Virtual Pain Care for High Risk Veterans on Opioids During COVID19 (and Beyond)

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1. Background

As the Veterans Health Administration (VHA) responds to the COVID-19 pandemic, it must also continue to respond to another devastating public health crisis. The opioid overdose crisis disproportionally affects Veterans[1] and kills 130 Americans per day.[2] The COVID-19 pandemic is exacerbating the challenges faced by Veterans at risk for opioid overdose, including Veterans prescribed moderate-to-high dose long-term opioid therapy (LTOT), whose usual treatment resources and coping strategies may be inaccessible. For this group, the VHA's clinical practice guidelines recommend a Veteran-centered, team-based approach that includes (1) regular, individualized assessment of benefits and harms of LTOT; (2) reduction and discontinuation of LTOT when benefits no longer outweigh harms; (3) switch to buprenorphine (BUP) if opioid dependence with difficulty tapering or opioid use disorder (OUD) emerge; and (4) optimization of non-pharmacologic and non-opioid pain treatment.[3,4] Opioid prescribers' duties and attention are shifted to COVID-related care, and many non-pharmacologic treatments such as exercise are difficult to access or unavailable, putting this vulnerable group is at disproportionately high risk. This substandard care could lead to worsened symptoms, treatment disengagement and even death, especially if indicated switches to BUP are delayed. The VHA must pivot quickly to deploy and evaluate virtual models of care for Veterans on high-risk LTOT that meet the dual challenges of maintaining social distancing and high quality of care.

Through VHA-funded research and quality improvement (QI) work, our team has developed novel clinical approaches well-suited to meet these challenges: opioid reassessment and opioid tapering,[5-8] BUP switch and maintenance,[9,10] and behavioral pain and OUD self-management,[11,12] with recent iterations using virtual delivery. Our overarching goal is to test the feasibility of combining these components into a single intervention --Video-Telecare Collaborative Pain Management (VCPM)--uniquely designed to address the need of a highly vulnerable group of veterans on LTOT during this time of heightened risk. VCPM's core is a Clinical Pharmacy Specialist (CPS) supported by a collaborating physician, both trained to full competency in opioid reassessment, opioid taper or switch to BUP as indicated, and promotion of evidence-based non-pharmacological pain management. Behavioral pain self-management in VCPM will be delivered via coordinated referral to local health psychology which is currently delivered via VCC at both sites. Opioid tapering and pain management support is bolstered using SUMMIT, a web-based app recently completed as part of IIR 17-228 (Becker, PI).

2. Specific Aims and Approach

In preparation for a larger randomized implementation/effectiveness study, specific aims are as follows: **AIM 1** – Examine the feasibility and acceptability of VCPM among 60 Veterans on risky LTOT using a quality improvement framework; **AIM 2** – Develop decision aids for ascertaining patient preference for communication and care delivery and examine feasibility of virtual outcome assessment as part of clinical care.

Study setting: This single-arm feasibility study will be conducted in two VA sites: The Chronic Pain and Wellness Center in VA Eastern Colorado and the Opioid Reassessment Clinic in VA Connecticut.

Study sample: Eligible participants must currently receive LTOT for chronic pain at ≥ 50 mg morphine equivalent daily dose. Exclusion criteria at baseline are: dementia diagnosis or moderate-severe cognitive impairment; unstable or severe untreated psychiatric disorder or medical disease that requires hospitalization; documentation of suspected controlled substance diversion; or inability to communicate by phone.

Enrollment: As the intervention components are not experimental and outcome assessment will not exceed clinical standards, this study will be QI. Informed consent will be sought in the usual clinical context of switching to BUP, if indicated. We will identify eligible patients in two ways: 1) Patients referred to either multidisciplinary pain program; and 2) direct outreach to patients identified by dose threshold on the opioid therapy risk report whose opioid prescribers assent to outreach. There are a sufficient number of eligible participants: In FY 19, The Chronic Pain and Wellness Center and the Opioid Reassessment Clinic received ~52 referrals/month and ~16 referrals/month, respectively. Enrollment starts once contact is made with the Veteran after receipt of referral or direct outreach. We anticipate 25% drop-off from enrollment to intake appointment; as below, we will seek acceptability data from Veterans who decline/do not attend the intake visit.

Intervention: VCPM is a multi-component intervention consisting of already-established care processes and materials. First, the patient is mailed or emailed (based on their preference) an informational packet prior to intake appointment. Second, using the collaborative medication management model established in VHA,[13] the intake appointment is led by the CPS using a standardized intake evaluation. The CPS and physician design a plan presented to the patient. If BUP switch is offered and accepted, the physician completes additional brief evaluations, including a history, medication review, treatment planning, and discussion of other VCPM components, using two-way audio-video visits (with telephone as a back-up). Participants complete follow-up

phone visits on days 4, 7 and 14 and at 1, 2, 3 months. At all patient preference decision points (opioid taper vs. BUP switch; therapist-delivered CBT pain management vs. SUMMIT – or both or neither) we will convert already-developed paper decision aids and materials into email-able PDFs and video testimonials. The patient's preference of modality for information receipt (web, email, regular mail) and communication (video vs. telephone) will guide all decisions; we will iteratively refine brief tools for ascertaining these preferences. Patients remain in the active intervention for 90 days.

Development of BUP-specific materials to improve patient initiation and engagement: With veteran input throughout, Moving Pictures, Inc—our prior collaborator in development of our SUMMIT app,—we will follow the same successful methods to create patient centered video testimonials of successful patients who have transferred to BUP.[9] These video testimonials are an important component of Aim 2, by expanding traditional communication methods with patients (e.g., health care professional discussion, brochures, etc.)

2. Research Team and Relevant Experience

The multidisciplinary team has a strong track record of successful collaboration.

- Brent Moore, PhD (Multiple PI; 6/8ths) is a Research Psychologist at VA Connecticut and expert in developing ehealth substance use disorder and pain interventions.[7,12,14,15]
- William C. Becker, MD (Multiple PI; 8/8ths) is a General Internist and core investigator at VA Connecticut's PRIME COIN, Director of the Opioid Reassessment Clinic at the VA Connecticut and expert in pain and opioid QI, pragmatic trials and implementation.[5,6,9,16-20]
- Audrey Abelleira, PharmD, (co-Investigator; 8/8ths) is a Clinical Pharmacy Specialist at VA Connecticut and expert in clinical care for chronic pain.
- Beth DeRonne, PharmD, (Co-Investigator; 8/8ths) is a Clinical Pharmacy Specialist at the Minneapolis VAMC and expert in chronic pain and multidisciplinary team collaboration for clinical interventions.
- Sara Edmond, PhD (Co-Investigator; 8/8th) is a Research Psychologist at VA Connecticut and expert in delivery and adaptation of behavioral pain self-management.[7,15,19]
- Joseph W. Frank, MD, MPH (Co-Investigator; 8/8th). is a General Internist, health services researcher and Chief of the Pain Medicine Section at VA Eastern Colorado, and expert in chronic pain and OUD .[8,9,21]
- Allison Schroeder, PharmD (Co-Investigator, 8/8ths) is a CPS in chronic pain management at VA Eastern Colorado (8/8ths).

Our team currently collaborates on three projects that are highly relevant to the proposed work: a QUERI-funded implementation study of a pharmacist-led clinical intervention to support opioid tapering and increased use of non-pharmacologic treatments,[16,22] a QUERI-funded implementation study of facilitation strategies to improve OUD treatment, and a PCORI-funded comparative effectiveness trial of team-based pain care, including a sub-study of BUP. Additionally, both research teams will be supported by an HSR&D Center of Innovation: The Center for Veteran-Centered & Value-Driven Care in Colorado, and the Pain Research, Informatics, Multimorbidities and Education Center in Connecticut. The proposed research staff are already employed within these Centers. Both Centers will provide analytic resources including access to a large group of qualitative and quantitative methodologists, dissemination and implementation scientists.

3. Data Sources

Administrative Data: VA datasets within the VA Informatics and Computing Infrastructure (VINCI) will be used to access patient data, covariates, and administrative outcomes. Patient demographics and physical and mental health diagnoses will be collected from inpatient and outpatient domains. Also, we will collect opioid dose, prescriptions and drug dispensing from outpatient pharmacy domains, and pain treatment variables from outpatient and lab chemistry data; outpatient pharmacy data; and outpatient procedure codes.

Acceptability/Feasibility: We will measure the feasibility and acceptability of the intervention overall, as well as each component; opioid reassessment, BUP transition and maintenance and behavioral pain self-management. Overall, we will examine the number of 1) referrals, 2) enrollment, 3) retention, and 4) data collection at baseline and 1 and 3 months. Feasibility and acceptability of opioid reassessment and buprenorphine switch and maintenance will be based on the total number offered BUP. Although the project will use shared decision-making with Veterans, the percent of patients who agree to transfer will provide a realistic indicator of overall feasibility/acceptability. Additional measures include engagement (percent who complete tapering or BUP transition) and retention (percent maintaining prescription at 1 month). Feasibility and acceptability of the behavioral self-management system will be drawn from administrative data of CBT for pain management health psychology visits and use data of SUMMIT. Patient and administrative system access is password-protected and encrypted. Feasibility and acceptability of virtual delivery will be measured as the

percent of attended sessions of schedule sessions. Patient satisfaction for each component will use Likert scale ratings. Patients who do not engage will be contacted for brief surveys.

Patient-reported outcome (PRO) data: Most PRO data will come from health factor data fields in already-developed CPS intake and follow-up notes. Assessment of opioid withdrawal will use the Subjective Opiate Withdrawal Scale at baseline, days 4 and 7, and 1 month. We will explore feasibility of using ANNIE, a text-based VHA app, for real time clinical surveillance of patient stability. We will determine the number of 4 timepoints in week 1 on which a participant reports at least moderate opioid withdrawal symptom severity. We will assess pain severity using the 3-item PEG Scale at baseline and 1 month. Brief measures of patient satisfaction using a brief/modified version of the Questionnaire on the Quality of Patient-Physician Interaction will be collected by research assistants by phone from all enrolled participants.

Data Analysis: Feasibility and acceptability measures will be evaluated based on descriptive statistics of central tendency and distribution. Feasibility and acceptability of VCPM will be based on *a priori* criteria of primary outcomes, which will determine whether a full-scale trial of VCPM is warranted, substantial modification (removing or replacing components) is required, or further evaluation should be terminated. A trial would not be warranted if feasibility or acceptability were low, as indicated by one of the following, 1) a majority of patients (>50%) not agreeing to recommended BUP transition, 2) Low overall treatment satisfaction (>50% negative satisfaction), or 3) Low treatment attendance (<50% sessions attended). Components should be dropped or modified (e.g., the buprenorphine specific modules) if the majority of patients (>50%) do not use them or report negative satisfaction. Preliminary efficacy evaluation of secondary outcomes will be evaluated pre-post or longitudinal analyses using ANOVA or Linear Mixed Models (LMM) for continuous measures to address missing data, and chi-square or General Estimating Equations for categorical outcomes.

4. Management Plan

The intervention will be delivered in two VA clinical sites: The Chronic Pain and Wellness Center in VA Eastern Colorado and the Opioid Reassessment Clinic in VA Connecticut. Both clinical sites are well-suited to execute the proposed project due to their existing multidisciplinary programs, participation in an ongoing PCORI-funded comparative effectiveness trial of team-based pain care and completion of the proposed BUP initiation method with multiple patients at both sites. Drs. Moore and Becker will be responsible for overseeing the study. The study team will conduct weekly cross-site study meetings by videoconference, which will include discussion of any anticipated or recent changes to the study protocol and procedures as well as a Community of Practice discussion of clinical care. Non-clinician members of the research team are working remotely, but have full access to VA computing resources, including statistical analysis programs (SAS, Atlas.ti, Microsoft Word and Excel). Printers, fax, copy machines, and office supplies, are available at the COIN offices, if needed.

5. Timeline

We have completed ClinicalTrials.gov registration. We will finalize the decision aids and develop the video testimonials in the first 4 weeks and will begin enrollment immediately after. We expect to enroll 12 patients/month for 5 months. We will conduct data analysis and submit the initial manuscript in Q3.

	Q1			Q2			Q3		
Implementation Plan									
Finalize decision aids and video testimonials									
Enrollment									
Data collection									
Analysis, manuscript submission									
Future Funding									
QUERI/HSR&D proposal submission									

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