

Mixed methods formative evaluation of a collaborative care program to decrease risky opioid prescribing and increase non-pharmacologic approaches to pain management**Word count: 3491/3500**

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Abstract:

Introduction: Opioid prescribing and subsequent rates of serious harms have dramatically increased in the past two decades, yet there are still significant barriers to reduction of risky opioid regimens. This formative evaluation utilized a mixed-methods approach to identify barriers and factors that may facilitate the successful implementation of Primary Care-Integrated Pain Support (PIPS), a clinical program designed to support the reduction of risky opioid regimens while increasing the uptake of non-pharmacologic treatment modalities.

Methods: Eighteen Department of Veterans Affairs (VA) employees across three sites completed a survey consisting of the Organizational Readiness for Implementing Change (ORIC) scale; a subset of these individuals ($n = 9$) then completed a semi-structured qualitative phone interview regarding implementing PIPS within the VA. ORIC results were analyzed using descriptive statistics while interview transcripts were coded and sorted according to qualitative themes.

Results: Quantitative analysis based on ORIC indicated high levels of organizational readiness to implement PIPS. Interview analysis revealed several salient themes: system-level barriers such as tension among various pain management providers; patient-level barriers such as perception of support and tension between patient and provider; and facilitating factors of PIPS, such as the importance of the clinical pharmacist role.

Conclusions: While organizational readiness for implementing PIPS appears high, modifications to our implementation facilitation strategy (e.g., establishing clinical pharmacists as champions; marketing PIPS to leadership as a way to improve VA opioid safety metrics) may improve capacity of the sites to implement PIPS successfully.

Keywords

Opioid; Chronic pain; Implementation science; formative evaluation; mixed-methods

Introduction

Opioid prescribing, predominantly for chronic pain, quadrupled from 1990-2015; meanwhile, rates of serious opioid-related harms have increased.[1] The most catastrophic harm—overdose—is now the number one cause of accidental death in the U.S. by a large margin.[2] Veterans have approximately twice the rate of opioid overdose compared with non-veterans.[3] Along with the myriad potential drawbacks of long-term opioid therapy (LTOT), mounting evidence suggests it has modest or absent benefit.[1] Moreover, survey-based studies of patients describe high levels of ambivalence about LTOT with fears about becoming dependent and concerns about waning benefit.[4]

With mounting evidence for harm and limited benefit of LTOT, both the Centers for Disease Control and Prevention and Department of Veterans Affairs/Department of Defense (VA/DoD) recently released guidelines for LTOT that stood out as marked departures from previous guidelines in that they both recommended avoiding initiation of LTOT.[5, 6] Regarding persons currently on LTOT, both strongly recommended tapering or discontinuing opioids if harm outweighs benefit. Despite the widespread calls for de-implementing LTOT, patient-centered methods of tapering or discontinuing LTOT are still needed.[7] One randomized controlled trial of a physician assistant led opioid tapering program compared to usual care found that the intervention group improved significantly more than the usual care group in self-reported pain interference, pain self-efficacy, and prescription opioid problems at 22 weeks.[8] However, there was no difference in the decrease in mean opioid dose across groups. In an evaluation of an organizational-level implementation intervention to improve pain care quality over four years, the proportion of primary care patients on LTOT did not change, despite improvement in several other metrics of pain care quality.[9]

In our prior qualitative study of barriers and facilitators to reductions in high-dose opioid therapy as well as uptake of non-pharmacologic treatment, patients expressed frustration about perceived inadequate communication regarding the rationale for pain treatment plans, lack of their own and provider knowledge about tapering, and care fragmentation.[10] Other VA-based work revealed that patients view the possibility of worsened pain and the specter of the system abandoning them as major barriers to initiating tapers.[11] They felt that having access to tailored information and timely follow up on treatment plans were important facilitators. Providers reported struggling to enhance patients' motivation to engage with tapers and were daunted by the close and frequent follow-up that changes in pain treatment would entail.[12]

Given all these factors, we developed Primary Care Integrated Pain Support (PIPS), a pharmacist-primary care provider collaborative care program to support voluntary reduction of high-risk medication regimens and engagement with non-pharmacologic treatment. Specific components of PIPS include use of an informatics dashboard to identify eligible patients (those on ≥ 90 mg morphine equivalent daily dose or combination LTOT and benzodiazepine therapy) with an upcoming appointment in primary care; mailing a patient-centered letter inviting patients to ask providers about PIPS; a referral template primary care providers use to refer patients to PIPS, and a structured intake and follow-up program where a pharmacist works one-on-one with patients for up to six months. The design of the clinical intervention was informed in part based on a successful model in VA,[13] our prior qualitative work with providers and their patients on LTOT for chronic pain that identified the need for better communication among providers and patients and improved coordination of pain care, and review of similar evidence-based interventions from the literature, including one that decreased opioid use[14] and one that decreased benzodiazepine use.[15] To promote uptake of PIPS, we deployed an implementation

facilitation approach that has been used successfully in VA primary care clinics.[16]

Implementation facilitation combines multiple strategies (e.g., engagement of key stakeholders, academic detailing, marketing and education) to enable and support individuals, groups, and organizations to adopt clinical innovations into routine practice.[17] It relies heavily on iterative problem-solving and relationship-building among an expert in the clinical innovation and its implementation (i.e., the external facilitator), someone within an organization familiar with its structure, policies, and culture who spearheads implementation of the innovation (i.e., an internal facilitator), and well-respected persons within the organization who are knowledgeable about the innovation and perceived as influential (i.e., champions). Each implementation site, described below, has an internal facilitator and 1-2 champions who meet routinely with the external facilitator to discuss program implementation. The external facilitator (author WCB) is located at VA Connecticut Healthcare System. Herein, we describe the results of a mixed methods formative evaluation to guide the development of our implementation facilitation approach to foster the adoption of PIPS within the participating VA sites.

Methods

Overview of PIPS implementation trial

The mixed methods formative evaluation occurred in the context of a three-site, hybrid type III implementation/effectiveness trial, designed to evaluate our facilitated approach to PIPS implementation. The hybrid type III design focuses primarily on establishing the effectiveness of the implementation facilitation strategy (e.g., implementation facilitation's capacity to increase the proportion of primary care providers who refer eligible patients to PIPS and proportion of these patients who receive PIPS), while observing or gathering information on the clinical intervention and related outcomes (e.g., PIPS' capacity to increase the proportion of patients

changed to safer medication regimens and engaged in non-pharmacologic pain treatments), [18]. The implementation period will be 18 months in duration and change in clinical outcomes, extracted from the electronic health record, will be assessed pre- and post-implementation using an interrupted time series analysis. Hybrid type III effectiveness-implementation studies are used when there is insufficient direct evidence for an intervention's effectiveness, yet policy mandates (e.g, VA/DoD guidelines for LTOT), pressing clinical problems (e.g. opioid overdose, LTOT ineffectiveness), and indirect support for an intervention exist, all conditions present for the PIPS trial. A formative evaluation preceded the actual implementation of PIPS to inform the selection and fine-tuning of strategies that comprise the implementation facilitation approach used in the study. VA Connecticut's Investigational Review Board (IRB) approved the overall formative evaluation and each site had a separate IRB-approved protocol for local work.

Setting

We are implementing PIPS at the VA Eastern Colorado Healthcare System in Denver, the Richard L. Roudebush VA Medical Center in Indianapolis; and the Central Arkansas Veterans Healthcare System in Little Rock; all three implementation sites are large VA facilities caring for 55,000-75,000 veterans in which primary care providers prescribe the majority of LTOT, clinical pharmacists are integrated into primary care team-based practice and non-pharmacological pain management options are readily available. At the time of study kick off, between 140 and 190 patients were eligible for PIPS at each site.

Participants

Internal facilitators and champions identified pain care clinical, administrative, and leadership stakeholders at their facilities. They approached a mean of 10 individuals per site individuals either in person or via email to invite them to participate in the formative evaluation. Potential participants received up to two additional reminder emails to schedule an interview, each 10 days apart from the prior query. Eighteen individuals agreed to complete the ORIC; 9 also agreed to participate in the interview.

Formative evaluation design, procedures and assessments

This mixed-methods formative evaluation consisted of (1) a survey about organizational readiness for change and (2) semi-structured telephone interviews, each described in detail below. Potential participants were identified and invited to participate by the internal facilitator at each site. Enrolled participants were first asked to complete the survey, distributed via REDCap, and then invited to participate in a semi-structured interview; not all survey respondents completed an interview. Interviews were conducted by phone by an experienced qualitative researcher (author KMM).

The survey consisted of the Organizational Readiness for Implementing Change (ORIC) instrument,[19] a 10-item survey measure for assessing the shared belief among members of an organization that their organization is ready for change – in this case PIPS. Each item is rated using a 5-point ordinal scale that ranged from “disagree” to “agree.” It has two subscales: change commitment (a shared resolve among organizational members to implement a change) and change efficacy (collective capability to implement a change). The total score ranges from 10-50, with higher score indicative of greater organizational readiness for change. Exploratory and confirmatory factor analyses, in studies involving a hospital’s readiness to implement use of electronic health records and international non-governmental organizations readiness to

implement mobile technology systems, revealed two correlated factors with high item loadings and good model fit consistent with the theorized subscales.[19] In addition, reliability analysis showed high subscale inter-item consistency (ranged from .88 to .92) and inter-rater agreement (ranged from .72 to .82).[19]

In addition, the authors developed a semi-structured interview guide to obtain information about factors that might support or hinder PIPS implementation and inform our use of the implementation facilitation approach during the trial. We relied upon the Consolidated Framework for Implementation Research (CFIR)[20] to develop a series of open-ended questions to identify how characteristics of PIPS, site features and processes, and external influences could function as implementation facilitators or barriers and inform implementation facilitation of PIPS (see Appendix). The guide was used flexibly to follow the flow of conversation while addressing all the topics, which included questions both about specific components of PIPS and pain treatment issues in general to better appreciate the implementation context. Each interview took approximately 30 minutes to complete and all were audio-recorded and transcribed verbatim using VA's centralized transcription service program.

Data analysis

We used descriptive statistics to characterize ORIC results. Frequencies and medians were calculated in SAS 9.4. Interview transcripts were analyzed qualitatively using procedures informed by grounded theory methodology,[21, 22] a systematic approach to deriving qualitative themes from textual data. We first conducted open coding in which an investigator identified key concepts emerging from the language used by participants and assigned codes (descriptive phrases) to segments of text. Atlas.Ti qualitative analysis software (Scientific Software Development GmbH, Berlin, Germany) was used to facilitate data coding and sorting. Themes

that emerged in the interviews were examined for similarities and differences in perspectives in a process known as constant comparison analysis. Subsequently, prominent themes and quotes exemplifying each were presented to the research team and refined through discussion.

Results

Table 1 describes the participants in the formative evaluation. Eighteen participants completed the ORIC and nine (50%) also completed a semi-structured interview. There was variable level of participation in the ORIC across sites (Denver=9 respondents, Indianapolis=2 respondents and Little Rock=7 respondents). Small numbers precluded formal testing of differences across sites.

Half of the participants were women (n=9) and half were men. The most common length of time that respondents were employed at VA settings was 2-5 years (44.4%), followed by >15 years (27.8%) (Table 1). Half of persons held administrative or leadership roles, while 27.8% of the sample were medical staff that provided direct care. A person may have more than one role in the VA so these professional categories are not mutually exclusive. Four of the clinicians reported holding administrative/leadership roles.

Organizational readiness for change

Survey results are displayed in Table 2. The total median score of 43 indicated a relatively high level of readiness for implementing PIPS. The median score on change commitment items was slightly higher than change efficacy (22.5 vs. 20.5). Scores were consistent across sites.

Semi-structured interviews

Nine participants, representing all sites, completed qualitative interviews; several salient themes emerged, some directly related to components of PIPS while others pertained to pain treatment, in general. Respondents expressed their perception that inter-provider “turf battles” represent

substantial barriers to pain management. In terms of patient barriers, respondents reported their perception that fear of abandonment and withdrawal of opioids would be important barriers to participation in PIPS. Finally, in terms of facilitators, participants highlighted the importance of patient engagement—noting that some patients had done quite well with opioid reductions—and most respondents viewed a multidisciplinary team approach as an optimal strategy for providing high-quality pain care.

Turf battles in pain management are a barrier to improving pain care. Several participants spoke about tensions between primary care providers and specialty pain clinic providers in terms of creating pain management programs that provided broad treatment access for veterans.

“You know, we have a strong-minded leader of our chronic pain management clinic. We have a strong leader leading our primary care program. And getting them on the same page and getting them focused on doing what they say they’re going to do have been very problematic. I will tell you the honest-to-god truth, there is not a lot of trust and I think that in a nutshell is what the problem is.”

Another participant noted the same struggle at her facility between primary care physicians and pain management providers:

“I think we struggle with the interactions between primary care and our pain program. The multi-disciplinary pain program was set up to be a referral option for primary care for patients who are high risk or you want to use non-pharmacological treatment. So, it was pretty restrictive and so initially it was just for patients who were on so many milligrams of opioids or high risk so they set up a lot of restrictions and I would say half the patients referred there never came back. A large number of patients never even got through it. And so, the providers did not perceive it as that helpful.”

Challenges for patients tapering off opioid medications. Most participants noted that a significant barrier to veteran participation was veterans' fear that they would be tapered off opioid medications with little or no support during the process.

"I guess the biggest challenge patients feel is that they feel alone. You know, if you're gonna recommend a taper because you can tell that the patient's got some red flags, they're kinda drowning and they don't know how to save themselves, then those patients don't want to stop typically and so the challenge is, is how to encourage them that, "Okay, we're gonna work together for what you need, not for what you want." That's a huge challenge, is to try to get buy-in."

Another participant concurred with these remarks:

"The patients want a substitute for what you're taking away, they want support and just someone to acknowledge the fact that it's not going to be easy and they want to know that they've got somebody to contact when and if things don't go right. To me the biggest challenge is just getting buy-in from the people who can't see themselves clearly in the mirror that they've got a problem, or that the opioids are not helping them have a better quality of life, just getting buy-in that there's a better way."

Other participants noted that patients may feel that they are being punished for their current opioid use by being referred into a tapering program:

"The resistance we get is if a patient thinks they are being punished for it. One of the worst things that we could possibly do is say to the patient, you've violated your pain agreement, now you have to come off of it because we're punishing you."

Patient engagement may be helpful in reducing "us" vs. "them" dynamic. Several providers remarked on the inherent tension generated by a dynamic where the providers/system are seen as

imposing dose reductions on highly ambivalent or even steadfastly resistant patients. One provider emphasized the importance of patient engagement in helping alleviate that tension:

“You know what would be satisfactory is if we started to get a lot more patient engagement. That the patients came forward and said, hey, you know, this makes sense, this works, I really feel like I can engage in this, and we get a lot more veteran empowerment and a lot more patient empowerment to say these are the changes that I want to make in my life to maybe get rid of some of these medications or get a very low dose of these medications, you know, do as much as I can to eliminate the dangerous medications that I’m taking and maybe come up with better plans for pain management. So, if we had a successful program which sort of reduced a lot of the disgruntled-ness from both the providers and the patient side, and they both were kind of moving together as a team with this, that would be success to me.”

Other providers noted the importance of improvements in quality of life and patient satisfaction:

“Their activities of daily living and their functional assessments have improved and quality of life and patient satisfaction. Actually, quality of life is probably better than patient satisfaction, because with patient satisfaction, get back to this politics, we have some people that are more satisfied when they get more opioids, or at least in the short run, right?”

Finally, other providers noted the importance of reducing patient deaths due to opioid overdoses:

“And so I would like to see a decrease in the amount of people on dangerous amounts of opiates. So one major concern is people overdosing on these medications, so that would be very, fewer of those deaths relating to being on opiates.”

Clinical pharmacists play important roles in multi-modal pain management. In considering opportunities for multimodal pain treatments, many participants spoke of the centrality of the clinical pharmacist on the team. Nearly all participants had worked closely with a clinical pharmacist to help manage medications for veterans.

One participant noted:

“Our clinical pharmacists are very active and very proactive in doing projects, research, working with providers, giving providers reports patients that aren’t being managed, especially in the management of all chronic diseases, diabetes, hypertension, heart disease. We have clinical pharmacists that are constantly reviewing the medication management of these patients and helping us making medical decisions.”

Another participant concurred:

“So, we utilize clinical pharmacists as part of the PACT model for quite a while now, seven or eight years and it’s been a very positive experience, So, each clinic has a clinical pharmacist and they have fairly designated roles, particularly chronic disease management so they work with protocols and diabetes management; hypertension, thyroid, smoking cessation and they are allowed to adjust medications as part of that management. So, I think that’s been, we’ve had a really good experience. They work very well embedded in the teams so they’re fairly integrated with the primary care team which has been very helpful too.”

Discussion

This mixed-methods formative evaluation served the purpose of refining an implementation facilitation strategy to promote uptake of PIPS, a collaborative clinical program designed to reduce risky medication regimens and increase non-pharmacological pain treatment.

The ORIC results revealed an overall high level of readiness for implementing PIPS, with some room to further enhance organizational change efficacy. Detailed analysis of the qualitative interviews revealed several potential targets on which the implementation facilitation teams could focus efforts to improve the likelihood of implementation success.

By qualitative theme, the first target was participants' perceptions of system-level barriers—particularly concerns that various disciplines struggle to collaborate towards a shared mission. This theme has emerged in complementary qualitative studies of VA primary care providers' and nurses' attitudes about pain care.[23, 24] In response to this challenge, the PIPS facilitation team increased efforts to engage facility leadership to emphasize the importance of collaboration among various disciplines to reach important VA healthcare system goals. For example, the external facilitator worked with the site-based internal facilitators and champions about marketing PIPS as a path to help facilities comply with the Opioid Safety Initiative, a directive from VA's Central Office to monitor and improve several metrics of opioid safety.[25]

The second theme was a patient-level barrier—patients would be too worried about being subjected to an involuntary or rapid (or both) opioid taper to engage in PIPS. To address this concern, PIPS was designed to place added emphasis on informing patients about evidenced-based, multi-modal non-pharmacological treatments (e.g., physical therapy,[26] cognitive behavioral therapy,[27] yoga,[26] and mindfulness based stress reduction[27]) and how opioid tapers would coincide with the introduction of alternative pain management strategies. In addition, motivational interviewing[28] serves as a platform in PIPS for clinical pharmacists to have collaborative conversations with patients about chronic pain and LTOT and helping them commit to safer and more effective multi-modal pain care. To this end, the clinical teams across sites involved in PIPS delivery participate in monthly community of practice calls in which they

discuss multi-modal pain care options, address challenging clinical situations (e.g. difficult tapers, less motivated patients), fine-tune communication skills, and identify new tools to promote high-quality pain care (e.g. use of an importance/confidence ruler, implemented by pharmacists, to aid in the motivational interviewing process). Finally, presuming patients will be successfully tapered and experience pain relief from nonpharmacological treatments promoted through PIPS, the facilitation team members will seek guidance from these patients about how best to market the program to others who may be reluctant to engage in it.

In addition, the qualitative analysis identified the important role of the clinical pharmacy specialist as a critical piece of the PIPS clinical program. In most VA facilities, including the three implementation sites, clinical pharmacy specialists are already integrated into primary care, performing chronic disease management one-on-one with patients. Considering the focus on medication safety, participants saw pharmacist involvement as a significant facilitator to PIPS implementation success. Hence, clinical pharmacy specialists are members of our implementation teams at each of the sites, and we intend to leverage their vital primary care role to remedy the problem of uncoordinated pain care silos mentioned in the semi-structured interviews. Of note, the pharmacists delivering PIPS at the three sites have experience with chronic pain management, so the goal of promoting and encouraging non-pharmacologic treatment modalities in conjunction with medication safety messaging was not a barrier. In fact, given their pain care expertise, they will serve as PIPS champions at each site and be directly involved in marketing PIPS to providers and educating staff about multi-modal pain management. Pharmacists without chronic pain management experience would likely need additional training in pain management approaches to feel comfortable and confident in this role.

Our study's findings should be interpreted in the context of the study's limitations. First, the study was performed exclusively in VA facilities and thus may not be generalizable outside the VA. That said, while non-integrated systems in community settings may have more substantive system-level barriers to implementing PIPS or a program like it, the perceived patient-level barriers reported by participants may be equally relevant in non-VA settings. Second, with a small sample size of 18 participants, only half of whom completed qualitative interviews, we may not have captured all the relevant, important perspectives that could impact successful implementation of PIPS. In particular, the participation of only two persons at the Indianapolis site may serve as a flag for future barriers to PIPS implementation. Furthermore, the high proportion of individuals with leadership roles in our sample may have obscured some of the barriers associated with day-to-day clinical issues and may have led to inflated scores on the ORIC. Nonetheless, several respondents reporting leadership roles also work in the clinics and thus likely have familiarity with the day-to-day challenges of pain care.

This formative evaluation guided modifications to an implementation facilitation strategy that will be used to promote uptake of a collaborative care program to improve quality and safety of chronic pain care. While organizational readiness for implementing PIPS appears high, the modifications to our implementation facilitation strategy based on this formative evaluation may further enhance the organizational readiness of the sites by bolstering capacity to put PIPS in place. Future research will focus on measuring what aspects of implementation facilitation were used during the implementation phase of the PIPS trial, which components of PIPS were implemented at the sites, and what effect PIPS had on patient-level outcomes (e.g., successful transition to safer medication regimens, utilization of non-pharmacological pain treatment modalities).

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Contributors

Dr. Becker had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Becker, Mattocks, Frank, Bair, Kerns, Fenton, Painter, Midboe, Martino

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Conflict of Interest

All authors declare that they have no conflicts of interest.

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Table 1: Description of survey participants (N=18)

Years in VA	N	%	Position(s)	N	%
<2	2	11.1	Administrator/ leadership	9	50.0
2-5	8	44.4	PCP (Physician, NP, PA)	5	27.8
6-10	1	5.6	Pharmacist	2	11.1
11-15	2	11.1	Psychologist/Psychiatrist	3	16.7
>15	5	27.8	Other/not specified	3	16.7

Table 2: Organizational Readiness for Implementing Change (ORIC) instrument

Domain	Survey Item	Median
Change commitment	People who work here are motivated to implement PIPS (Q9).	5.00
	People who work here want to implement PIPS (Q5).	5.00
	People who work here will do whatever it takes to implement PIPS (Q3).	4.00
	People who work here are committed to implementing PIPS (Q1).	4.00
	People who work here are determined to implement PIPS (Q7).	4.00
Change efficacy	People who work here feel confident that they can keep track of progress in implementing PIPS (Q2).	5.00
	People who work here feel confident that the organization can support people as they adjust to PIPS (Q4).	4.00
	People who work here feel confident that they can keep the momentum going in implementing PIPS (Q6).	4.00
	People who work here feel confident that they can manage the politics of implementing PIPS (Q10).	4.00
	People who work here feel confident that they can coordinate tasks so that PIPS implementation goes smoothly (Q8).	4.00
Change Commitment Subscore	SUM OF Q1, Q3, Q5, Q7, Q9	22.50
Change Efficacy Subscore	SUM OF Q2, Q4, Q6, Q8, Q10	20.50
Total Score	SUM OF ALL	43.00

Appendix: Semi-structured Interview Guide

Introduction/Orientation

Thank you for agreeing to be interviewed about the plan to implement a new chronic pain management program at [name of VA]. The program is called Primary care-Integrated Pain Support or PIPS. The PIPS program uses a care management strategy in an attempt to decrease the proportion of Veterans on high-risk medication regimens for chronic pain, while increasing the proportion of Veterans treated with non-pharmacologic pain treatment modalities (NPMs).

As you are well aware, chronic pain care and opioid prescribing have received a lot of attention within and outside of the VA healthcare system. The VA Opioid Safety Initiative (OSI) has set up expectations for facilities and PACTS/PCPs to provide safer and more effective pain treatment for Veterans. To date, much of the OSI's emphasis has been on monitoring practices (urine drug tests, querying the prescription drug monitoring database) and patient education (signed informed consent). Less attention has been given to implementing new programs designed to help patients transition to safer medication regimens and make greater use of non-pharmacologic pain treatment modalities (NPM) such as cognitive behavioral therapy for pain, yoga, acupuncture, and meditation.

The PIPS program will facilitate collaboration between primary care physicians and pharmacists. PIPS has several components including:

1. Mailing a letter to eligible Veterans in advance of a routine primary care appointment that explains the nature of and rationale for PIPS and encourages Veterans to speak about it with their primary care provider.
2. During the routine appointment, the primary care provider guides the Veteran through a brief, templated pharmacy consult request.
3. Cued by the consult, the pharmacist has up to two weeks to arrange an initial meeting with the Veteran in which the pharmacist will build rapport, review preferences, start the taper plan, and set a schedule for follow-up. The pharmacist will use a protocol for dose tapering that will specify dose and number of pills supplied at each 2-week interval and use clinical judgment to alter the schedule as needed. Primary care providers will electronically sign prescriptions.
4. Pharmacist follow-up will match the Veterans' needs, and will include one session per week for the first 4 weeks followed by biweekly sessions for 12 weeks. Veterans may receive support from PIPS pharmacists for up to 6 months. Follow-up sessions (a blend of telephone or face-to-face meetings) will involve monitoring of (a) progress with medication changes, (b) safety, and (c) engagement with NPM. Primary care providers will be added as additional signers to pharmacist notes indicating the progress of tapers and expected date of patient's discharge from PIPS, ensuring seamless transition. In addition, the pharmacist will submit referrals for the patient's preferred NPM, track their attendance, and address barriers to NPM adherence. In addition, pharmacists will have the ready assistance of RN care managers.

Interview: I'd like to ask you a few questions about plans to implement PIPS at [name of VA].

CFIR Construct	Questions	Probes
First, I would like to ask you a few questions to help me understand your role in your facility and in providing pain care at your facility.		
Role in Facility	Tell me a little bit about your experience working here in the VA.	How many years have you worked at VA? Which service line are you a part of? What are your primary job responsibilities?
Now let's talk a little bit about pain care at your facility.		
Inner Setting - Compatibility	Describe your facility's organizational stance (or mindset) toward pain? How much have you heard about multi-modal pain care in your facility? Are you aware of efforts at your facility to reduce high dose opioids or to increase uptake of non-pharmaceutical pain treatments?	If you have a pain strategy, is it facility-based or coordinated across the VISN?
Process - Champions	Is there an individual or a group of individuals who would be considered pain champions within your facility or VISN?	Who would be effective in championing PIPS at your facility? What would this individual/champion need to do to help integrate PIPS into the practice?
Process - Opinion Leaders	Who are the key influential individuals to get on board with implementing a new pain management program like PIPS?	How could they be influential?
Characteristics of Individuals – Self-Efficacy (This question is for PCPs)	Please describe your experience collaborating with clinical pharmacy specialists as part of patient care for other conditions.	How comfortable are you referring your patients to clinical pharmacy specialists? Have you collaborated with clinical pharmacists to taper patient medication? If so, what was that experience like?

<p>Characteristics of Individuals – Self-Efficacy</p> <p>(This question is for Clinical Pharmacists only)</p>	<p>Please describe your experience collaborating with PCPs and/or MH providers as part of patient care.</p>	<p>In general?</p> <p>In the context of pain management?</p> <p>Where medication tapering is part of patient care?</p>
<p>Characteristics of Individuals – Self-Efficacy</p> <p>(This question is for Mental Health Providers only)</p>	<p>Please describe your experience collaborating with primary care as part of patient care.</p>	<p>Have you collaborated with primary care where a patient has been prescribed both opioids and benzos? If so, what was that experience like? (ONLY ASK PSYCHIATRISTS THIS QUESTION)</p> <p>Have you ever worked with clinical pharmacists to taper patient medication? If so, what was that experience like? (ONLY ASK PSYCHIATRISTS THIS QUESTION)</p>
<p>Now let's talk about discussions you might have with your patients relating to medication tapering and discontinuation.</p>		
	<p>How comfortable are you discussing medication tapers with your patients?</p>	
	<p>Would you be willing to check a box in a consult that says you had a conversation with the patient about medication tapering?</p>	
<p>Characteristics of Individuals – Individual Identification with Organization</p>	<p>Do you have experience with motivational interviewing?</p>	<p>Have you ever engaged in motivational interviewing with patients? Do you feel like your facility supports motivational interviewing as a means by which to motivate behavioral change in patients?</p>
<p>Next let's talk about the PIPS clinical program.</p>		
<p>Inner Setting - Access to Knowledge & Information</p>	<p>We described the PIPS program a little earlier – is that the first time you had heard of it? If you were aware of PIPS</p>	<p>What other ways would be useful to inform providers and patients about PIPS?</p>

Characteristics of Individuals - Knowledge and Beliefs about the Intervention	before today, where did you hear about it? What have you heard?	
Intervention Characteristics - Evidence Strength & Quality	What kind of information or evidence would be useful to you about how/whether the PIPS program works?	Information from your own experience, knowledge of consensus guidelines, published literature, or other sources? From co-workers? From supervisors? Is there additional/other information or evidence that you would find useful?
	What would success look like in the PIPS program? What kind of outcome would you consider a success?	
Intervention Characteristics - Relative Advantage	What aspects of PIPS seem useful for Veterans? Providers?	What else about PIPS seems attractive? 1. One on one counseling with pharmacist 2. Patients learn about and participate in NPMs
Outer Setting - Patient Needs & Resources Outer Setting – Available Resources	What barriers will patients face to participating in the PIPS program? External (e.g., transportation costs, time)? Internal (e.g., lack of staff)?	
Outer Setting - External Policy & Incentives	How would PIPS fit into your VA's efforts to comply with the OSI?	How well does PIPS fit with other initiatives at your VA? Which ones?
Inner Setting - Networks & Communications	How has the staff been informed about PIPS at your facility? How else should we get the word out about PIPS?	How do you work together? Meetings? Personal contact? Distributed materials? E-mail communications? Other?
Characteristics of Individuals – Individual Stage of Change	Is there a specific type of patient with pain that you think would definitely be appropriate for the PIPS program? Not appropriate for the PIPS program?	How do you decide which patients might be open to hearing about a program like PIPS?
Inner Characteristics - Adaptability	Are there any things about PIPS that you think should be changed or added to it? If yes, what are they?	Do you think other people might suggest changes to PIPS? If yes, how so?
Finally, let's talk about what kind of information you would like regarding implementation of PIPS as it relates to your patients.		

Inner Setting - Access to Knowledge & Information	<p>What kind of information or feedback would you want/need about your patients who are participating in PIPS?</p> <p>How would you like that information provided/communicated to you?</p>	<p>Weekly treatment notes with you as a cosigner?</p> <p>A single note with the patient stating when the patient entered treatment and if they completed/dropped out?</p>
Inner Setting - Goals & Feedback	<p>What feedback (if any) would you like related to PIPS? (e.g., referral reports, % of patients completing the program)</p>	<p>What data should be reported?</p> <ul style="list-style-type: none"> # letters sent? # signed consults completed? # Veterans meeting with PIPS pharmacist # PIPS meetings completed per Veteran
Conclusion. Thank you so much for participating in this interview.		
	<p>Is there anything that we haven't asked that you think might be important for us to know?</p>	

Highlights

- Stakeholders support the intervention but organizational barriers persist.
- Motivating patients to agree to opioid tapers was a prevalent concern.
- Pharmacists were viewed as ideal collaborators with patients and primary care physicians.

ACCEPTED MANUSCRIPT