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Research paper

Decreasing risk among HIV patients on opioid therapy for chronic pain: Development of the TOWER intervention for HIV care providers

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ABSTRACT

Many people with HIV (PWH) experience chronic pain that limits daily function and quality of life. PWH with chronic pain have commonly been prescribed opioids, sometimes for many years, and it is unclear if and how the management of these legacy patients should change in light of the current US opioid epidemic. Guidelines, such as the Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain (CDCG), provide recommendations for the management of such patients but have yet to be translated into easily implementable interventions; there is also a lack of strong evidence that adhering to these recommendations improves patient outcomes such as amount of opioid use and pain levels. Herein we describe the development and preliminary testing of a theory-based intervention, called TOWER (**TOW**ard Saf**ER** Opioid Prescribing), designed to support HIV primary care providers in CDCG-adherent opioid prescribing practices with PWH who are already prescribed opioids for chronic pain. TOWER incorporates the content of the CDCG into the theoretical and operational framework of the Information Motivation and Behavioral Skills (IMB) model of health-related behavior. The development process included elicitation research and incorporation of feedback from providers and PWH; testing is being conducted via an adaptive feasibility clinical trial. The results of this process will form the basis of a large, well-powered clinical trial to test the effectiveness of TOWER in promoting CDCG-adherent opioid prescribing practices and improving outcomes for PWH with chronic pain.

1. Introduction

Chronic pain is a common and significant problem for people with HIV (PWH). It affects up to 83% of PWH, and is associated with functional disability [1], frailty [2], high resource utilization [3,4], reduced quality of life [4], poor retention in care [5,6], suboptimal antiretroviral therapy (ART) adherence [5], and risk behaviors that can transmit HIV to others [7–10]. Past enthusiasm for opioids as a treatment for chronic pain and under appreciation of their risks has created a large group of "legacy patients" who have been maintained on chronic opioids for pain, sometimes for years [11,12]. Evidence based best practices for managing these patients are lacking, and providers are left uncertain as to whether maintenance of the status quo or opioid taper is the better course, and what role patient preference should play in this decision.

Guidelines have been established in an attempt to facilitate this decision-making process. In March 2016, the Centers for Disease Control

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and Prevention (CDC) published a Guideline for Prescribing Opioids for Chronic Pain (CDCG) which was intended to harmonize and supersede prior guidelines and to be used in general primary care settings with opioid naïve as well as legacy patients [13]. With regard to legacy patients, although the CDCG is lengthy, its recommended actions can be conceptualized as serving one of three overarching goals: 1) obtaining data to assist in the opioid risk-benefit assessment (e.g. from regular visits, prescription drug monitoring programs, urine drug testing and inquiry regarding opioid side effects); 2) using these data to perform the risk-benefit assessment; and 3) acting to treat pain and minimize opioid-related risk (e.g. offering non-opioid/non-pharmacologic therapies, patient education, minimizing opioid doses, co-prescribing naloxone, avoiding benzodiazepines, and treatment of opioid use disorder (OUD) when present). Subsequent to the publication of the CDCG, the HIV Medicine Association (HIVMA) published a guideline for the management of chronic pain in HIV, which while more specific to PWH, was less specifically focused on opioids [14]. To date, the limited data that exist suggest that in general care settings CDCG uptake has been modest and partial [15]; data specific to HIV care settings and/or the HIVMA guidelines do not exist, although a clinical trial examining an alternative intervention is ongoing [16]. Moreover, a theoretical framework for understanding prescribers' behaviors regarding CDCG implementation has not been established.

The Information, Motivation and Behavioral Skills (IMB) model is an appropriate framework for understanding both provider and patient behaviors relevant to the prescription and use of opioids for chronic pain. The IMB model, which is supported by over 30 years of research including work targeting PWH and their healthcare providers [17–20], asserts that relevant information, motivation, and behavioral skills are fundamental and highly generalizable determinants of behavior (e.g. adherence to guidelines) [19,21]. According to the model, accurate ***Information*** that is directly relevant to the performance of a behavior is a prerequisite for practicing the behavior. ***Motivation*** is an additional critical determinant that influences whether one will be inclined to act on what one knows and consists of *attitudes* toward and *social normative* support for the behavior. Finally, ***Behavioral Skills*** consisting of one's *objective skills* and *perceived self-efficacy* with respect to the (often complex) sequence of acts involved in performing a behavior are a third prerequisite [19,21–25]. The IMB model is mediational and specifies that an individual's information and motivation are generally independent constructs [19,26] that work primarily through, and are limited by, one's level of behavioral skills.

Herein we describe the process by which we used the IMB model (articulated to both patient- and provider-opioid relevant behavior change) and extensive stakeholder engagement (patient and provider) to develop the **TOW**ard Saf**ER** Opioid Prescribing (TOWER) intervention. TOWER is a provider-focused intervention, intended to support HIV primary care providers (PCPs) in adherence to the CDCG, with the specific goal of improving outcomes for legacy patients. We also outline the protocol for an ongoing adaptive feasibility trial of the TOWER intervention designed to optimize the intervention itself and determine the most appropriate methods to measure its efficacy in improving patient outcomes in future clinical trials.

2. Methods

An overview of the intervention development process is schematized in Fig. 1. We conceptualized CDCG implementation as a process of provider behavior change. Thus throughout the intervention development process we sought to establish providers' IMB needs for change.

Step 1: Initial provider engagement. Step 1 has been described previously [27]; its purpose was to understand providers' needs for implementing the CDCG in real world clinical practice. Briefly, we began by developing an operationalized version of the CDCG recommendations potentially suitable for use during a patient visit, accompanied by suggested communication strategies based on widely used physician communication models (e.g. the REDE and 4 habits models) [28,29]. We provided printed copies of these materials during one-on-one interviews with nine practicing physicians of diverse specialties (primary care, family medicine, rehabilitation medicine, pain management, and hospitalist). Interviews were audio recorded, transcribed, and analyzed using a thematic qualitative methodology [30]. Physicians reported numerous informational needs such as knowledge of the availability and insurance coverage of non-opioid treatments; information on opioid dosing and equivalencies; and information on prescribing naloxone. In terms of motivation, the desire to avoid prolonged and difficult interactions with patients was a significant motivator for providers' current opioid management practices. Behavioral skills needs reported by providers focused on skills to perform all the recommended care processes within the time constraints of practice, and the ability to effectively weigh the risk/benefit ratio of opioids for individual patients. Providers recommended that development of innovative information technology (IT) solutions and training in their use would be needed to enable these tasks.

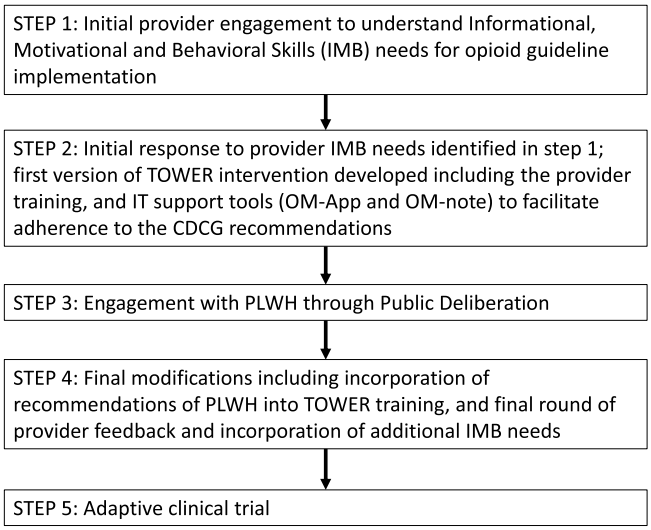

Fig. 1. Process for TOWER intervention development and refinement.

Step 2: Initial response to provider IMB needs. For the first iteration of TOWER, we developed a training with content aimed at the providers' specific IMB needs, including communication strategies to lessen aversion to the opioid conversation, and a suggested approach to weighing the risk and benefit of opioids for individual patients (Appendix A). We also addressed behavioral skills needs in the manner suggested by the providers by developing two IT solutions: the opioid management app (OM-App) and opioid management note (OM-note).

The purpose of the OM-App is to provide the patient a means of directly reporting data needed by the provider to assist in the opioid risk-benefit assessment, focusing on information more likely to change frequently (e.g. pain intensity) rather than more static data (e.g. history of substance use disorder). The intention was to reduce time burden on the provider, while engaging the patient more actively in the opioid management process. OM-App is a short messaging system (SMS)-based app which delivers a daily text message to the patient containing a link to a brief survey that presents a rotation of 2–3 questions (out of a total of 18) each day (Fig. 2). Questions fall into three categories, namely: 1) assessment of benefit (e.g. data on pain severity and interference, progress toward a treatment goal); 2) assessment of risk/harm including physical side effects (e.g. gastrointestinal and cognitive) and alcohol and drug use (including illicit opioids, overdose, opioid craving, sharing of

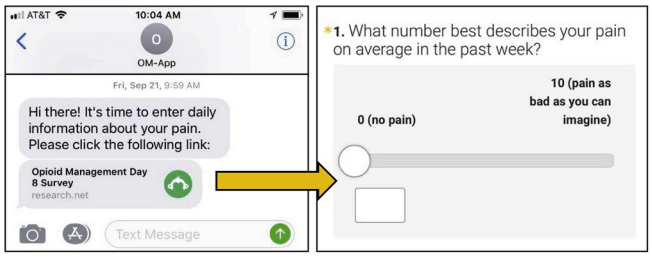

Fig. 2. Patient interface with OM-App.

opioid medications, obtaining opioid medications from other sources); and 3) utilization of pain treatments, including both non-pharmacologic treatments and opioid adherence. Responses are organized by topic in a password-protected HIPAA-compliant website accessible to the provider from any web browser. The provider has the option of reviewing all the data and/or a summary report from the previous 30 days (Fig. 3).

The OM-Note is a progress note template designed to help the provider move efficiently through a CDCG-adherent opioid management visit. It begins with organization of the data needed for the opioid risk-benefit assessment including data from the OM-App, the electronic medical record (EMR), and external websites (e.g. prescription monitoring programs). It then provides decision support for risk-benefit assessment and acting to treat pain and minimize risk.

Step 3: Patient engagement. Step 3 employed the method of public deliberation (PD) which is a means of stakeholder engagement used to gather informed public input on decisions that cannot be addressed with technical information alone [31–33]. We used PD to obtain PWH's recommendations on implementation of the CDCG in the HIV clinic. Forty-three PWH (with and without chronic pain) participated in one of two day-long sessions that included interactions with experts in chronic pain, opioid prescribing and other relevant topics; discussion of case studies; and development of recommendations. We asked participants to incorporate their experiences as PWH in addressing three specific topics: the patient information which should be used in the provider's opioid risk-benefit assessment; provider communication strategies for the opioid management process; and measures to reduce prescription opioid risk. Participant recommendations are summarized in Table 1.

Although the PD was focused on obtaining the recommendations of PWH regarding the practices of prescribers, we also elicited patients' IMB needs for changing their own opioid risk behavior. These data were collected with the expectation that they would inform future additions to TOWER, particularly a provider training in the use of IMB to lower patient opioid risk behavior. Patient informational needs included knowledge of the effectiveness, risks, and side-effects of opioids versus non-opioid pain treatments, and the risk of sharing prescription opioids with others. Important motivational factors for lower opioid risk behavior included feeling empowered as a partner in opioid management and secure in the knowledge that prescription opioids would not be withdrawn without their consent. Key behavioral skills were positive pain coping mechanisms, and the ability to manage social pressure to share their prescription opioids.

Table 1
Recommendations of PWH for opioid prescribing for chronic pain elicited during public deliberation.

Topic	Recommendations
Patient factors which are justifiable to consider in the prescription opioid risk-benefit assessment	Medical/mental health Substance use Being "in control" of life Adherence to HIV treatment Presence of social support systems Strength and duration of the patient-doctor relationship
Recommendations for provider communication with patient	Establish rapport by learning about a patient's history in advance Begin with neutral topics and open-ended questions Provide direct and honest rationales for decisions Express concern and empathy Make realistic recommendations and referrals Normalize potentially sensitive practices (e.g. urine drug testing) by referring to guidelines Acknowledge and encourage positive behaviors
Recommendations for reducing patient risk	Limit pill supplies Patient and family education Safe storage of medication Close follow-up and open communication with a care team Routine co-prescribing of naloxone

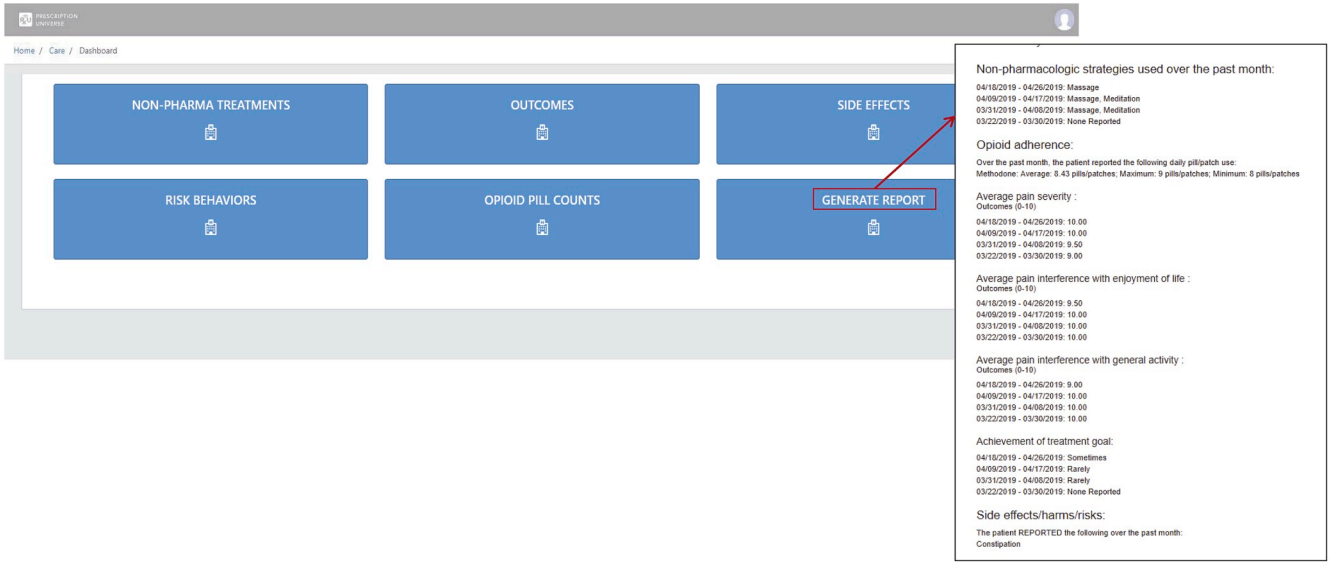

Fig. 3. Opioid Management App (OM-App) Provider Dashboard.

Step 4: Final modifications. Following the PD sessions, we modified the provider training to incorporate the recommendations of PWH, especially in the area of communication strategies. We then sought final feedback from a more specialized group of 12 providers (6 physicians and 1 physician's assistant working in HIV primary care, 1 substance abuse expert, 1 psychiatrist, 1 psychologist, and 2 pain management physicians) in one-on-one sessions in which the revised TOWER materials were presented. During these sessions we sought any additional IMB needs that the materials were not yet addressing. We discovered one additional informational need (the role of interventional pain treatments). Also in terms of motivation, providers reported that differences in opioid prescribing practices caused them to feel isolated from peers and that more uniform practices could create social normative support and thus motivation. We also found that the lack of evidence for the CDCG's ability to improve patient outcomes was an impediment to motivation for implementing them, but a positive motivation to participate in research to improve the evidence base. Finally, poor pre-existing behavioral skills in use of the EMR was a barrier to adopting new care processes including more intensive opioid management. We modified our training to address each of these issues. Fig. 4 summarizes all the patient and provider IMB needs identified during steps 1,3 and 4.

Step 5: Adaptive clinical trial. Upon completion of the intervention development process, we initiated a randomized, controlled, 9-month, exploratory, adaptive pilot clinical trial of the TOWER intervention. The intent of the trial is two-fold: 1) to allow the content of TOWER to evolve in response to feedback so that by the end of the trial it is optimized; and 2) to establish the best design for a future well-powered clinical trial to test the efficacy of TOWER.

The TOWER protocol. In the TOWER protocol (which is approved by the Institutional Review Board of the Icahn School of Medicine at Mount Sinai) 10 HIV PCPs are randomized to TOWER vs. control and assessed for CDCG adherence over time. Enrolled patients (N = 50) are PWH with chronic pain who are prescribed opioids by an enrolled provider, and are monitored over time for pain control, opioid misuse, and other outcomes.

Recruitment and inclusion criteria. Both PCPs and patients are recruited from our institution's network of primary care HIV clinics which together care for approximately 10,000 PWH. Inclusion criteria for the PCPs are: attending physician or advanced practice provider practicing in one of the participating clinics; the designated PCP for at least 5 patients to whom he/she prescribes opioids; and willing and able to adhere to study procedures including randomization and refraining from discussion of study procedures with other clinic staff or patients. Exclusion criteria for the PCPs are: unwillingness to undergo randomization; and plans to leave the clinic system within the study period. We work with the clinic medical directors and data analytic staff to identify the most appropriate PCPs, targeting higher volume PCPs since they are likely to have more eligible patients. PCPs are approached by a physician member of the research team and are provided a total of $750 for participation.

Inclusion criteria for patients are: HIV-infected adult (≥18 years old); currently prescribed ART (regardless of current CD4 count or viral load); at least 4 visits with the PCP over the past 12 months; chronic pain defined as pain present for ≥3 months, of any etiology (other than cancer-related pain); opioids prescribed by the PCP for the chronic pain condition; no treatment for HCV within the past 3 months; and opioid prescriptions are filled in New York State, or in another state whose prescription drug monitoring program is linked to the New York State Program. Exclusion criteria for patients are: medical or other condition that would preclude safe participation in the study (in the opinion of the study investigators or PCP); office visits with PCP conducted in a language other than English; undergoing active cancer treatment, palliative care, or end-of-life care; and lack of a mobile device which is compatible with the OM-App.

Enrollment procedures. All PCPs provide written informed consent and demographic and practice information, and complete the "Opioid Therapy Provider Survey" which measures attitudes toward opioid prescribing [34]. We also conduct a semi-structured interview regarding IMB needs relevant to opioid prescribing. The interview tool (see Appendix B) is based on instruments developed by Fisher et al. to ascertain the IMB needs of providers counseling PWH on safer sex behaviors [18,26,35]. PCPs are then provided with a list of all patients to whom they prescribe opioids and asked to identify any patients who they know would be ineligible or who they believe would find contact from the research team unwelcome; such patients are removed from the list. A waiver of informed consent was granted by our IRB for the generation of these lists. PCPs are then randomized to either the TOWER intervention or control; in order to ensure 5 PCPs in each group a modified block randomization technique is used (performed by the PI).

Following enrollment of the PCP, we contact patients from the list in

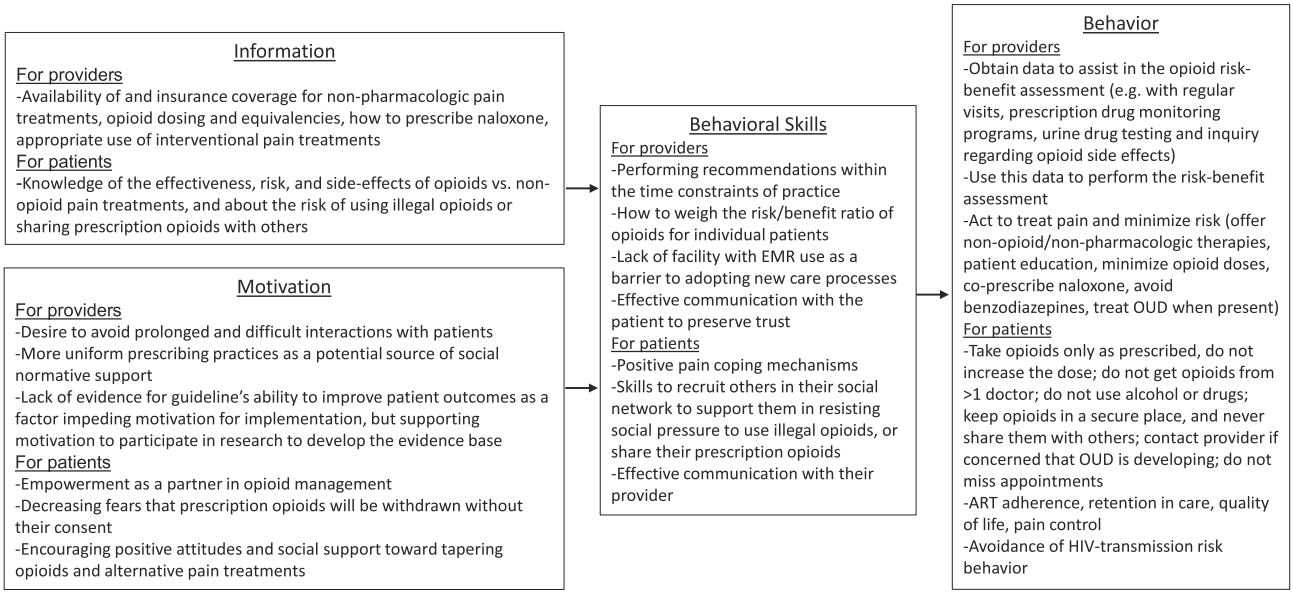

Fig. 4. Provider and patient IMB needs for guideline consistent prescription opioid management.

random order until we recruit approximately five; we also track the entire recruitment process (e.g. percentage of patients agreeing to participate etc.). The patient screening/baseline assessment visit begins with the informed consent process and assessment of eligibility criteria. We then obtain comprehensive and standardized demographic and medical history information via patient interview and EMR review. We verify prescribed opioids by accessing the New York State Prescription Monitoring Program (NYS-PMP), collect urine for detailed drug testing and administer the following validated instruments: World Mental Health Composite International Diagnostic Interview (CIDI) substance use disorders module [36]; the Quantitative Analgesic Questionnaire (QAQ) [37]; AIDS Clinical Trials Group (ACTG) antiretroviral adherence questionnaire [38]; Current Opioid Misuse Measure (COMM) [39]; Self-Reported Misuse, Abuse, and Diversion (SR-MAD) [40]; Brief Pain Inventory (BPI) [41,42]; Hospital Anxiety and Depression Scale (HADS) [43]; Trust in Provider Scale (TIPS) [44]; HIV Stigma Scale (HSS) [45]; Brief Perceived Ethnic Discrimination Questionnaire-Community Version (BPEDQ-CV) [46]; Internalized Stigma of Chronic Pain (ISCP) [47]; and selected questions from the Clinician & Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS) survey [48].

All patients (intervention and control) are then provided with the OM-App and trained in its use. Intervention patients are counseled that their provider will have access to all information they provide via OM-App; control patients are informed that the OM-App data will not be shared with their provider. We chose to provide the OM-App to control as well as intervention patients mainly in order to have a larger sample of usability data in this pilot phase, and also to determine whether reporting varied by group assignment. However the tradeoff is that the control is not truly "usual care," and therefore less similar to plans for future efficacy-oriented clinical trials in which controls would likely not receive the OP-App. Patients receive $50 for all in person visits with the research team. In addition, they receive $25 per month if they complete at least 80% of the OM-App questions.

Once enrollment of his/her patients is nearing completion, the intervention-PCP undergoes the TOWER training. This includes: content of the CDCG, use of the OM-App and OM-note, information on non-opioid and non-pharmacologic pain treatments, calculation of morphine equivalents, use of interventional pain management referrals, ordering and interpreting urine drug testing, prescribing naloxone, making referrals for opioid use disorder treatment, use of the prescription drug monitoring program, risk/benefit assessment, opioid tapering, patient responsibilities for opioid management, and communication strategies. The intervention providers are instructed to use what they learn during the training at their regularly scheduled appointments with their enrolled patients. The control providers receive no specific training and are instructed to follow their usual care practices.

Follow-up procedures. In addition to the screening/baseline visit and their clinic visits with their PCP, all patient-participants have assessment visits approximately 3, 6, and 9 months after enrollment. The 9-month visit is the official end-of-study visit; however, we continue to observe the patient passively through review of the EMR until approximately 12 months from enrollment. The 3, 6, and 9 month patient assessment visits follow the same procedure and include the same measures as the screening/baseline visit with the exception that the Patient Global Impression of Change (PGIC) is added [49]. This schedule of repetitive visits was chosen to help us to ascertain the ideal study length for a future clinical trial, focusing on issues of the time needed to capture an adequate number of patient-provider encounters and the ability of patients to remain engaged (e.g. with the OM-App) over the several month time frame.

Intervention fidelity and usual care. We assess PCPs throughout the course of the study for intervention fidelity and to understand any feasibility issues which may occur in the intervention group, and to understand more precisely what "usual care" consists of and if there might be a better alternative for the control group. We do this in four different ways. First, we audiotape and transcribe five clinic visits for each PCP (intervention and control). We stratify these observations so that for each PCP the observations are spread out over time, and each patient-participant is observed only once. Second, we access and review the EMR record for each visit between PCP and participant during the study period. Third, we contact patients after their clinic visits (typically by phone) to administer a post-clinic visit questionnaire to assess their experience of the visit and whether they recall the use of major intervention elements. This questionnaire was adapted from a similar instrument by Fisher et al. which was used to evaluate an intervention targeting safer sex in the HIV-care setting [18]. Finally, we ask all PCP-participants to complete an end-of-study visit, which consists of the "Opioid Therapy Provider Survey," [34] a brief survey seeking feedback regarding the intervention, and an audiotaped exit interview. These data are transcribed and qualitatively analyzed. In addition to these formal assessments, PCPs are encouraged to provide feedback and ask questions in real time throughout the study.

3. Results

An important design consideration that this pilot study is meant to address is the best choice of outcome measures for a future large clinical trial. Conceptually the intervention's proximate goal is to improve provider adherence to the CDCG, with the ultimate goal of improving outcomes for PWH prescribed opioids for chronic pain. There are currently no validated tools to measure provider adherence to any opioid prescribing guidelines including the CDCG. A commonly used outcome in prior studies is opioid dosage (in morphine mg equivalents). This has the benefit of being easily and reproducibly calculated but is a very limited reflection of the opioid management process that does not necessarily correlate with high quality care. For example, if opioids are abruptly discontinued without provision of alternatives or adequate support, the opioid dose would be lower, but the patient may be significantly worse off. Thus, following procedures similar to prior work developing new quality of care measures [50,51], we developed and are evaluating the Safer Opioid Prescribing Evaluation Tool (SOPET) as an outcome measure to capture CDCG adherence more holistically. The SOPET includes opioid dose as well as items such as: use of non-opioid pharmacologic and non-pharmacologic pain treatments, establishment of a treatment goal, discussion of patient responsibility for opioids, risk-benefit assessment, regular follow-up, use of prescription drug monitoring programs and urine drug testing, avoidance of benzodiazepines, prescription of naloxone and referral for opioid use disorder treatment when indicated.

Clinically relevant elements of a successful patient-focused outcome for PWH prescribed opioids for chronic pain would include avoidance of opioid misuse (including opioid use disorder and overdose) and maintenance of pain control and function. In addition, given that we are working in the HIV clinic, the primary goal of HIV care, i.e. maintenance of virologic control, must also be considered. We are measuring each of these outcomes individually with the Current Opioid Misuse Measure verified by urine drug testing (UDT), the Brief Pain Inventory, the ACTG antiretroviral adherence questionnaire, HIV viral load, and retention in care. We are also evaluating the suitability of a novel composite dichotomous outcome intended to reflect successful prescription opioid management; this includes: no opioid use disorder at the end-of-study visit (as assessed by the CIDI); no opioid overdoses during the study period; stable or improved pain control and function, defined as no clinically significant worsening (<30%) in the BPI (comparing baseline to end-of-study visits); and undetectable HIV-1 viral load at the end-of-study visit.

4. Discussion

There is an urgent unmet need for a standardized, effective, evidence-based approach to prescription opioid management, especially

for potentially vulnerable patient populations such as PWH who have already been prescribed opioids long term for chronic pain, the so-called legacy patients. Although definitive data are lacking, reports are emerging that suggest that legacy patients may be at high risk for poor outcomes as providers seek to curtail the amount of opioids they prescribe [52–54]. Such negative outcomes reported in individual patients and larger studies have included discontinuation of care, transition to illegal opioid use and an associated increase in opioid overdose risk, and even death [52–54]. In turn, our qualitative data confirm that many providers experience prescription opioid management as an unpleasant and challenging task, in which they must balance real or perceived external pressure to reduce opioid prescribing, with the desire to avoid conflict with patients and provide the best care in the setting of genuine uncertainty.

The TOWER intervention to improve adherence to the CDCG was developed using an iterative process of input from providers and PWH, drawing from the IMB model as a theoretical framework. TOWER includes material to help providers address chronic pain including data from the OM-App on changes in pain levels, and information in the provider training to help them address this at their visits. The process of TOWER development and testing has reached the stage of an ongoing adaptive, feasibility clinical trial in which the TOWER intervention is being optimized, and the key design features of a future large clinical trial, designed to demonstrate TOWER's efficacy, are being established. The TOWER intervention is unique in that it takes a collaborative, provider- and patient-informed approach to decreasing opioid risk while fostering positive patient pain- and HIV-related secondary outcomes (e.g., pain control, ART adherence, retention in care); it is also theory based, relying on the well-tested IMB model of heath behavior change [55]. We believe that this is a critical way to proceed at this juncture in order to maximize positive outcomes and minimize any potential for negative effects. Future research in the form of a well-powered randomized controlled trial will be needed to ascertain the ability of TOWER to improve outcomes in PWH who are prescribed opioids for chronic pain.

Sources of support

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2019.100468.

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