Study Protocol
Adapting and Implementing the Blended Collaborative Care Model in CBOCs

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Background:

Integrated Care - Our analyses indicate that 40% of all VHA enrollees were diagnosed with a MH disorder in FY11. The integration of MH treatments into PC settings is an evidence-based approach to managing common depression and anxiety disorders.[1,2] True integrated care is based on the biopsychosocial model of illness in which both physical *and* mental illnesses are seen as the result of biological, psychological and social influences. With VHA's adoption of Patient Aligned Care Teams (PACT), the PC setting represents a health home, where all aspects of health care are delivered in a continuous, coordinated and patient-centered manner. Integration increases: 1) temporal access to MH care by making it available during PC encounters, 2) geographic access to MH care by making it available on-site in the PC clinic, and 3) cultural access to MH care by making it available in the less stigmatizing PC setting. In VA clinics where PC MH integration (PC-MHI) was deployed in FY07 and FY08, the detection, diagnosis and treatment of depression, anxiety, post-traumatic stress and substance use disorders increased significantly more than in clinics were PC-MHI was not deployed.[3] Because of the greater geographic and cultural barriers to MH treatment in rural areas, the benefits of PC-MHI are even greater for the 41%[4] of VHA enrollees who live in rural or highly rural areas. In fact, Veterans treated in CBOCs have significantly fewer MH encounters than Veterans treated at VA Medical Centers.[5] Veterans treated in the smaller contract CBOCs have even fewer MH encounters than Veterans treated in VA staffed (i.e., owned and operated) CBOCs.[6] Lack of engagement in MH care among rural Veterans may contribute to the higher MH severity levels[7-9] and suicide rates[10] observed among rural compared to urban VHA enrollees. Therefore, PC-MHI is critical to the well being of rural Veterans.

Integrating MH care into PC settings is a major priority of the OMHS.[11] The *Uniform Mental Health Services Handbook* mandates the blending of the two predominant, evidence-based models of integrated care (the Care Management model and the Co-Located model) at VAMCs, very large CBOCs, (>10,000 uniques) and large CBOCs (5,000-10,000 uniques).[12] Because there is no scientific evidence to support its implementation, the Blended model is not mandated at medium CBOCs (1,500-5,000 uniques) or small CBOCs (<1,500 uniques). Based on numerous experiences facilitating the deployment of integrated care models in CBOCs, our PC-MHI and VISN 16 Mental Health Product Line (MHPL) partners report that implementation of integrated care models is extremely challenging for CBOCs that lack a full range of MH staff (which also include many large CBOCs as well). These challenges are highlighted by findings of several preliminary studies described in the original grant application.

Briefly, we found that, while CBOCs are very important to the VHA healthcare system (half of primary care users receive care in CBOCs), the implementation of PC-MHI is lagging in these settings. While 6.2% of the PC encounters at VAMCs were PC-MHI encounters, only 2.9% of the PC encounters at CBOCs were PC-MHI encounters. Small and medium sized CBOCs had an even lower proportion of PC-MHI encounters. We have also shown that the co-located referral model, in which traditional "silo" MH services are physically co-located in a PC clinic, produces clinical outcomes that are inferior to outcomes of patients receiving enhanced referral to off-site mental health specialty care. Further, Dr. Fortney (Co-I) and colleagues found that usual MH care (i.e., Co-Located Referral Model) results in sub-optimal outcomes for rural Veterans treated in small and medium CBOCs. However, a Care Management Model, developed by depression researchers based on the chronic care model,[13,14] and specifically tailored by Drs. Fortney and Pyne for CBOCs that lack on-site psychiatrists and PhD psychologists, found significant improvements in adherence to medication, treatment response, and remission of depression for patients assigned to the care management condition as compared with those in usual care.[15,16]

Preliminary Studies: Drs. Fortney and Pyne, in collaboration with the Medical Directors of

VISN 16 (Dr. Enderle) and VISN 22 (Dr. McDougall), conducted a HSR&D QUERI-funded study (IMV 04-360) to test the Evidence Based Quality Improvement (EBQI) implementation strategy, similar to the one proposed in this application. This non-randomized implementation trial of EBQI was conducted at 11 CBOCs (associated with 3 VAMCs) lacking psychiatrists and PhD psychologists. The Plan phase of the EBQI process involved the localized tailoring and adaptation of the Telemedicine Based Care Management model to each VAMC and their affiliated CBOCs. Researchers ensured that the adaptations were evidence based. Clinical and administrative staff were responsible for adapting the care management model for local needs, priorities, preferences and resources. Planning was based on the *Steps and Decisions Guide for Implementing Depression Care Management Models* which was developed specifically for the study.[17] Depression care managers were trained using the *VA Mental Health QUERI Depression Care Manager Training Manual* which was specifically developed for the study. In addition, a web-based decision support system (NetDSS - Net Decision Support System), and a *NetDSS User's Guide* were specifically developed for the study to promote care manager fidelity.[18] Do-Study-Act cycles were used to refine the program over time. Outcomes were based on the RE-AIM Framework (described later in the Research Design and Methods section) and used data from multiple sources: administrative records, web-based decision support system, surveys and key-informant interviews.[19] Adoption*:* 69.0% (58/84) of PCPs referred patients to Telemedicine Based Care Management. Reach*:* 9.0% (298/3,296) of PC patients diagnosed with depression who were not already receiving specialty MH care were enrolled in the program. Fidelity*:* During baseline care manager encounters, education/activation was provided to 100% (298/298) of patients, barriers were assessed and addressed for 100% (298/298) of patients and depression severity was monitored for 100% (298/298) of patients. During follow-up, symptoms were monitored using the PHQ9 at 100% of encounters, medication adherence was assessed at 99.1% of encounters and side effects were assessed at 92.4% of encounters. Clinical Effectiveness*:* 40.9% (122/298) of patients had positive outcomes, including 18.8% (56/298) who remitted and another 22.1% (66/298) who responded. Maintenance*:* 91.9% (10/11) of the CBOCs chose to sustain the program after research funds were withdrawn. Despite the organizational barriers to implementation at smaller contract CBOCs, EBQI was found to be an effective facilitation strategy for disseminating Telemedicine Based Care Management.

Finally, collaborator Dr. Andrew Pomerantz has studied the Co-Located Collaborative Care Model, in which MH providers are *embedded* in the PC team,[20,21] and there is *true integration* of the biological and psychosocial care models. In contrast to the disease-specific Care Management model, the Co-Located Collaborative Care model addresses a wide array of MH disorders commonly seen in PC, as well as behavioral factors that negatively impact chronic medical conditions (e.g., smoking, medication non-adherence). Co-located MHPs include both prescribers such as a psychiatrist or advanced practice nurse (APN) and therapists such as PhD psychologists. These MHPs see patients *in conjunction* with PCPs and provide "curb side" consultation to PCPs in real time, which allows for the recognition and treatment of biological, psychological and social determinants of illness during *a single encounter*. The MHPs staff an open access clinic and PCPs conduct warm handoffs to MHPs in real time, virtually eliminating no shows (a chronic problem with the referral model). The Co-Located Collaborative Care Model was developed independently at Cherokee Health Systems (a Federally Qualified Health Center in Tennessee) and the White River Junction VAMC (which earned it the American Psychiatric Association's *Gold Achievement Award* and the Secretary of VA's *Advanced Clinical Access National Champion Award*). The Co-Located Collaborative Care Model was developed by providers rather than researchers, and rigorous scientific evidence is lacking regarding its impact on clinical outcomes because of the difficulties associated with randomizing patients (discussed in detail in the Research Design and Methods section). One non-experimental study

in the VA demonstrated that patients completing a Co-Located Collaborative Care protocol had greater improvements in depression severity than non-completers.[22] Other non-VA quasi-experimental pre-post studies have found that it improves patient access to MH care by decreasing wait times and no-show rates,[23-26] and increases patient functioning.[27,28] Another non-VA study found high rates of patient and provider satisfaction.[29] However, none of these studies had a control group and there was no random assignment to treatment conditions, making the findings difficult to interpret. The Co-Located Collaborative Care Model has been deployed into routine care by VHA, Kaiser Permanente, the United States Air Force, and Federally Qualified Health Centers. Also, Dr. Pomerantz has conducted several pre-post studies evaluating the Co-Located Collaborative Care model at the White River Junction VAMC.[23,24,27,28] Patients received care based on the traditional Referral model in the pre-period and based on Co-Located Collaborative Care in the post period. In one study, patients screening positive for depression (n=670) were followed retrospectively. The Co-Located Collaborative Care model was associated with a greater proportion of patients who had screened positive being treated for depression (52.3% vs. 37.8%; p<0.001), and received guideline concordant depression treatment (11% vs. 1%; p<0.001). In addition, the reallocation of MH staff from the specialty MH clinic to the Co-Located Collaborative Care clinic resulted in more patients with a positive screen seeing a MHP (36.0% vs. 9.0%, p<0.001). Another pre-post study evaluated the Co-Located Collaborative Care model implemented at both the White River Junction VAMC and its affiliated CBOCs.[24] Results at the White River Junction VAMC were similarly positive, but outcomes did not improve significantly at the CBOCs. This last finding suggests that the Co-Located Collaborative Care model needs to be adapted for smaller CBOCs.

Blended Model of Integrated Care: In their roles as the National MH Director, Integrated Services, and National Primary Care Director for PC-MHI, Drs. Pomerantz and Post recently developed the Blended Model of integrated care, which includes clinical activities associated with both Care Management and Co-Located Collaborative Care. The Blended model was designed to be staffed by on-site PhD level psychologists, psychiatrists (or APN) and nurse care managers. Like the Co-Located Collaborative Care model, the psychologists and psychiatrists staff an open access clinic facilitated by warm handoffs from PCPs. All patients (regardless of diagnoses) referred to the co-located MHPs receive at least one telephone call from the care manager to follow-up with progress towards the treatment plan and the co-located MHPs can choose to involve the care manager for longer depending on the patient's need. PCPs can also choose to refer the patient (regardless of diagnosis) to the care manager directly, bypassing the co-located MHPs (e.g., to monitor antidepressant adherence). Thus, the Blended model addresses a wide array of disorders and behavioral problems commonly seen in PC settings. Drs. Pomerantz and Post have facilitated the implementation of the Blended Model at VAMCs nationwide. However, because there is no scientific evidence documenting that the Blended model is clinically effective in CBOCs lacking on-site psychiatrists and PhD psychologists, PC-MHI does not currently mandate that the Blended model be delivered in smaller CBOCs that serve rural Veterans.

Integrated Care for Veterans with Infectious Diseases: Hepatitis C Virus (HCV) afflicts approximately 5% or 1,100,000 Veterans [30]; one quarter of HCV+ are also living with HIV. [31,32] Comorbid mental health problems also disproportionately affect HCV+ and HIV+ individuals.[33,34]. Further, HCV, HIV, and their associated conditions (e.g., cirrhosis, depression, early mortality) are more prevalent among racial minority Veterans than white Veterans.[35] There are evidenced-based treatments for HIV, HCV, and comorbid depression, including Care Management; however, because of limited treatment rates, there appear to be several barriers to care that need to be explored and addressed in future interventions.

HCV Treatment. New antiviral treatments available in VA can essentially cure HCV. VA continues to fund HCV treatment, including $500 million last year.[36] Less than 30% of HCV+ Veterans have received treatment. [37] In a non-systematic literature review, researchers identified barriers to HCV treatment among Veterans and non-Veterans within the health care system (e.g., insufficient funding), patients (e.g., adherence), providers (e.g., referral behavior), and clinical encounters (e.g., communication issues).[37] However, no data exist exclusively from Veterans on treatment experiences and barriers or facilitators, especially since the new HCV treatment emerged.

HIV & Depression Treatment. One treatment program exists to improve a condition associated with HIV—depression—and it can improve viral load and reduce depressive symptoms among Veterans [38] and is also cost-effective in VA.[39] Briefly, the HIV/depression treatment is Care Management for depression in HIV clinics. This model of depression care is preferred by HIV+ Veterans. [40] However, barriers exist at multiple levels for HIV/depression treatment in VA, [40] include geographic access to care for rural-dwelling Veterans. [41] There are implementation data of HIV/depression treatment from eight Veterans[42] and more are needed to reach saturation of themes, especially among vulnerable Veterans.

Exploratory research is needed on racial minority and rural-dwelling populations to identify treatment preferences, barriers, and facilitators to using Care Management and other evidence-based treatments in VA for Hepatitis C, HIV, and comorbid mental health problems.

Known and Potential Risks and Benefits, if any, to Human Participants:

This minimal risk study will consist of participants completing questionnaires about their health care, health status, mental health symptoms, comorbidities and other outcomes, and also of providers, clinical managers and other staff discussing care processes and intervention components. The study will examine the effect of care models that have been endorsed and implemented throughout the VA as compared with usual care in CBOCs. Possible risks for participants are tiredness and boredom; however, the research staff are skilled in conducting assessments and will take all precautions to ensure that any distress is minimized. Loss of confidentiality is also a possible risk; however all information will be treated as confidential and safeguarded in accordance with the Privacy Act of 1974.

Veterans may benefit from knowing that their participation may be useful to VHA leaders who are seeking to improve mental healthcare and infectious disease care for patients receiving care in CBOCs; however, study participation in itself will not likely result in any direct benefit to participants.

Population to be Studied:

Human Subjects Involvement and Characteristics

Veteran Participants: For the Specific Aim 2 Formative Evaluation of the initial implementation at the 6 sites, which will assess adaptation of the Blended model to the CBOC setting during the implementation phase at each site, approximately 24 Veteran patients will be enrolled to participate in qualitative interviews. For the Specific Aim 2 Effectiveness test, we propose to enroll approximately 750 Veterans who screen positive on routinely administered VA MH screens (e.g., depression, alcohol, PTSD) at the 6 study CBOCs, for 18 months beginning at the first implementation period and continuing until the last two sites have completed the implementation phase (see methods section). Only those patients receiving specialty MH treatment in the 6 months prior to recruitment; those with a diagnosis of substance dependence; and those with a psychotic disorder diagnosis (schizophrenia, bipolar disorder, other psychotic disorders) will be excluded. Patients who consent to participate will participate in an initial assessment of health status by telephone and a follow-up telephone assessment six months later.

For the exploratory third aim at the CBOCs, up to 40 total Veterans will be enrolled to participate in qualitative interviews about their HCV or HIV/mental health treatment experiences and preferences. Two subsets of Veterans will comprise the total sample for this aim:

1. 20 Veterans diagnosed with HCV.
2. 20 Veterans diagnosed with HIV and screen positive on a depression screen.

Provider Participants: For post-implementation interviews (Specific Aim 2 Formative Evaluation), the CBOC director, site champion, and any other relevant staff they recommend to us at each of the 6 study CBOCs will be recruited to participate in qualitative interviews. The telehealth MHPs involved in the study will also be interviewed.

Inclusion of Non-Veteran Participants: All patient participants will be Veterans. Because some of the provider and manager participants will not be Veterans, the study will request approval to recruit non-Veterans.

Sources of Materials

Study data will be collected through qualitative interviews; interviewer administered self-report questionnaires and rating scales; and extraction of Corporate Data Warehouse (CDW) data for the study sites (6 CBOCs and the 3 parent VAMCs) through the VA Informatics and Computing Infrastructure (VINCI). Information obtained from the CDW will be used to identify potential participants for the Effectiveness Trial. This information will be will be collected specifically for research purposes. We will also seek access to local CPRS systems at the study sites, or access to CPRS information at the sites that is available in the Compensation and Pensions Records Interface (CAPRI).

Statement of Compliance:

This study will be conducted in compliance with the protocol, good clinical practice, VA and CAVHS HRPP requirements, as well as other applicable regulatory requirements.

Purpose and Specific Aims:

Providing mental health (MH) care to rural Veterans in Community Based Outpatient Clinics (CBOCs) is a major priority of the Office of Rural Health (ORH). Likewise, integrating MH into Primary Care (PC) is one of the highest priorities of Mental Health Services (MHS) and the Office of Mental Health Operations (OMHO). However, at most smaller CBOCs serving rural Veterans, on-site mid-level MH providers (MHPs) and/or off-site tele-psychiatrists and tele-psychologists deliver traditional referral-based specialty treatment (Referral model) rather than integrated care. This often results in long wait times and little collaboration between MHPs and PC providers (PCPs). For VAMCs and larger CBOCs, the Primary Care Mental Health Integration (PC-MHI) initiative mandates the implementation of the Blended model of integrated care, which requires implementing both of the predominant models of integrated care: 1) Care Management model and 2) Co-Located Collaborative Care model. The cornerstone of the Care Management model is a care manager (e.g., nurse supervised by a psychiatrist) who proactively conducts structured outreach encounters with patients between visits to their PCP. There is rigorous scientific evidence from randomized trials that the Care Management model is effective in facilities with a full range of on-site MH staff. Dr. Fortney conducted a randomized trial demonstrating that the Care Management model can be successfully adapted using telemedicine technologies (Telemedicine Based Care Management model) for patients treated for depression at CBOCs lacking on-site psychiatrists and PhD psychologists.[15]The cornerstone of the Co-Located Collaborative Care model is an open access clinic staffed by behavioral specialists (e.g., PhD psychologist, psychiatrist) who work side-by-side with PCPs. There is evidence from quasi-experimental studies conducted by Dr. Andrew Pomerantz of Mental

Health Services that the Co-located Collaborative Care model is effective for facilities with a full spectrum of on-site MH staff.[23,24] However, there is no evidence that the Blended model of integrated care is effective in smaller CBOCs that lack on-site psychiatrists and PhD psychologists. As a result, PC-MHI does not mandate that the Blended model be implemented in small and medium size CBOCs, where many rural Veterans receive care. This project contributes to Specific Aim 3 (*Test clinical interventions to improve quality and outcomes of MH care at CBOCs)* of the Little Rock CREATE (see Appendices 1 and 2) by filling critical gaps in the scientific evidence base about integrating MH into PC in smaller CBOCs.

The goal of this proposed Hybrid Type 2[43] pragmatic effectiveness-implementation trial is to generate the scientific evidence needed to justify the national dissemination of the Blended model adapted to accommodate the clinical context of smaller CBOCs and to test the feasibility of using facilitation and the Evidence Based Quality Improvement (EBQI) implementation strategy to deploy the Blended model in smaller CBOCs. Building on Dr. Fortney's (co-I) experience developing and implementing the Telemedicine Based Care Management model[15] and Dr. Pomerantz's experience developing and implementing the Co-Located Collaborative Care model, we propose to blend these models and adapt them for CBOCs lacking on-site psychiatrists and psychologists by using telemedicine technology. The resulting Telemedicine Blended model will be compared to the Referral model in a pragmatic trial, where the intervention will be delivered by clinical staff available in routine care settings and fidelity will be monitored but not controlled. Similar to our previous implementation science projects, some of this project's activities involve implementation of standard, evidence-based care models. We consider the related implementation activities to involve standard clinical and administrative efforts, integral to, but separate from the research activities described in this application.

Specific Aim 1 (Quality Improvement/Implementation Aim): Use an expert panel comprised of clinical providers and managers who are applying telemedicine to provide a Blended model for CBOCs lacking on-site PhD psychologists and psychiatrists to document the core components of a Telemedicine Blended model and using a facilitated PDSA process, implement this model in six CBOCs.

Specific Aim 2 (Research Aim): Conduct a Hybrid Type 2 pragmatic effectiveness-implementation trial of the adapted Telemedicine Blended model by assessing **RE-AIM** outcomes including: provider **R**each into the patient population, **E**ffectiveness at improving clinical outcomes, **A**doption by providers and **I**mplementation fidelity.

> *Hypothesis 1 (Reach): Compared to Veterans who receive the Referral model, a higher proportion of Veterans who receive the Telemedicine Blended model will have a MH encounter over a 6 month period.*
>
> *Hypothesis 2 (Effectiveness): Compared to Veterans who receive the Referral model, Veterans who receive the Telemedicine Blended model will have better clinical outcomes at the 6 month follow-up.*

Specific Aim 3 (Exploratory Aim): In this exploratory study, we will conduct qualitative interviews to identify up to 40 Veterans' perception of factors associated with implementation of VA-approved treatments for HCV, HIV, and mental health treatment among Veterans with documented health disparities of HCV and HIV (i.e., racial minority Veterans). Specifically, we aim to:

a. Identify Veterans' experiences and preferences for HCV and/or HIV and mental health treatment.
b. Identify barriers and facilitators to accessing HCV and/or HIV and mental health treatment.

Because there is a lack of scientific evidence documenting that the Blended model is effective in smaller CBOCs, PC-MHI does not currently mandate that it be delivered in these facilities. If the proposed study is successful, our clinical partners, Dr. Pomerantz (MHS), Dr. Post (PC-MHI) will use the results to justify implementation of the Telemedicine Blended model. Further, we can harness information gained in our exploratory aim to begin developing implementation strategies to better treat racial minority Veterans with HCV and/or HIV and depression, possibly through Care Management.

Study Design:

The overall objective of this proposed Hybrid Type 2 pragmatic effectiveness-implementation study is to generate the scientific evidence (clinical effectiveness and other implementation outcomes) needed to justify the national dissemination of the Blended model in smaller CBOCs lacking on-site psychiatrists and PhD psychologists and to test facilitation and EBQI as an implementation strategy in CBOCs. A hybrid study design has dual aims of assessing clinical effectiveness and implementation success. A Type 2 hybrid design simultaneously tests a clinical intervention and an implementation strategy.[43] Hybrid effectiveness-implementation studies should increase the efficiency of translating research into practice compared to the more traditional approach of first conducting an effectiveness trial and then conducting an implementation trial. The proposed research will contribute to the development and refinement of this newly emerging translational science methodology. The proposed study design also employs many core elements of pragmatic comparative effectiveness trials including: 1) comparing the intervention to a commonly used active treatment, 2) applying relative few exclusion criteria, 3) enrolling a diverse set of patients, 4) delivering the intervention using clinical staff available in routine care settings, 5) monitoring, but not controlling fidelity, 6) defining clinical outcomes as changes in patient-reported symptoms, and 7) using intent-to-treat analyses to examine group differences.[44]

Building on Dr. Kirchner's (co-PI) extensive experience implementing and studying the implementation of PC-MHI models, Dr. Owen's (PI) previous experience developing and implementing side effect monitoring in mental health settings, Dr. Fortney's experience implementing the Telemedicine Based Care Management model and Dr. Pomerantz's experience developing and implementing the Co-Located Collaborative Care model, **we propose in Specific Aim #1 to adapt the Co-Located Collaborative Care model for CBOCs lacking on-site psychiatrists/psychologists using telemedicine technologies and blend it with the Telemedicine Based Care Management model.** This aim involves typical quality improvement activities rather than research—we will get input from experts who have already implemented this model, and then work with key clinical staff at sites to adapt the model so that the psychologists and psychiatrists deliver evidence-based "co-located" collaborative care using tele-video.

Then, in Specific Aim #2, we will conduct an effectiveness trial comparing the Telemedicine Blended model to usual care (i.e., Co-Located Referral model). This research trial will use a stepped-wedge design, which will allow us to: (1) extend implementation support to the maximal number of clinics, and (2) enhance the formative evaluation of our implementation process.

In Specific Aim #3, we will conduct telephone interviews with up to 40 racial minority Veterans (up to 20 HCV+ and up to 20 HIV+). These participants may or may not be also offered the opportunity to participate in Aim #2, depending on whether they meet inclusion criteria for Aim #2. The proposed study will provide preliminary data to our operational funding partner, the Office of Health Equity, to inform HCV/HIV treatment policy in VA and future grant submissions.

Procedures:

Adaptation and Refinement (Specific Aim 1)

The PARiHS implementation framework proposes that successful adoption of an evidence based practice (EBP) depends on: 1) evidence, 2) context, and 3) facilitation.[45] Evidence includes results from randomized trials, as well as anecdotal evidence from clinical experience.[46,47] Context includes both factors internal to the organization such as culture, climate and capacity,[48] as well as external forces such as mandates and performance measures. Facilitation typically involves an integrated set of implementation strategies to promote adoption. In this study, we will facilitate implementation of the telemedicine blended model by facilitating the development of implementation plans by the clinical stakeholders, guiding them about the application of the evidence base, and measuring fidelity to the core components of the EBP. In addition to providing expertise, researchers also facilitate problem solving and provide ongoing technical support for developing data collection/analysis tools, informatics, and training materials. The facilitation also emphasizes continuously revising the adapted EBP based on feedback during Plan-Do-Study-Act (PDSA) cycles, and thus should lead to adapted EBPs that are aligned with MHS/OMHO policy, as well as adapted EBPs that are robust, user-friendly, and feasible to deploy in real-world practice settings.

Sites: We propose to work with the three parent VAMCs, which will each identify two CBOCs that lack on-site full-time psychiatrists and psychologists, or CBOCs with full-time psychiatrists and/or psychologists, but for which the VAMC Mental Health Chief identifies a major need for PC-MHI services, for a total of 6 CBOCs. Potential Parent VAMCs include the Central Arkansas Veterans Healthcare System (Little Rock, AR); Veterans Health Care System of the Ozarks (Fayetteville, AR); Overton Brooks VA Medical Center (Shreveport, LA); and Southeast Louisiana Veterans Health Care System (New Orleans, LA). Final selection will be based on recommendations from Network Mental Health leadership and VAMC willingness to participate. All sites will have on-site Licensed Clinical Social Workers (LCSWs) and interactive video equipment available for telepsychiatry. Note: as of June 29, 2017, site selection has been finalized. We will study implementation at four CBOCs affiliated with CAVHS, and two CBOCs affiliated with the Overton Brooks VAMC.

Expert Panel: Prior to adapting the Blended model, we will conduct an expert panel comprised of clinical providers and managers who are applying telemedicine to provide a Blended model for CBOCs to document the core components of a Telemedicine Blended model. Based on these core components we will create a steps and decision guide that can be used to develop site specific implementation plans at each of our CBOCs. This expert panel will be led by Dr. Karen Oliver (our External Facilitator), an epidemiologist who has supported the implementation of the blended model in CBOCs in VISN 12.

Implementation Planning: Once participating CBOCs have been identified, the CBOC executive director will be asked to identify a site level champion for the program implementation. Local champions will likely be MH staff who would be involved in the delivery of the Telemedicine Blended model or supervisors such as the Medical Director or Director of Nursing. As part of a formative evaluation, Dr. Oliver and another member of the facilitation team will conduct pre-site visit phone calls with the CBOC executive director, the on-site MHP and the site champion to discuss potential barriers to and facilitators of implementation, and how the program will be implemented at the site, given the site's organizational context. In addition, we will request that each informant anonymously complete the Organizational Readiness for Change (ORC) scale through a sharepoint or the VA Research Electonic Data Capture (REDCap) site which will be located behind the VA firewall. This scale will be used to provide information to the site that will help them plan their implementation. The information recorded

during these interviews about implementation barriers and facilitators and about the site's experiences and preferences with regard to implementation of PC-MHI integration models will be reviewed and organized for each site in order to provide efficient feedback to the facilitation team and inform the implementation process. The research team has used these techniques successfully in the past to implement evidence-based practices in VAMCs.[42]

Adaptation: The blending of the Care Management and Co-Located Collaborative Care models requires offering both types of functions simultaneously. Using the steps and decisions guide developed in Specific Aim 1, the Co-Located Collaborative Care model will be adapted for CBOCs lacking on-site PhD psychologists and psychiatrists and then blended with the Telemedicine Based Care Management model. Dr. Oliver and another team member will conduct a site visit to each CBOC where they will provide academic detailing on the blended model and meet with key stakeholders to help them adapt the program to meet local needs. Stakeholders will include on-site champions, mid-level MHPs, nursing and PC leadership; and off-site telephone nurse care managers, tele-psychiatrists, tele-psychologists and VISN TMH leadership. One key adaption issue is whether the brief focused psychosocial assessments should be conducted face-to-face by the on-site LCSW or by a tele-psychologist staffing an open access clinic. Psychologists have a more diverse skill set than LCSWs, but warm handoffs via interactive video may not be effective. The availability of desktop interactive video units at some CBOCs could facilitate tele-handoffs in PC exam rooms. Older wall-mounted or cart-based interactive video units may be more appropriate for team meetings/huddles. The facilitation team will *customize* the Telemedicine Blended model for each participating CBOC while retaining the core elements of the Care Management and Co-Located Collaborative Care models. This adaptation process will constitute the Plan phase of the PDSA cycle. Throughout this pre-implementation adaptation phase, Dr. Oliver and the other facilitation team member will track these activities and adaptation decisions in a facilitation field log. Dr. Drummond, a medical anthropologist and implementation scientist, will review these logs and conduct debriefings with Dr. Oliver and the other facilitation team member at regular intervals to document adaptation in detail.

Implementation: The Do stage of the PDSA cycle involves the implementation of the Telemedicine Blended model tailored for each site based on the outcomes of the Planning phase. The Blended model will be staffed by reallocating and retraining existing MHPs. Tele-psychology and tele-psychiatry staff involved in delivering the Blended model will be trained by research team members or collaborators with expertise in the Co-Located Collaborative Care and Care Management models. If possible, there will be a face-to-face training conducted in a central location in VISN 16; it is possible that travel constraints will require that training be conducted using tele-video or telephone conferences. Post-training conference calls will be offered every two weeks with staff involved in the delivery of the Telemedicine Blended model. Each CBOC will have the option to pilot the Telemedicine Blended model for half day a week for 2 months. We know that delivering the Blended model for a half day is feasible because the Bennington CBOC (associated with the White River Junction VAMC) runs an open access clinic in the morning and a referral clinic in the afternoon as part of routine care. Each site may pilot test a different version of the adapted model (e.g., one CBOC may pilot test a version where the on-site LCSW receives the warm handoff, while another CBOC pilot tests a version where the tele-psychologist receives the warm handoff). Throughout implementation, Dr. Oliver and the other facilitation team member will continue to provide facilitation of activities at each site, and will continue to track activities and decisions in an implementation log. As above, Dr. Drummond will review these logs and conduct debriefings to fully document facilitation and implementation in detail.

Effectiveness Trial (Specific Aim 2)

Overview: To accomplish Specific Aim 2, we will enroll patients before, during and after the implementation phase to assess outcomes, using a stepped-wedge design. We will also enroll and interview approximately four patients at each participating CBOC during early implementation to assess Veteran perspectives on barriers to and experiences with PCMHI care. Findings from these interviews will be provided to the facilitators and inform the formative evaluation of each site (see Specific Aim 1 above and Formative Evaluation section below).

We will employ the RE-AIM framework to assess Reach, Effectiveness, Adoption, Implementation, and Maintenance of the program. Post-implementation, we will conduct interviews with key informants at each site to collect feedback which will help us to interpret outcomes at each site as well as to improve facilitation and implementation processes for future efforts.

Overall Study Design of Effectiveness Trial- The outcomes of the effectiveness trial will be based on the **RE-AIM** Framework (Reach, Effectiveness, Adoption, Implementation, Maintenance).[49-52] ***Reach*** represents the proportion of eligible or targeted patients who receive the EBP.[49] ***Adoption*** represents the proportion of staff who use the EBP.[49] ***Implementation*** represents the fidelity of the EBP as implemented in routine care.[49] ***Effectiveness*** represents the clinical impact (on patient outcomes) of the EBP as implemented in routine care settings.[51] *Maintenance* represents the degree to which the implementation of the EBP is sustained.[49] The proposed effectiveness trial will focus on Adoption, Reach, Implementation Fidelity and Effectiveness. To have an impact on the health of the target population, an EBP must be adopted by providers, reach a large proportion of the targeted patient population, be implemented with high fidelity, effectively improve outcomes and be maintained after the research funds are withdrawn. Importantly, by measuring both *Reach* into the patient population and the *effectiveness* of those reached, we will be able to estimate the "population level impact" of PC-MHI.[53]

Randomization - Randomization to the intervention or usual care cannot be conducted practically at the patient-level, as is done in most traditional RCTs, because the Telemedicine Blended Model (especially the Co-Located Collaborative Care components) represents a clinic-level transformation. The Co-Located Collaborative Care model completely reorganizes clinic flow (i.e., team meetings, open access, warm handoffs, shared treatment plans) and it would not be practical to randomize a subset of patients to the intervention. For example, randomization at the patient-level would disrupt the flow of warm handoffs from PCPs to MHPs and hinder the development of shared treatment plans if busy PCPs become confused about which patients had been randomized to the intervention and which had been randomized to usual care. This is why there are no RCTs of the Co-Located Collaborative Care model. When an intervention must be delivered to all or none of the patients in a "cluster", investigators traditionally use cluster-level randomization. The two most common types of cluster randomization are provider-level and clinic-level. Provider-level randomization is not feasible in our context because the mid-level Co-Located MHP could not simultaneously staff an open access clinic for some PCPs and a referral clinic for other PCPs. We discussed the possibilities of using clinic-level (e.g., CBOC) randomization with our Steering Committee, including our clinical partners, who felt that a **stepped wedge** controlled trial design would better serve the clinical needs of our sites. The stepped wedge controlled trial design will allow us to: (1) extend implementation support to the maximal number of clinics, and (2) enhance the formative evaluation of our implementation process. Stepped wedge designs are a recent development in controlled trial design that entails providing the intervention of interest to all participants, but staggering the introduction of the intervention. This design is increasingly used where all participants must receive the intervention for policy or ethical reasons.

Instead of starting all intervention and control sites together, the design staggers the introduction of the Telemedicine Blended Model. Stepped wedge designs thus have the disadvantage of exposing the aggregate of sites to a longer period of potential secular trends; however, by aligning in time sites awaiting intervention with sites undergoing intervention, stepped wedge designs can identify and control for these trends better than parallel-groups randomized controlled trials[38]. Figure 1 displays the progressive nature of the stepped wedge design.

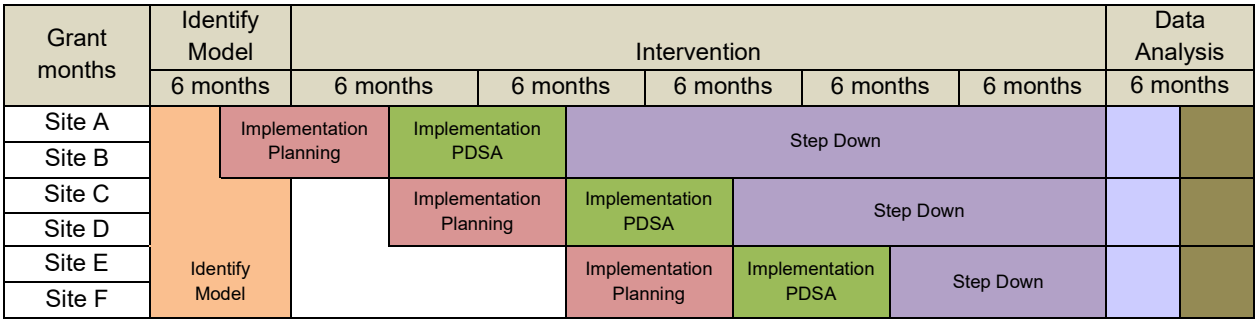
CBOCs are the unit of randomization, with CBOCs randomized to an intervention start date using the stepped wedge design. A total of 6 CBOCs will participate in the study, with two CBOCs allocated to each of the 3 start dates. Because sites may differ with regard to organizational/program characteristics, we will use the restricted selection method of randomization to balance key site characteristics over time. For example, if somewhat larger CBOCs (with regard to number of uniques) were randomized to participate in the first wave of implementation and the smallest sites were assigned to the last wave, this would make it likely that urban and rural sites occur both in early and late waves of implementation. We will utilize a computer-based algorithm to balance site characteristics as much as possible using key site characteristics including:

- CBOC size (number of uniques served)
- Parent VAMC
- Number of on-site mental health providers/staff
- Percent of appointments that are conducted with specialists via telemedicine

We may use additional characteristics suggested by clinical partners. Obviously, a small number of sites and multiple categories of site characteristics rule out perfect balance. The algorithm provides as much balance as possible in the spirit of an ANOVA balanced incomplete block design. Randomization will be computer-generated by the statistician. A subset of patients will be selected at each CBOC during each of 5 measurement periods shown in the diagram below (implementation planning, implementation and step down).

Patient Recruitment: We will initiate recruitment at all sites 3 months into the first 6-month study period (labeled as “Identify Model” in the diagram above), during the implementation planning for Sites A and B. We will complete recruitment 3 months before the data analysis period begins. Thus, Veteran follow up will extend into the first 3 months of the data analysis period for all sites. Since the duration of the implementation period may vary from site to site, we will consider a site’s first referral to the Telemedicine Blended Model (with a PC-MHI telemedicine stopcode) as the index date with all Veterans enrolled prior to that date designated as controls and all Veterans enrolled after that date designated as intervention participants.

Figure 1: Implementation Timeline



Inclusion Criteria: We will sample from the patient population who screen positive on routinely administered VA MH screens (e.g., depression, alcohol, PTSD) at the 6 CBOCs, beginning 6

months prior to the first implementation period (for sites A and B) and continuing through the 6 month period following the implementation phase for sites E and F (see above diagram). We will exclude only those patients receiving specialty MH treatment in the 6 months prior to recruitment; those with a diagnosis of substance dependence; and those with a psychotic disorder diagnosis (schizophrenia, bipolar disorder, other psychotic disorders). Receipt of specialty MH care will be defined as having an encounter with a 500 series stopcode (except 534, which represents a PC-MHI encounter such as a telephone care manager encounter). The justification for this exclusion criterion is that patients enrolled in specialty MH care are already receiving a higher level of care than Telemedicine Blended and would not be expected to benefit clinically. The justification for excluding patients with substance dependence and a psychotic disorder diagnosis (schizophrenia, bipolar disorder, other psychotic disorders) is that currently there are no evidence based PC-MHI interventions for such patients. Finally, by focusing on all patients not already enrolled in specialty MH, it allows us to estimate the intervention's "population level impact" rather than its efficacy for a narrowly defined group of patients.[53]

Participant Recruitment and Consent: Using methods developed in a prior RCT we propose to extract appointment data from the Corporate Data Warehouse (CDW) and identify those Veterans with upcoming PC CBOC appointments scheduled at least one month in advance and who have no MH encounters in the previous 6 months. Real SSN access will be requested so that we can obtain contact information for potentially eligible patients. We are requesting a Wavier of Informed Consent and a Waiver of HIPAA Authorization for this initial phase of the recruitment process. We will send opt-out letters to the identified Veterans, noting that we may contact them about participation in a research study. Veterans may opt out by telephone or mail. On a daily basis, we propose to extract mental health screening data from the Corporate Data Warehouse and identify those Veterans who have not opted out of the study and who screen positive for alcohol abuse, depression, or PTSD. An RA will attempt to contact each such Veteran by telephone in order to conduct the informed consent process and complete the baseline interview. We are requesting a Waiver of Documentation of Informed Consent, as well as a HIPAA Waiver of Authorization for participation in the Effectiveness trial because we need to conduct the initial assessment interview as soon as possible after the clinical encounter with a positive screen. The study qualifies for these waivers because it is minimal risk, because it would not be practicable to conduct the study without the waivers (see above), because the research team will never be physically interacting with the participants in person, and the interaction with patients involves activities for which informed consent is not required when they occur in the course of standard clinical care (see Supplements L). When we send the opt-out letter, we will include information required for the informed consent process, so that the potential participants will have this available during the telephone contact. Those who are unable to understand or engage in the informed consent process (e.g., cognitive impairment, intoxication) will be excluded. The recruitment phase will last for 3 years. Opt-out letters will be sent to Veterans 3-4 weeks prior to the upcoming appointment. Those patients not opting out (by 1-800 telephone or mail) within two weeks, attend their primary care visit and screen positive for depression, alcohol, or PTSD during this visit will be contacted for recruitment. If we contact eligible patients who have not opted out of the study, but they state they cannot recall receiving the opt-out letter and study information, we will send another letter and study information sheet. We will contact them a week after the 2nd letter is mailed. This will ensure that we can reach them within the study recruitment window.

Usual Care: Patients at CBOCs that have not (yet) implemented the Blended model will receive usual treatment under the standard Co-Located Referral Model which is described in the Background section.

Intervention Group: At CBOCs that are implementing the Blended model as called for by the stepped wedge design, patients will have access to the Blended model described in the Background section as adapted for CBOCs using telemedicine technologies during Specific Aim 1.

Administrative Data: VA service utilization will be collected from the CDW, where all VA facilities upload and store encounter data, using methods we have employed previously.[54] Data will be collected on all patients at the study sites (hereafter referred to as the administrative sample) regardless of whether the patient was recruited and provided informed consent to participate in the primary data collection efforts associated with the trial. Encounter data will be collected for each patient for the 6 months following their first encounter in each 6-month observation period. Encounters to 500-599 stopcodes at CBOCs and VAMCs will be classified as MH. Encounters using the 534 stopcode (a stopcode used only for PC-MHI visits) will be classified as Telemedicine Blended. We will identify all patients (by scrambled social security number) with encounters to the study CBOCs and categorize them to the intervention or usual care group based on the date of their first encounter. We will also extract administrative data about MH diagnoses, age, gender, marital status, percent service connection and zipcode. MH diagnoses will be used to define diagnostic categories including: adjustment disorders, alcohol use disorders, anxiety disorders, attention deficit disorders, bipolar spectrum disorders, dementia, depressive disorders, drug use disorders, personality disorder, sleep disorders, stress reaction disorders, and other. The rurality of Veterans will be measured based on their zipcode using two different methods: 1) Rural Urban Commuting Area (RUCA) codes, and 2) VA definition. A zipcode to census tract crosswalk will be used. RUCAs are a census tract-based classification scheme that utilizes the standard Bureau of Census Urbanized Area and Urban Cluster definitions. RUCA also takes into account commuting patterns to Urbanized Areas, Urban Clusters, or smaller population centers to classify census tracts into 33 distinct categories, which typically are combined into 4 categories: 1) Urban - areas have Metropolitan cores and substantial commuting flow patterns to Urbanized Areas, 2) Large Rural Towns - have Micropolitan cores and substantial commuting patterns to Urban Clusters, 3) Small Rural Towns - have primary commuting flows to or within population centers of between 2,500 and 9,999 residents, and 4) Isolated Rural Towns - are less populated rural areas with no commuting flows to Urbanized Areas or Urban clusters.[55] VA's classification scheme defines census tracts that belong to Urbanized Areas as Urban and all others as Rural, except for those in counties with average population density of less than 7 residents per square mile, which are defined as Highly Rural.[55] The Real SSN Crosswalk file will be used to link primary data to the administrative data for participants enrolled in the effectiveness trial.

Dependent Variable for <u>Adoption</u>: Patients will be assigned to PCPs using the Patient Care Management Module from the Austin Automation Center which records every patient's PCP assignment start date and assignment end date. We have used this file successfully to measure provider adoption in a recent QUERI funded study (SDP 08-316). We will classify each Veteran in the administrative sample as having received Telemedicine Blended services if they had a 534 stopcode during their first encounter or a 534 stopcode encounter during the 6 month follow-up period. To measure provider adoption, we will categorize CBOC PCPs as adopters if they have at least one patient with the 534 stopcode encounter. In addition, we will document the percent of the PCP's patients that with a 534 stopcode encounter.

Data Analysis for <u>Adoption</u> - The percentage of PCPs adopting the intervention will be calculated. The adoption percentage will also be reported at the CBOC level.

Dependent Variable for <u>Reach</u> (Hypothesis 1): To measure Reach into the patient population, we will classify each Veteran in the administrative sample as having received MH services if they had a 500-599 series stopcode (including 534) during their first encounter or any encounter

during the 6 month follow-up period. Exploratory analysis will also examine *number* of MH encounters. We will also report the percentage of Veterans in the administrative sample who had a PC-MHI (534) stopcode during their first encounter or any encounter in the 6 month follow-up period in order to document the proportion randomized to the intervention who received Telemedicine Blended care.

Data Analysis for Reach (Hypothesis 1): A dummy variable representing intervention group assignment will be specified as the explanatory variable of interest. An alpha significance level of 0.05 will be used to reject/accept the null hypothesis. Significant intra-class correlation violates the independence assumption of standard regression models and may cause underestimation of coefficient standard errors, possibly leading to incorrect inferences concerning the rejection of the null hypotheses. Therefore, the first step of the statistical analysis will be to test for lack of independence among observations within clusters using intra-class correlation coefficients at CBOC level. Specifically, using a likelihood ratio test, we will compare the -2log likelihoods for an unrestricted model to a model that restricts the intra-class correlation to be zero. Raudenbush recommends that unconditional models (i.e. without explanatory variables) should be estimated prior to considering conditional models (i.e., with explanatory variables).[56] If it turns out that the -2log likelihoods are not significantly different, the hypotheses will be tested using a standard logistic regression model. The following casemix factors will be included in the regression equation: MH diagnostic categories, age, gender, race, marital status, percent service connection and rurality. Missing race data will be handled by specifying an unknown race category. Conversely, if the results of the likelihood ratio test suggest that the intra-class correlation is significant, a mixed logistic model will be used.[57,58] The mixed-model will include a random effect for the intercept and fixed effects for the patient-level variables (including treatment group assignment). The variance-covariance matrix will be specified to be unstructured.

Chart Review Data: For the Veterans who are enrolled in the Effectiveness trial during the intervention period (the period following the study index date at each site), we will conduct a chart review to determine whether they received high fidelity integrated care during the six months after enrollment, obtaining access to either the CPRS system at each site or accessing CPRS information through the national Compensation and Pension Record Interchange (CAPRI), as Dr. Owen did in a recent study (IRBNet #219-789). If we elect to access the CAPRI system, we will only request access to local data/records at the study CBOCs and their parent facilities (6 CBOCs and 3 VAMCs).

Once the Blended model has been adapted, the patient-level fidelity tool will be developed with our national partners, Drs. Pomerantz and Post based on the *Primary Care-Mental Health Integration Blended Programs Functional Tool* (See Appendix 4). This tool was recently designed to assess program-level fidelity to the Blended model and will need to be modified to assess patient-level fidelity. Using methods developed for our NIMH R01 MH076908 depression care management trial, care management fidelity will be assessed based on whether the following clinical activities are documented in progress notes: 1) symptom severity measured using structured assessments: PHQ9 (depression), GAD7 (generalized anxiety), PCL (PTSD), AUDIT-C (alcohol) scores, 2) self-management activities, 3) antidepressant adherence assessments and side-effect assessments (for those prescribed antidepressants) and 4) counseling adherence assessment (for those initiating psychotherapy). Co-Located Collaborative Care fidelity will be assessed based on whether the following clinical activities are documented in progress notes: 1) warm handoff (determined from encounter dates/times with PCP and co-located MHPs) during initial visit, 2) brief initial assessment with therapist (determined from CPT codes – e.g., 90804), 3) brief initial assessment with MH prescriber (determined from CPT codes – e.g., 90805), 4) initial assessment is problem focused, 5) initial

assessment includes behavioral health issues (e.g., smoking, weight management), 6) inter-professional communication at each encounter (determined by PCP and co-locate MHPs co-signing notes), 7) co-located MHPs use motivational interviewing, self-management, problem solving therapy, cognitive techniques, and brief alcohol interventions, and 8) symptom severity is measured using structured assessments (e.g., PHQ9).

Dependent Variable for Implementation Fidelity: Fidelity will be measured as a percentage: with the numerator specified as the number of documented clinical activities and the denominator specified as the number of clinical activities relevant to that patient. For example, medication adherence and side-effect assessments will only be specified in the denominator if the patient has been prescribed medications.

Data Analysis for Implementation Fidelity: - The mean, median, standard deviation and range of implementation fidelity will be reported for all Veterans enrolled during the intervention phase, as well as the sub-sample with a PC-MHI (534) stopcode. The fidelity measures will also be aggregated at the CBOC level.

Interview Assessment Data: We will administer research assessments to those Veterans providing informed consent to participate in the primary data collection efforts associated with the trial. The baseline assessment will be conducted within two weeks following the regularly scheduled PC appointment and six months afterwards. Assessments will be administered over the phone by trained RAs using a CATI system. Table 3 lists the instruments and Appendix 5 contains the actual survey items to be used in the baseline interview. The demographics section, barriers assessment, perceived access inventory, and readiness ruler will only be administered at baseline and used for casemix adjustment. All other instruments will be administered at both baseline and follow-up. The rurality of Veterans will be measured based on their self-reported zipcode using the methods described above.

Dependent Variable for Effectiveness (Hypothesis 2): Change scores between baseline and six months will be calculated for non-disease specific outcomes including: MH status (SF12V MCS), physical health status (SF12V PCS), pain (Pain scale), sleep (Jenkins sleep scale), disease specific symptoms such as depression (PHQ9), general anxiety disorder (GAD7), panic disorder (PDSS-SR), PTSD (PCL-5) and alcohol use (AUDIT-C), and self-management of chronic disorders such as diet and exercise (Prime-Screen), smoking (BRFS tobacco use items) and medication adherence (Miklowitz adherence scale). The primary outcome for this hypothesis is the MCS from the SF12V. The other outcome domains will be examined in exploratory analyses. Exploratory analysis will also examine the variation in SF12V and disease specific outcomes across diagnostic categories (identified by baseline scores of the PHQ9, GAD7, PDSS-SR, PCL-5, and AUDIT-C).

Table 3 - Research Assessments

Instrument	Construct
Socio-Demographics	18 items that measure socio-economic and military characteristics
Hoge Barriers Assessment	14 item measure of perceived access, need and treatment effectiveness[59]
Perceived Access Inventory	43 item perceived access instrument developed by CREATE Project 1
Readiness Ruler	3 items that assess perceived readiness to seek treatment[60]
Miklowitz-Adherence Scale	2 item medication adherence scale[61]
SF12V	12 items addressing overall physical and mental health functioning[62]

Pain Scale	Single item participant rating of the average overall level of pain for the past week rated on a continuous scale from 0 to 10.
Jenkins Sleep Scale	4 item measure that assesses trouble falling and staying asleep, and feeling tired during the daytime[63]
Prime-Screen	6 item assessment of dietary and exercise habits/behaviors[64]
PHQ9	9 item inventory that yields a continuous and dichotomous assessment of depression[65]
GAD7	7 item inventory that yields a continuous and dichotomous assessment of generalized anxiety disorder[66]
APA DSM 5 Severity Measure for Panic- Adult	10 item inventory that yields a continuous and dichotomous assessment of panic disorder[67]
PCL-5	20 item inventory that yields a continuous and dichotomous assessment of PTSD[68]
AUDIT-C	3 items that yield a continuous and dichotomous assessment of alcohol use[69]
BRFSS Tobacco Use	5 items to assess current tobacco use
CSQ-8	8 items to assess client satisfaction with MH services [70]

Note: The Perceived Access Inventory is currently being developed as the main product of a project led by Dr. Jeffrey Pyne, and is expected to be finalized in early 2016. In the Patient Survey document that contains copies of all the other questionnaires, there is a placeholder page for this survey. We will submit this questionnaire to the IRB once it is completed and before using it in our assessment interviews.

Measures Taken to Minimize/Avoid Bias, such as Randomization and Blinding

We will use CDW data and an opt-out approach to recruit a representative sample of Veterans meeting the eligibility criteria for the effectiveness trial. Sites will be randomized with regard to timing of implementation. Research assistants will be blind to the status of implementation at the sites.

Formative Evaluation: Qualitative Interviews with Veterans during Early Implementation and with Site Personnel Post-Implementation

In order to minimize burden on sites, and because gold standard facilitation involves activities normally conducted for both pre-implementation and progress-focused formative evaluation (and thus will be completed as part of the quality improvement activities of Specific Aim 1), we will only conduct parts of the formative evaluation under Specific Aim 2. Specifically, study team members will conduct progress-focused interviews with a sample of eligible Veterans who receive PCMHI care early in the implementation effort at each site, and post-implementation interviews with site personnel, including the CBOC Executive Director, the study site champion, and any other relevant staff they recommend to us.

Veteran participant interviews:
Patients will be identified by the PC-MHI provider (co-located or tele-co-located), who will provide names and contact information via encrypted e-mail or telephone, or the list will be uploaded to a secure research sharepoint site at CAVHS. The potential patient participants will be sent an opt-out letter and recruited by phone if they do not opt-out (by 1-800 telephone or mail) within two weeks. Because we need to interview patient participants soon after they receive their mental healthcare, we are requesting a Waiver of Documentation of Informed Consent and a Waiver of HIPAA Authorization for participation in this study component. We will obtain verbal consent over the phone, and document that we have obtained verbal consent in the research record.

In order to understand Veteran experiences and preferences regarding receiving PC-MHI services via telehealth, we will conduct interviews with approximately four patients at each site (approximate n=24: 4 interviews X 6 CBOC sites). We will use semi-structured interview guides (see Appendix 3) covering the topics of Veteran experiences with the telehealth intervention, barriers encountered in receiving services via telehealth, and preferences for receiving care via telehealth or otherwise. These results will be fed back to the implementation/facilitation team for use in further refining how PCMHI via telehealth is being implemented and improved at each site. As part of our overarching aims of the various CREATE projects, we will also ask questions designed to refine the SOTA model of barriers rural populations experience in accessing care (see Appendix 3).

Post-Implementation Interviews:
We will conduct key informant interviews with personnel at each CBOC to gather feedback on the intervention. Potential participants will include the CBOC Executive Director, the study site champion, and any other relevant staff they recommend to us. Dr. Oliver will also recommend participants based upon her experiences in working with the sites. Dr. Drummond will conduct these interviews and take extensive notes. She will then abstract these notes into a summary template for each interview, and later compile templates across interviews within a given site.

CBOC staff recruitment and consent: Following procedures we have used in other studies for these kinds of interviews, a study team member will email potential participants to explain the purpose of the interview and attach a study information sheet. We are requesting a Waiver of Informed Consent for recruitment and a Waiver of Documentation of Informed Consent for participation, which enhances employee participant anonymity and confidentiality. We will obtain verbal consent over the phone and document that we have obtained verbal consent in the research record.

Exploratory Study of HCV/HIV & Depression Treatment Experiences (Specific Aim 3):

Overview: Given prevalence of these diseases, barriers to care, and racial disparities, research is needed to improve implementation of HCV and HIV depression treatment for racial minority Veterans. Data are needed on HCV and HIV depression barriers and facilitators to treatment for Veterans who have documented disparities in these conditions, especially given VA spending on the new HCV treatment option. Specific data are also needed to develop implementation strategies to increase treatment for Veterans in rural areas who have unique barriers because of geographic location (14,15). The proposed study will address this by conducting qualitative interviews with Veterans with HCV and/or HIV and depression to examine treatment experiences, preferences, barriers, and facilitators.

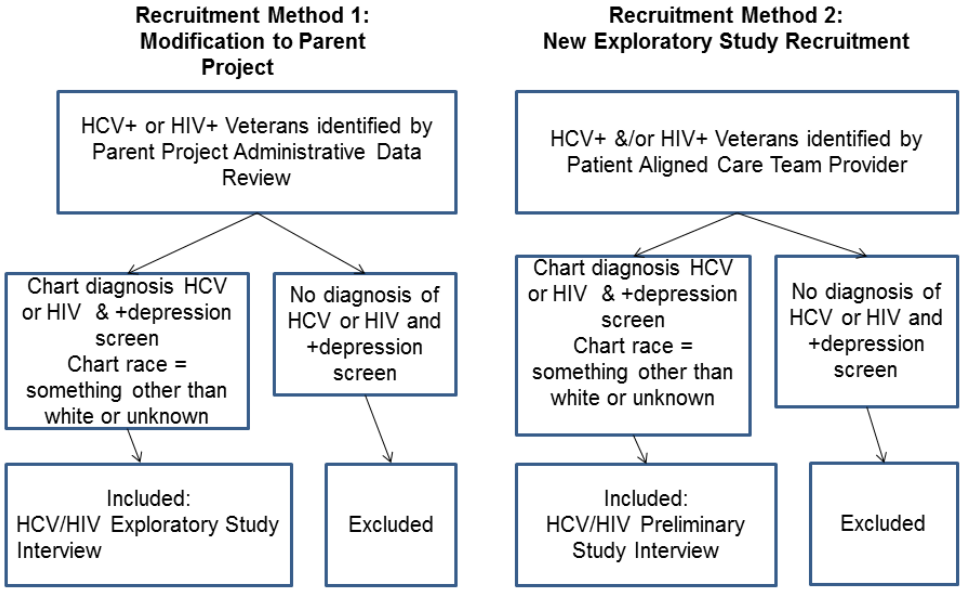
Sites: We will recruit participants from the same sites utilized in Aims #1 and #2: potential parent VAMCs including the Central Arkansas Veterans Healthcare System (Little Rock, AR); Veterans Health Care System of the Ozarks (Fayetteville, AR); and Southeast Louisiana Veterans Health Care System (New Orleans, LA). Final selection will be based on recommendations from Network Mental Health leadership and VAMC willingness to participate – final sites are CBOCs affiliated with CAVHS and the Overton Brooks VAMC.

Study Design: Because this is an exploratory aim and the goal is to generate data and hypotheses about barriers and facilitators to adequate HCV, HIV, and comorbid mental health care, we will conduct qualitative interviews with up to 40 Veterans.

Patient recruitment and consent: We will utilize a one-time recruitment strategy to enroll participants using a recruitment process separate, but similar, to those in Aim #2. See

Figure 2. We will harness recruitment efforts currently existing in the parent study and if we are unable to generate adequate sample size using this method, Veterans will be identified by their Patient Aligned Care Team provider. Through either method, Veterans will first be sent an opt-out letter. If Veterans do not call our research team within two weeks to opt out of the study, they will be called by our research team to assess interest and confirm eligibility in the study using a screening questionnaire. We are requesting a Waiver of Informed Consent for recruitment and a Waiver of Documentation of Informed Consent for participation. We will obtain verbal consent over the phone and document that we have obtained verbal consent in the research record. If Veterans are eligible and consent to participate, they will be scheduled with Dr. Woodward for an interview via phone at their convenience.

Figure 2. Recruitment Flowchart for Exploratory Study (Aim #3)



Inclusion Criteria: All Veterans in the exploratory aim must identify with a race other than white--.e.g, black, African American, or Latino. There are two subsets of inclusion criteria, one for each subsample within this exploratory study aim. (1) HCV: Veterans must have a chart diagnosis of HCV. (2) HIV. Veterans must have a chart diagnosis of HIV and screen positive for depression.

Data sources: There are two potential sources of data for this exploratory Aim #3:

(1) Administrative Data also utilized for Specific Aim #2 (Effectiveness). Data will be collected on all patients at the study sites regardless of whether the patient was recruited and provided informed consent to participate in the primary data collection efforts associated with the trial. From this larger administrative dataset, Veterans diagnosed with either HCV or HIV will be recruited and sent opt-out letters, allowing them two weeks to opt out of the exploratory study.

(2) Interview Data: This includes questions about HCV or HIV/depression treatment experiences, preferences, barriers, and facilitators; a demographics questionnaire.

Timeline: Recruitment will occur between July – September 30, 2016.

Follow-up Interviews: We will contact participants with HCV who are enrolled for Aim 3 by telephone to assess whether they have initiated HCV treatment since the interview and if so, assess their reasons for doing so. These Veterans agreed at the end of the initial interview that they would allow our research team to contact them again, if needed. The phone call will last approximately 5-10 minutes and will follow a semi-structured script, allowing the interviewer (either Dr. Woodward or the original research assistant who called the participant) to systematically ask questions while also exploring other themes Veterans highlight. The purpose of these follow-up interviews is to assess whether the initial interview itself (especially the education provided to Veteran participants about the new HCV treatment) served as a proxy or intervention for helping Veterans initiate HCV treatment. We may also ask Veterans to clarify or comment on any results from our analysis of their initial interviews—this "member checking" procedure is common in qualitative analysis to ensure valid data interpretation.

Analysis: Dr. Woodward and other research staff will code the qualitative data using qualitative analytic techniques.

Measures Taken to Minimize/Avoid Bias, such as Randomization and Blinding:

We will use CDW data and an opt-out approach to recruit a representative sample of Veterans meeting the eligibility criteria for the exploratory aim. Because this is an exploratory aim, randomization and blinding is neither possible nor required for proper scientific rigor.

Expected Duration:

Participation for the formative evaluation interviews will be limited to one interaction for qualitative data collection. Participants in the effectiveness trial will be interviewed at the time of enrollment and 6 months thereafter, as described above. Participants in the exploratory aim will be interviewed at time of enrollment between July and September 30, 2016.

Stopping or Discontinuation Criteria for Individual Participants:

Participants are free to discontinue participation in interviews at any time. An individual's participation will be discontinued if the participant appears to be experiencing severe distress related to the intervention or assessments.

Selection and Withdrawal of Participants:

For the effectiveness trial, Veterans with an upcoming CBOC appointment who screen positive on routinely administered VA MH screens (e.g., depression, alcohol, PTSD) at the 6 study CBOCs will be identified for recruitment. Only those patients receiving specialty MH treatment in the 6 months prior to recruitment, substance dependence, and those with a psychotic disorder diagnosis (schizophrenia, bipolar disorder, other psychotic disorders) will be excluded.

During the formative evaluation, we will enroll key informants (employees and Veteran patients). Veteran patients will be identified by the local MHP based on their exposure to the telemedicine blended care model, and recruited by study staff. Potential employee participants at each site will include the CBOC Director and the site champion, who will recommend other relevant individuals. The study team facilitator will also recommend CBOC staff who participated in implementation activities.

For the exploratory aim, Veterans identified for recruitment will be diagnosed with either HCV or HIV and screen positive for depression during phone screening. Only those patients

without an HCV or HIV diagnosis, are diagnosed with HIV but do not screen positive for depression, or whose race is white will be excluded.

Participants may withdraw at any time from any aim of this study. If a participant withdraws before completion of the baseline assessment, they will be replaced with another participant. Data from the withdrawn participant will not be used for the study.

Assessment of Safety:

The study consists of qualitative telephone interviews with employees and Veterans (formative evaluation), and telephone assessments of clinical status and outcome with Veteran patients. There are also activities by the research team to facilitate implementation of the telemedicine blended care model. These activities do not constitute physical safety risks beyond regular healthcare activities. In addition, the questionnaires and interview questions being used in this study are unlikely to cause distress, but the research staff will discontinue any study procedure, whether by interview or telephone contact, if a participant reports or the study staff member detects substantial distress. If this occurs, the interviewer will aid the participant in returning to emotional equilibrium before the end of the session. Participants will be asked at the end of the sessions whether they have any questions or concerns. If distress is reported, or if an individual continues to appear distressed, the interviewer will probe further to determine the nature and severity of symptoms and provide referral as needed. In emergent situations (e.g., acute psychological distress or voiced thoughts of harming themselves or others) the research staff member will follow the appropriate suicide risk procedure (see Suicide Risk Assessment document). For participants who voice thoughts of harming themselves or others, the interviewer will stay on the line with the patient while connecting to the National Suicide Prevention Lifeline, using the phone number for within-VA transfers to the crisis line: (585) 393-7938. The interviewer will introduce the patient and relay all pertinent information and reason for the call. After the warm hand off to the crisis line staff, the interviewer will alert the PI (Richard Owen) via encrypted email. For patients at Overton Brooks (Shreveport) CBOCs, the interviewer will also alert the Shreveport Suicide Prevention Coordinator, providing all information about the interaction. For patients affiliated with CAVHS or Overton Brooks whose responses to safety risk questions indicate moderate suicide risk, Dr. Owen or the designated "on-call" clinician-co-investigator who is covering for Dr. Owen in his absence will be alerted within 24 hours via encrypted email.

Data Analysis for <u>Effectiveness</u> (Hypothesis 2):

Randomization

CBOCs are the unit of randomization, with CBOCs randomized to an intervention start date using the stepped wedge design. A total of 6 CBOCs will participate in the study, with two CBOCs allocated to each of the 3 start dates. Randomization will be computer-generated by the statistician. A subset of potential patients (based on inclusion criteria) will be selected at each CBOC on a daily basis during the 5 measurement periods shown in Figure 1: Grant Activity Timeline (the formative evaluation control period(s), implementation, and step down period(s)).

Blinding

CBOCs and the research team will not be blinded to the intervention start dates. However, outcome assessment by independent evaluators (research assistants) will be blinded.

Statistical Analysis

The analyses will be conducted using the intention-to-treat principle, with CBOCs analyzed according to their randomized, crossover time irrespective of whether crossover took place at

the specified time. The results across the unexposed (control phase) observation periods will be compared with those across the observation periods in which the CBOCs are exposed to the Telemedicine Blended Model intervention (intervention phase). Characteristics of the patients and the CBOCs will be summarized by exposure status to examine potential selection bias or lack of balance.[81] Because we have a small number (3) of randomization steps, we will compare numbers of patients analyzed, cluster (CBOC) size, CBOC characteristics and patient characteristics by randomization group. Patient-level data will be collected, with the primary analysis being patient-level.

The CBOC-level analysis will examine the primary and secondary outcomes, summarized as the mean and standard deviation across CBOCs before and after implementation of Telemedicine Based care. At each facility, we will determine the index start date at which the first utilization of the telemedicine based service began. This will allow us to take into account the differing lengths of time it may take to implement the intervention at various CBOCs. Before this index date, patients participating in the study at that CBOC will be considered as being in the control period and those participating after the index date will be considered in the intervention phase. Analyses of before to after implementation will be conducted for continuous outcomes using linear mixed models. The interaction of intervention by CBOC will test if results differ by CBOC. We will adjust for baseline differences among CBOCs in the model.[82]

The patient-level analysis will be a generalized linear mixed model (GLMM) which includes fixed terms for intervention (usual care referral model versus Telemedicine Based care) and time (6-month time periods for each step). The model will use random effects to model the correlation of patients within CBOCs.
The random effects model is:

$$Y_{ijl} = \mu + \beta_j + X_{ij}\theta + u_i + \varepsilon_{ijl} ;$$
$$u_i \sim N(0, \sigma^2_b) , \varepsilon_{ijl} \sim N(0, \sigma^2_w)$$

where β_j = fixed effect of time; X_{ij} = 1 if intervention, 0 otherwise; θ = intervention effect; u_i = random effect for cluster i; ε_{ijl} = residual; i = 1,2,…,k clusters; j = 1,2,…,T time periods; and l = 1,2,…,m individuals.[83, 84] In addition, we may consider adjusting the analyses to deal with lags in the intervention effect. This delayed intervention effect occurs if the intervention does not become fully effective during the step in which it is introduced.[85] If, for example, we expect the lag in the intervention effect to be 50% in the implementation step and 100% effective within 6 months, we could follow the suggestion of Hussey and Hughes of using fractional values for the treatment indicator.[83]

Because this is a cross-sectional design in which different patients are sampled at each step in the study, we do not need to include a random effects term for repeated measures on the same individuals. The effect size adjusted for calendar time and its 95% confidence interval will be calculated to assess the estimated change in outcomes after introduction of the intervention.

Although the primary analysis will be intention-to-treat, if necessary, we will include an analysis of what actually happened if the CBOCs do not crossover to the intervention at the original specified time.

Per Hemming et al.,[81] we will report the estimated intra-cluster correlation for use in design of future trials. In addition, we will report the time effect from the fitted model to allow assessment of possible confounding effects of calendar time. We may include an effect modifier term in the model representing the length of the period up to the current observation during which the CBOC has been exposed to the intervention. This will allow examination of the way the impact of the Telemedicine Based care develops over time once introduced into the CBOC.

Power Calculation for Hypothesis 2. We calculated the sample size for the stepped wedge design following the approach of Woertman et al.,[86] which has been corrected by Hemming, Girling, and Taljaard.[84, 87, 88]

We first determined the sample size needed if individuals were randomized (N_u). This is then multiplied by a design effect, DE_{sw}, to correct for both clustering and the stepped wedge design.

$$DE_{sw} = \frac{1 + \rho(tm + m - 1)}{1 + \rho(0.5tm + m - 1)} * \frac{3(1 - \rho)}{2\,(t - 1/t)}$$

where m is the number of subjects within a cluster in each measurement period, ρ is the intra-cluster correlation (ICC), t is the number of randomization steps, and k clusters are measured at each of T measurement periods. The required sample size for analysis using the stepped wedge design is then $N_{sw} = N_u * DE_{sw} * T$. Finally, we adjusted the required sample size formula to account for 20% attrition over the 6-month period to obtain the number of patients that need to be selected for assessment, N.

In our study, the 6 CBOCs will be randomly allocated two at a time to one of the t = 3 randomization steps. Based on earlier work, the intracluster correlation coefficient, ρ will be estimated as .01. There will be a total of 5 measurements for each cluster, including the control period(s), implementation, and maintenance period(s) (see schematic diagram). We assumed for the power calculations that approximately m=18 participants would be available within each CBOC in each 6-month time interval.

The calculations are based on having 80% power at a significance level of 0.05 to detect a medium effect size (Cohen's d=0.42) between the usual care referral model (EU) and the Telemedicine Blended model intervention group (TB) in our primary outcome measure for the effectiveness hypothesis, MCS from SF-12V. This represents a difference of 4 points in the MCS scores between the referral model group and the Telemedicine Blended Model group, assuming a pooled standard deviation of 10. This gives the unadjusted total sample size, N_u, of 128 for the two-sided, two-sample t-test of equal means.

The total number of patients to be selected for assessment across the 6 CBOCs will be 750. This was determined after adjusting the total sample size required under individual randomization N_u, for the design effect, multiplying by the 5 measurement periods, and accounting for a 20% attrition rate. This will result in approximately 600 patients providing baseline and 6-month follow-up data for analysis, accounting for attrition.

The assumption of approximately 18-30 participants at each CBOC in each 6-month period does not represent the maximum that can be recruited at a site in any six-month period; it is a possible average based on our experience in the first six-months of recruitment. We will recruit all eligible participants at the study sites as described elsewhere in the protocol.

Direct Access to Source Data/Documents:

Only authorized persons will have access to the information gathered in this study. Authorized persons may include regulatory agencies such as, the Government Accounting Office (GAO) or the Office for Human Research Protection (OHRP), Office of Research Oversight (ORO), as well as members of the Research Administration staff of CAVHS.

Data Safety and Monitoring Plan:

Although unlikely and unanticipated, a possible risk for this study is loss of confidentiality. All data will be managed to minimize the risk of loss of confidentiality. Consent forms and raw data forms will be stored in locked file cabinets in locked offices, or will be stored on the password protected VA computer network as appropriate. Study staff will only have access to the data they need for their work. Participants' names and contact information will not be included in the main study database nor in any datasets used for analysis. Instead, participants will be identified by study ID code only. A table linking participants' names with their study IDs will be stored in a separate database on the server. Only investigators and the research staff (including the study programmer) will have access to the key linking participants' names and study ID codes. The identifiers will be destroyed as early as possible as allowed by VA policies. All study databases will be stored on the secure VA network, not on local hard drives. Specifically, data will be stored on the HSR&D Service Drive at \\VHAV16FPC42.V16.MED.VA.GOV\PI Project Folders\Owen\Adapting and Implementing the Blended Collaborative Care Model in CBOCs. Data will also be stored on VA VINCI. The study protocol will be submitted to the CAVHS IRB and R&D Committee for approval before research begins.

Ethics:

This study will comply with principles of the Belmont Report. Ethical considerations specific to this study include the potential for loss of confidentiality. To avoid loss of confidentiality in any publication or other communication based on this data, no information specific enough to identify a participant will be included.

Data Handling and Recording:

Data will consist of questionnaires filled out by participants, qualitative data from interviews, and data extracted from the CDW. All data, other than CDW data extracts and required electronic enrollment logs, will be de-identified according to VHA policy for truly de-identifying data. All paper materials, including consent forms, will be stored in CAVHS building 58, rooms 105A or 254 (the private offices of the study coordinator and the PI) in a locked filing cabinet. Databases consisting of the data collected will be maintained in files on the password protected, secure VA HSR&D server \\VHAV16FPC42.V16.MED.VA.GOV (see above folder location) and VA VINCI. Removal of study access will be completed for research personnel when they are no longer part of the research team. Records will be retained indefinitely until the VA RCS has been revised regarding disposition of research records. VA approved methods will be utilized to destroy data when permitted.

If, in spite of the implemented precautions, participant data is lost, stolen, or compromised, it will be reported immediately to the PI. The PI or designee will report the event to the IRB, the ISO, the PO, and the ACOS/R&D as soon as possible, but no longer than 1 hour after learning of the breach of confidentiality.

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