assessment and randomly assigned on a 1:1 ratio to Standard Medication Counseling (SMC) or MI-MTM.

Control Condition

Standard Medication Counseling (SMC) is the control condition for this study as it is the Centers for Medicaid and Medicare Services requirement for pharmacists in the US wherein patients filling prescriptions receive information and opt-in counseling.[25] We chose to employ SMC only, not augmented with a higher level of care as a control given our concern for additional burden on pharmacy staff and to ensure a real-world comparison for MI-MTM. SMC in Pennsylvania requires pharmacists to: (1) offer counseling, (2) document counseling has been offered, (3) document patient refusal of counseling, (4) offer a counseling process for patients not present (i.e., a call-in number for mailed medications; not applicable in the current study), (5) discuss generic prescription substitution, (6) distribute written medication materials. The duration of SMC in the current study is a single 5–10 minute session delivered by a pharmacist other than the study pharmacist. Because of these regulatory requirements, all study participants will receive SMC with a non-study pharmacist who possesses equivalent education and professional training to the study pharmacist when they pick up their medications (a non-study pharmacist in order to prevent condition contamination).

Intervention/Development

Described in detail elsewhere,[26] to develop the study MI-MTM intervention, experts were gathered in a one day meeting. This meeting followed an evidence-based protocol designed for adapting behavioral interventions.[27] We applied this framework to adapting Screening, Brief Motivational Intervention, and Referral to Treatment for opioid medication misuse among pharmacy patients.[26] Experts included: an opioid overdose prevention and harm reduction expert (n=1), health services pharmacy expert (n=1), pharmacologic opioid treatment expert (n=1), practicing addiction pharmacist (n=1), psychosocial addiction treatment expert (n=1), practicing community pharmacists (n=2), behavioral intervention experts (n=3), and brief intervention and addiction experts (n=4).[26] Results of thematic analysis of the meeting recording showed attendees recognized Screening, Brief

Motivational Intervention, and Referral to Treatment alone, while having many necessary components for eliminating misuse, would be strengthened by combining it with additional evidence-based practices—specifically Medication Therapy Management (MTM) for medication adherence, Patient Navigation (PN) to activate patients in self-management of health conditions that elevate risk for misuse, and naloxone training and referral to safeguard against fatal overdose.[26]

Thus, MI-MTM is the overarching model made up of 4 evidence-based components, which components include: Medication Therapy Management (MTM); Brief Motivational Intervention (BMI); Patient Navigation (PN), and naloxone training and referral (Table 3). Each component is sequentially delivered within the model and addresses a critical aspect of opioid medication misuse and risk for misuse. The pharmacy-based portion of MI-MTM (MTM combined with BMI) is delivered by a PharmD level pharmacist. The study pharmacist was selected based on this individual's previous MTM training, interest, and availability in the pharmacy. All other components of MI-MTM (PN and naloxone referral) are delivered by a master's level navigator, both of whom are trained in motivational interviewing.[28] The study pharmacist and navigator each received 16 hours of motivational interviewing training [28] tailored to the study intervention protocol, which focuses on opioid misuse and health behavior. Motivational interviewing was selected as the paradigm for therapeutic communication given its broad effectiveness and application in health care settings and health behavior change.[28] MI-MTM sessions (both the pharmacist portion and navigation) are all set up on an appointment basis and all audio-recorded, with a small subgroup of recordings randomly selected for fidelity review based on session checklists developed by the study team, which recording and fidelity assessment is common in intervention development studies such as this project.[29,30] The pharmacist, patient navigator, and participants are not blinded to recordings happening. Fidelity review for all portions of the intervention will be carried out regularly throughout the course of the study for quality assurance and to provide feedback for improvement.

Before beginning the pharmacist or navigator portions of the interventions, the study pharmacist and patient navigator receive a baseline report of physical, mental, and behavioral health status of participants based on the baseline assessment. Presentation of these data to the study pharmacist and navigator is intended to simulate health and prescription record information that may be available to care professionals within a managed care environment.

Medication therapy management—The first MI-MTM component is Medication Therapy Management (MTM) targeting improvement in opioid medication adherence. MTM is an evidence-based intervention delivered in community pharmacy involving a 30 minute session where medications are reviewed and medication-related barriers are addressed. The overarching MTM framework is particularly relevant compared to other possible models given its common use in pharmacy practice and because is reimbursable by Medicare and several commercial insurance plans,[31] which could provide a conduit for potential scalability in the future. A core goal of MTM is to empower patients in the active management of their medications.[32–34]

MTM in the current study is based on the American Pharmacists Association and National Association of Chain Drug Stores Foundation service model.[35] The pharmacist in the current study will interact with participants one-on-one in a private room to conduct MTM with emphasis on opioid medication, wherein the pharmacist: (1) reviews the opioid medication(s) being taken and any possible problematic interactions, (2) discusses misuse screening results, (3) explores behaviors indicative of misuse (e.g., early refills, taking medications too often/higher dosages than prescribed), and (4) identifies/documents possible targets for adherence improvement.

Brief motivational intervention—BMI is subsequently delivered within the MTM session to address opioid medication misuse. BMI is a widely used and reimbursable[36] evidence-based standard of care for addressing alcohol problems[37–40] and drug use[41–43] in a variety of ambulatory and inpatient healthcare settings. BMI delivered by pharmacists and other providers has demonstrated positive outcomes for medication adherence.[44–48] Individuals with problematic prescription opioid use have also shown significant misuse reductions following BMI.[42]

The current BMI intervention delivered is based on motivational interviewing, a brief evidence-based approach for promoting health behavior change. [28] Pharmacists delivering BMI in this study: (1) facilitate a non-directive discussion regarding motivation to change, (2) discuss importance/confidence to avoid misuse, (3) assist to resolve ambivalence towards eliminating misuse, and, if appropriate (5) refer to substance treatment. BMI sessions specifically include referral to PN (i.e., Patient Navigation). To conclude the session, pharmacists provide a written record of change plans to participants. The MTM and BMI components of MI-MTM are a single 30–45 minute session (a common duration for medication counseling in outpatient pharmacies[49]).

Patient navigation and naloxone—PN is the primary target of referral following the SBIRT component of MI-MTM, with PN's objective being to increase patient engagement in self-management of health conditions that elevate risk for misuse. Patient navigation, opposed to other care models, was selected because of its focus on chronic condition management within health care systems given the multiple care needs patients with misuse possess. PN is distinct from other models such as care coordination or case management as it focuses on guiding patients through complex/fragmented healthcare and social systems. [50,51] PN has a strong evidence base for self-management activities and chronic disease prevention, such as cancer screening/treatment, accessing primary care services, and cardiovascular health promotion.[9,52] PN specifically encompasses 2 complementary and necessary themes, which unite and permeate PN models. First, PN breaks down barriers that prevent patients, typically the underserved, from accessing healthcare services. [9,52] Second, to understand the patient and address their barriers to care, patient navigators develop one-on-one relationships to provide personalized support focusing on individual needs.[9,52]

In the current study, participants are referred to PN within 1 day of completion of the pharmacist portion of the MI-MTM intervention. PN will involve 8 weekly telephonic sessions lasting 30–45 minutes (telephonic in order to support lower-costs, sustainability, and scalability). Session 1 involves development of therapeutic alliance/rapport and goal

setting. Sessions 2–3 focus on identifying barriers and problem resolutions. The navigator elicits motivation and discusses this in context to readiness to change heath behavior and self-management skills. Sessions 2–3 also involve navigators supporting/assisting patients to fill out paperwork and enroll in needed social services and/or mental, behavioral, physical healthcare. For session 4, all MI-MTM recipients review the Substance Abuse and Mental Health Services Administration Overdose Prevention Tool-kit[53] with the navigator and are referred/directed to a naloxone prescription/training. Naloxone is recommended for all patients given increased chances for overdose among this population.[23] All states possess naloxone access laws,[54] and 40 states specifically having standing order policies.[55] Sessions 5–7 focus on encouraging and reinforcing treatment adherence, reviewing and identifying other care needs, and offering linkages to service providers as applicable. The final session examines continued challenges to self-care and goals and formulates plans to continue progress post-PN.

Sample Size and Justification

Sample size is not based on a power estimate. Rather, sample size is based on our pilot work for how many patients can be screened and consented within the study timeframe.[56] Not powering this study was appropriate given the pilot nature of this trial assessing feasibility, acceptability, preliminary clinical effect of the proposed intervention, and limitations of the budget. Based on calculations of recruitment patient flow from our pilot work, we will have a misuse positive rate at this pharmacy of 17%. If we are able to screen 80% of our anticipated patients filling opioids over 14 months (N=424), and if we have 80% consent rate, we have sufficient time and resources to recruit 46 participants (SMC=23, MI-MTM=23).

Assessment and Compensation

Outcome data are collected in-person by research assistants who are assisting participants to complete self-administered portions of the questionnaires (Table 4). All participants are assessed at baseline, 2 months (upon PN completion for MI-MTM recipients), and 3 months at the study pharmacy or other appropriate locations. Participants are compensated $20 for the baseline assessment, $30 for the 2-month assessment, and $75 for the 3-month assessment.

Feasibility and Acceptability Outcomes

A construct chart for all quantitative study measures can be seen in Table 4. Achievement of feasibility is being measured by delivery of all intervention components to 85% of MI-MTM recipients. Achievement of MI-MTM acceptability is being measured at month 2 and is captured by intensive audio-recorded qualitative interview following a semi-structured interview guide focusing on participant opinions and experience with MI-MTM. Interviews will last ≤30 minutes. Acceptability is also being captured at month 2 by assessing patient satisfaction using the Patient Satisfaction Survey for Comprehensive Medication Management (PSSCMM),[57] a reliable and content/factorial valid 10-item self-report instrument[57] that assesses patient satisfaction with the pharmacist-delivered portion of MI-MTM. Satisfaction is also being captured by the Patient Satisfaction Questionnaire-18 (PSQ-18),[58] a reliable and criterion valid 18-item self-report instrument[58,59] that assesses

satisfaction with PN services. We have adapted the PSQ-18 by exchanging provider terminology to reflect PN. Last, acceptability is being assessed by MI-MTM recipient retention (85%) at study completion.

Clinical Outcomes

Preliminary clinical effect for eliminating opioid medication misuse and increasing participant self-management activation for comorbid health conditions that increase risk for misuse is being assessed at the baseline and at 2- and 3-month follow ups. Opioid medication misuse elimination is being captured by the Prescription Opioid Misuse Index (i.e., POMI; Table 1), a 6-item criterion valid and reliable measure that assesses prescription opioid misuse behaviors and opioid medication misuse (sensitivity=0.82; specificity=0.92).[22] Additionally, we are capturing participant adherence to their prescribed opioid regimen at each study time point with the reliable and criterion valid 8-item Opioid Compliance Checklist (OCC).[60] Increases in self-management activation for concomitant health issues that elevate risk for misuse are captured by the Patient Activation Measure (PAM), a 10-item content and criterion valid measure with demonstrated reliability.[61] PAM constructs include patient beliefs that self-management activation is important, confidence to take action, taking action, and remaining activated despite stress.[61] In addition to these main outcomes, we are collecting validated measures of physical and behavioral health conditions, service utilization, and medication use across the study time points in order to adjust multivariate models (Table 4)

Analyses

Our measure of feasibility (i.e., session delivery) will be analyzed by calculating the total number of participants who completed all MI-MTM sessions divided by total number of MI-MTM participants. For acceptability, intensive qualitative interviews will be analyzed by a 2-cycle open coding process,[62] in which cycle-1 will review the content of all interviews and then develop a coding scheme. Cycle-2 will involve applying the coding scheme to the interviews during a second review extracting themes.[63] All coding will occur directly on audio files using qualitative data management software. Acceptability will also be analyzed by assessing patient satisfaction with the pharmacist and navigator interventions reported on the PSSCMM and PSQ-18. These measures will be analyzed by calculating frequencies of responses, measures of central tendency, and proportions. Finally, acceptability will be analyzed by calculating number of recipients retained at 3 months divided by number of consented recipients.

To analyze preliminary study effect, we will conduct an a priori intent-to-treat analysis of the longitudinal data using generalized linear mixed models. A multilevel framework is optimal for longitudinal clinical trials and allows for flexible treatment of time where change in a putative outcome may be nonlinear, or may accelerate or decelerate at different rates across time.[64] We will specifically compare the difference between participants receiving MI-MTM versus SMC on the opioid misuse (POMI), opioid adherence (OCC), and self-management activation (PAM) outcomes. For testing a preliminary clinical effect across the three time points between groups at an alpha level of 0.05 for each outcome, we have 80% power to detect a large effect of 0.39, f-squared.

Results

This study is currently recruiting and results are forthcoming.

Discussion

The opioid medication epidemic continues to have a major impact on public health in the US.[65] The current study represents a critical advancement for community pharmacy and will demonstrate feasibility, acceptability, and preliminary effect of a pharmacist and patient navigator delivered integrated health intervention for patients who misuse their opioid medications. Currently, an evidence-based protocol does not exist to guide clinical practice for engaging community pharmacy patients with opioid medication misuse and concomitant health conditions associated with misuse risk. Study findings will be the foundation for future research to establish this model of practice.

Subsequent research projects will advance the current project in four important ways. The first advancement will be to implement a future study testing MI-MTM within a fully powered multisite trial framework in order to extend the external validity of the intervention. Second, a multisite design will also allow for a greater number of patients to be recruited into the study in order to fully power analyses to detect change within and between intervention groups. Understandably, a single site trial might be the logical next step for demonstrating internal validity of the intervention; however, based on our experience, a single community pharmacy site likely would not have the capability within the pharmacy workflow and patient volume to reach adequate enrollment numbers. Third, with greater power to detect differences between groups, dismantling study designs could also be subsequently employed to observe the incremental effects of the pharmacist and the PN portions of the intervention. Finally, future larger scale studies would allow for appropriate measures to answer questions of cost effectiveness. By addressing these questions of efficacy and effectiveness, these data will consequently set the stage for implementation research.

While the current clinical trial will provide the initial evidence for further and larger scale testing of intervention efficacy, future questions that will need to be addressed are workforce training and how MI-MTM will fit into current payment models for community pharmacy. Regarding training, future research will be required to better understand the methods and requirements to successfully prepare the workforce for engaging in such efforts. Fortunately, given large-scale efforts, such as those led by federal agencies, for substance use intervention trainings across the health professions (that have included pharmacy), [66] such training models likely would be applicable in the case of MI-MTM. We acknowledge that MTM already occurs regularly and is reimbursed by Medicare and some private insurers.[31] However, need for these services is often identified by payers and transmitted to pharmacists. Conversely, in our model, the pharmacist is working proactively to identify patients without initial prompting from payers. While no reason exists why payers could not move to support proactive pharmacist screening and billing for services, having payers work to identify potential misuse among patients via claims analyses[2,8] and subsequently transmitting need for MI-MTM services to pharmacists could likely be a feasible approach incorporated into our current model.

In addition to pharmacist actions within our intervention, another crucial aspect of financial stability and scalability of the intervention following implementation will be the navigation portion of this model. The navigation portion of the MI-MTM intervention was intentionally selected to be delivered via telephone. This decision was made in order to simulate telephone-based services health insurance plan enrollees may receive, which could possibly be paid for in practice through care management or care coordination codes. Such considerations for payment necessarily should be addressed as this work moves forward.

Conclusion

The current study signifies an important advancement both for community pharmacy and for the national response to the current opioid epidemic. This single-blinded randomized clinical trial is incorporating a pharmacy-based integrated care model for opioid medication misuse among community pharmacy patients. The results of this study will provide necessary foundational data that will permit further testing of this intervention model in a larger multisite clinical trial. Importantly, these results will provide needed monitoring and health care improvement for patients who otherwise may be overlooked within community pharmacy and that have elevated risks for adverse medication events, including addiction and overdose.

Acknowledgments

Funding support: This project was supported by a grant from the National Institute on Drug Abuse (R21DA043735 01)

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Key Points

Background

1. Community pharmacy can play an important role for augmenting the national response to the opioid epidemic.
2. Currently, an evidence-based clinical protocol does not exist to enable community pharmacists identify, engage, and refer patients with opioid mediation misuse to appropriate care.

Findings

1. This paper describes the protocol for a pilot single-blinded randomized controlled trial implementing an evidence-based integrated behavioral intervention into a community pharmacy setting to address opioid medication misuse among patients.
2. Study results will provide crucial foundational evidence to support this integrated care model for larger scale testing and possible future dissemination.

Table 1

Items of the Prescription Opioid Misuse Index

Item	Question
1	Do you ever use MORE of your medication, that is, take a higher dosage, than is prescribed for you? Yes/ No
2	Do you ever use your medication MORE OFTEN, that is, shorten the time between dosages, than is prescribed for you? Yes/ No
3	Do you ever need early refills for your pain medication? Yes/ No
4	Do you ever feel high or get a buzz after using your pain medication? Yes /No
5	Do you ever take your pain medication because you are upset, using the medication to relieve or cope with problems other than pain? Yes/ No
6	Have you ever gone to multiple physicians including emergency room doctors, seeking more of your pain medication? Yes/ No

Table 2

Study Exclusion Criteria and Rational

Exclusion Criteria	Rationale
Pregnancy	Given potential pre/post-natal opioid use complications among pregnant women/offspring
Psychotic and/or manic episode in the last 30 days	To ensure reliability of results and consistent contact/follow up
Filling buprenorphine only	Some formulations are not indicated for pain
Do not have a reliable landline or mobile phone	To ensure consistent contact/follow up
Cannot provide collateral contact information for ≥2 contact persons	To ensure consistent contact/follow up
Plan to leave the area for an extended period of time in the next 3 months	To ensure consistent contact/follow up

Table 3

Overview of Brief Motivational Intervention-Medication Therapy Management

Interventionist/ education	Overarching Intervention Component	Session Content
PharmD level pharmacist	Medication Therapy Management	Reviewing the opioid medication(s) being taken
		Discussing misuse screening results
		Exploring behaviors indicative of misuse (e.g., early refills, taking medications too often/higher dosages than prescribed)
		Identifying/documenting possible targets for adherence improvement.
	Brief Motivational Intervention	Facilitating a non-directive discussion regarding motivation to change
		Discussing importance/confidence to avoid misuse
		Assisting to resolve ambivalence towards eliminating misuse, and, if appropriate
		Referring to treatment, including but not limited to referral to Patient Navigation
Master's level navigator	Patient Navigation and naloxone referral	Session 1: development of therapeutic alliance/rapport and goal setting.
		Sessions 2–3: identifying barriers and problem resolutions.
		Session 4: reviewing overdose prevention tool-kit and referring/ directing to a naloxone prescription/training.
		Sessions 5–7: encouraging and reinforcing treatment adherence, reviewing and identifying other care needs, and offering linkages to service providers as applicable.
		Session8: examines continued challenges to self-care and goals and formulates plans to continue progress

Table 4

Study Measures Construct Chart

Construct	Measure	# items	Screen	Baseline	2 month	3 month
Opioid Misuse/Adherence	Prescription Opioid Misuse Index	6	x		x	x
	Opioid Compliance Checklist	8		x	x	x
	Name, dose, and frequency of opioid medication use	3		x	x	x
Health self-management	Patient Activation Measure	10		x	x	x
Intervention acceptability (MI-MTM arm only)	Patient Satisfaction Survey for Comprehensive Medication Management	10			x	
	Patient Satisfaction Questionnaire-18	18			x	
Behavioral health	Timeline follow back	NA [a]		x	x	x
	14 panel drug urinalysis	NA		x	x	x
	Alcohol Use Disorders Identification Test-C	3		x	x	x
Mental health	Patient Health Questionnaire (i.e., depression/anxiety)	11		x	x	x
	Primary Care-Posttraumatic Stress Disorder assessment	4		x	x	x
Physical health functioning	Short-form 36	36		x	x	x
Services utilization	Treatment Services Review-6	56		x	x	x

[a]NA=Not applicable: Measurement instrument does not include a specific number of items