

# **TELEMEDINCE FOR PTSD (TOP) IMPLEMENTATION PROJECT**

**Protocol**

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## A. Specific Aims

Rural Veterans with PTSD treated at CBOCs experience little to no improvement in their symptoms over time. A major contributor of poor PTSD outcomes is that trauma-focused evidence-based psychotherapy is not being provided to Veterans in the CBOC setting. Moreover, long travel distances and other travel barriers prevent most rural Veterans from receiving trauma-focused evidence-based psychotherapy from a PTSD Care Team (PCT) or Behavioral Health Interdisciplinary Program (BHIP) located at parent VAMCs. The Telemedicine Outreach for PTSD (TOP) *promising practice* is a technology-facilitated virtual care clinical intervention that is designed to enhance access to evidence based psychotherapy and pharmacotherapy. The VA Office of Rural Health (ORH) intend to deploy the TOP promising practice nationally with support from the Virtual Specialty Care QUERI program. The proposed project will lay the ground work for this national implementation initiative.

**Impact Goal** - The goal of this proposed Type III Hybrid effectiveness-implementation project is to support the national deployment of the TOP promising practice and evaluate its clinical effectiveness in routine care.

To achieve this goal, the following three specific aims are proposed.

### **Specific Aim 1 – Compare the effectiveness of a standard VA implementation strategy to an enhanced implementation strategy in promoting uptake of TOP.**

*Hypothesis 1 – For sites not implementing TOP performance metric benchmark with a standard implementation strategy, those randomized to the enhanced implementation strategy will have better reach and engagement outcomes than those randomized to continued standard VA implementation. Reach is defined using two variables: 1) the likelihood of having a care manager encounter and 2) the likelihood of having an evidence based psychotherapy encounter. Engagement is defined using two variables: 1) the likelihood of having 8 care manager encounters and 2) the likelihood of having 8 evidence based psychotherapy encounters.*

### **Specific Aim 2 – Determine if implementation of TOP in routine care improves PTSD outcomes for rural Veterans.**

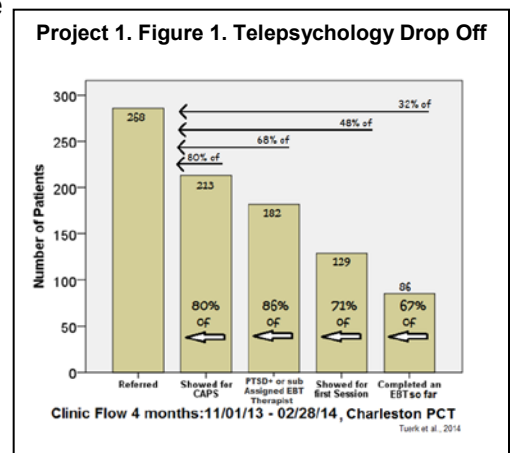
*Hypothesis 2 –For sites not implementing TOP performance metric benchmark with a standard implementation strategy, those randomized to the enhanced implementation strategy will have better perceived access and PTSD outcomes than those randomized to continued standard VA implementation.*

## B. Rationale

Over half a million veterans (n=502,546, 9.2%) enrolled in the VA healthcare system were diagnosed with PTSD in 2012, including 119,482 veterans (23.6%) who served in OEF/OIF/OND. Although psychotherapy and pharmacotherapy for PTSD have proven to be efficacious in RCTs and have been disseminated widely by VA, stigma and geographical barriers often prevent rural veterans from engaging in these evidence-based practices. A large portion (38%) of VA enrollees diagnosed with PTSD live in rural areas, and two thirds live closer to a CBOC than to a VAMC. While it is typically not feasible to hire on-site psychiatrists or psychologists with PTSD expertise at many CBOCs, it is critical to improve PTSD treatment in the accessible CBOC setting.

**Patients Fall Through the Cracks** - Enhancing the referral rate from primary care to specialty mental health care is notoriously difficult, even in an integrated system of care like VA. Figure 1 demonstrates that referral drop off at a trauma-focused evidence-based telepsychotherapy program at one of our study sites that has a short appointment wait time (<7 days) and a sophisticated referral tracking system that uses frequent appointment reminders. Less than half of Veterans with PTSD who are referred attend one session and less than a third complete treatment. Clearly, the better we can integrate trauma-focused evidence-based psychotherapy into Patient Aligned Care Teams (PACT) and Primary Care Mental Health Initiative (PCMHI) the better.

**Collaborative Care** - Collaborative Care (e.g., TIDES, Behavioral Health Lab) is an evidence based model of care that has been shown to improve depression and anxiety outcomes in nearly 80 RCTs. The collaborative care model operationalizes the principles of the chronic care model to improve access to evidence based



mental health treatments for primary care patients. Collaborative care is an integral component of PCMHI, although relatively few patients with PTSD are enrolled in a collaborative care program.

**Telemedicine Based Collaborative Care for Rural Veterans** - Telemedicine Based Collaborative Care is an evidence-based adaptation of the collaborative care model that leverages telehealth, eHealth and potentially mHealth technologies to facilitate digital communications among a virtual care team. Telemedicine Based Collaborative Care for depression is feasible to implement in CBOCs and is clinically- and cost-effective when implemented in routine VA care. Drs. Morland and Tuerk (Co-Is) have demonstrated that Cognitive Processing Therapy (CPT) and Prolonged Exposure (PE) Therapy can be feasibly and effectively delivered via interactive video. Thus, it is feasible to incorporate trauma-focused evidence-based psychotherapy into telemedicine based collaborative.

**Telemedicine Outreach for PTSD (TOP) RCT** - PTSD is more treatment resistant than depression and collaborative care does not always improve outcomes. The key element to successful collaborative care for PTSD appears to be enhancing access to trauma-focused evidence-based psychotherapy. In a recent pragmatic RCT conducted in 11 CBOCs in four states, Dr. Fortney (PI) evaluated the effectiveness of Telemedicine Based Collaborative Care for PTSD (TOP) that enhanced access to CPT by providing it via interactive video technology in the CBOC setting. The virtual care team was comprised of on-site CBOC providers and off-site telephone care managers, telepsychologists and telepsychiatrists. Over half (54.9%) of patients randomized to TOP initiated CPT compared with only 12.1% of patients randomized to usual care (OR=18.1,  $P<0.001$ ). Likewise, 27.1% of patients randomized to TOP completed  $\geq 8$  or more sessions of CPT compared with only 5.3% of patients randomized to usual care (OR=7.9,  $P<0.001$ ). As a result, patients randomized to TOP had significantly larger reductions in PTSD symptom severity at the 6 and 12 month follow-ups ( $p=0.02$  and  $p=0.04$ ).

### C. Procedures

**Setting** – The project will be conducted at 6 VAMCs in 6 states. There is considerable variation across these sites with regard to how PTSD services are organized, as well as the adoption of virtual technologies. CBOCs served by these 6 VAMCs without on-site psychiatrists and psychologists (trained in CPT or PE) will be included.

**Population** – The TOP RCT (described above) enrolled Veterans with a diagnosis of PTSD who were currently symptomatic and were not engaged in specialty PTSD care in the past six months. Using administrative data from CDW, we will identify all Veterans at participating CBOCs with a PTSD diagnosis, positive PTSD annual screen (PC-PTSD $\geq 3$ ) and no encounters in a specialty mental health clinic (according to stopcode) at the VAMC in the past six months. We will sample Veterans from this group and administer the 20-item PTSD Check List for DSM-5 (PCL-5) by phone to assess whether they are currently symptomatic and ask questions about geographical, temporal and cultural access to care. Veterans ( $n=100$ ) will be sampled in each of four time periods (pre-implementation and three implementation steps) for a total sample size of 600. Local clinicians at implementation sites will have the flexibility to decide who is eligible to receive the TOP promising practice, but we expect there to be considerable overlap between those who are eligible for the evaluation and those who are targeted for the promising practice at each site.

**TOP Promising Practice** – TOP is delivered by a virtual care team comprising a CBOC provider, telephone care manager, telepsychologist and telepsychiatrist. The telephone care manager activities include: education, activation, barrier assessment/resolution, medication adherence and side-effect monitoring, therapy/homework adherence monitoring and symptom monitoring. Another element of care management is coordinating the transition from PCMHI or PACT team to specialty PTSD care and back again after the completion of time limited psychotherapy. The telepsychologist activities include the delivery of trauma-focused evidence-based therapy (e.g., CPT or PE). The telepsychiatrists activities include conducting case reviews and psychiatric consultations. The core element of the TOP intervention is a case review by the virtual care team (telephone care manager, telepsychologist and telepsychiatrist) of all patients newly enrolled in care management and all those not responding to treatment, along with documentation of the case review in CPRS for the CBOC provider. There is also a considerable degree of flexibility in the how the TOP model is implemented. The telephone care manager can be administratively housed in PACT, PCMHI, BHIP, or PCT. The care manager can use Behavioral Health Lab software or the TIDES-PTSD templates as the registry. The trauma-focused evidence-based therapy can be either CPT or PE. The telepsychiatry and telepsychology can either be delivered via interactive video to the CBOC or via clinical video telehealth to home. The Veteran and the telepsychologist can choose to use smartphone apps (CPT Coach or PE Coach) designed to augment these two trauma-focused evidence-based therapies.

**Standard VA Implementation Strategy (Control)** – The standard VA implementation strategy will focus on internal facilitation. Standard VA implementation strategies will include disseminating the TOP Clinical Protocol, TOP Implementation Guide and care manager training modules, as well as technical support from the facility level telehealth technician. The TOP Implementation Guide is intended to be used by the internal facilitator (i.e., local clinical champion). The facility level telehealth technician will provide technical support to providers in the use of interactive video and clinical video telehealth to home. In addition, using ORH *matching funds*, each VAMC will receive a full-time telephone RN care manager for three years devoted to managing CBOC patients with mental health disorders including PTSD.

**Enhanced VA Implementation Strategy** – The enhanced implementation strategy will include both internal and external facilitation. External facilitation will begin with an assessment of the current workflow at the VAMC and the affiliated CBOCs. **Qualitative Interviews (Formative Evaluation)** – Using Rapid Ethnographic Assessment methods, Dr. Reisinger will conduct site visits at each VAMC and conduct telephone interviews with CBOC staff. To assess clinical workflow, she will observe the administrative structure of the clinical units, staffing patterns, scopes of practice, service mix, standard operating procedures (e.g., patient check-in, screening, referrals, coding), job descriptions and annual evaluation criteria, and use of technology including telehealth, eHealth, mHealth, and CPRS. For the TOP promising practice, key clinical workflow elements include: 1) how patients are referred to the care managers, 2) whether care managers are located at the VISN, VAMC or CBOC and whether they are part of PCT, BHIP, PCMH or PACT, 3) what type of psychotherapy is provided at the CBOC (e.g., anger management, PTSD groups, etc.), 4) formulary restrictions and prescribing patterns, 5) how psychiatric consultations are arranged, 6) how frequently patients are seen in mental health and primary care, caseloads, and wait times, 7) appointment scheduling procedures for mental health and primary care, 8) no show rates, 9) care manager software availability, 10) use interactive video, clinical video telehealth to home, SmartPhone apps, 10) use of psychiatric rating scales, and 11) how workload credit is distributed. Dr. Reisinger will also conduct key informant interviews with providers to gain an in-depth understanding of these issues. During the site visit, Dr. Reisinger will invite clinicians to participate in the interview. The qualitative interviews will be voluntary, anonymous and confidential. Interviews are expected to require 30 minutes and with the verbal permission of the interview will be audio-recorded and transcribed. The internal and external facilitation team (local clinical champion, Dr. Reisinger and Dr. Fortney) will then generate a clinical workflow chart that describes the current process of care. The internal and external facilitators will then incorporate the clinical process of the TOP promising practice (including use of technology) into the current clinical workflow chart, making changes to the TOP promising practice and/or current clinical workflow as needed. The internal facilitator will also meet monthly with external facilitators to troubleshoot and make refinements.

**Study Design** – We will use an Adaptive Stepped Wedge trial design for this proposed Type III Hybrid Effectiveness-Implementation study. The study will compare the effectiveness of the standard VA implementation strategy to the effectiveness of the enhanced implementation strategy. **This design will allow us to compare rates of patient reach, as well as to document improvements in the clinical outcomes of patients at sites that successfully implement the TOP intervention.** We will begin by collecting *pre-implementation* effectiveness data from a sample of patients with a PTSD diagnosis and not engaged in specialty PTSD care and assess them for eligibility by administering the PCL-5 over the phone. Next we will initiate the standard VA implementation strategy staggered over nine months at all six VAMCs and their affiliated 12 CBOCs. After a nine month start-up phase, we collect reach, access, and effectiveness data from the sample of patients. To conduct the Adaptive Stepped Wedge trial design it will be necessary to specify a **performance measure benchmark** that will be used to determine whether the initial implementation effort is successful. The performance measure benchmark will be 75 patients enrolled in care management in 9 months AND 35% of enrolled patients initiating evidence based psychotherapy for PTSD (Prolonged Exposure Therapy, Cognitive Processing Therapy, or EMDR). If the performance measure benchmark is attained, the VAMC will discontinue the standard VA implementation efforts, but we will continue to collect evaluation data to assess maintenance and sustainability. If the performance measure benchmark is not attained, the VAMC will be randomized to either continued standard VA implementation strategy or the enhanced implementation strategy in the next step. After another 9 months, we will again collect reach, access, and effectiveness data from the sample of patients. If the performance measure benchmark is attained in the second step at standard or enhanced implementation sites, the VAMC will discontinue implementation efforts. If the performance measure benchmark is not attained at standard implementation sites, the VAMC will receive the enhanced implementation strategy in the next step. If the performance measure benchmark is not attained at enhanced implementation sites, the VAMC will continue to receive enhanced implementation.

**Outcome Measures** – The evaluation of the implementation strategies will be based on the RE-AIM framework. Data will be collected from patient survey, CDW, and chart review for all patients sampled for the evaluation. For sampled patients, **reach** will be measured as whether there was documentation in CPRS of a care manager encounter and evidence based psychotherapy encounter. For each patient sampled, effectiveness data will be collected at four different time points. The first time point will be shortly after they are sampled at three nine month follow-ups. **Effectiveness** will be specified as a continuous change in the PCL-5 score between baseline and follow-up. **Perceived Geographic, Temporal and Cultural Access** will be measured with three survey questions. 1. “How much does having to travel to VA appointments interfere with getting the PTSD services you want?” 2. How much does having to wait for VA appointments interfere with getting the PTSD services you want?” 3. “How much does lack of trust in VA providers interfere with getting the PTSD services you want?” The response options are 1. Does not interfere at all, 2. Interferes a little bit, 3. Interferes somewhat, 4. Interferes a great deal, or 5. Completely interferes, with higher scores representing a greater barrier.

**Costs** –We will measure the cost of both implementation strategies and intervention services. The duration of implementation activities will be documented by the internal and external facilitators using an excel spreadsheet. Costs will be categorized into implementation phases and activities and will include the cost of both the facilitators and other stakeholders. The time spent by facilitators and other stakeholders will be multiplied by their hourly salary to estimate costs. The implementation cost of the internal and external facilitators and the stakeholders will be determined by multiplying each persons’ time spent on implementation by each persons’ salary taken from the VAs Personnel and Accounting Data (PAID) System database. The PAID systems is housed in CDW. Intervention costs will be measured from CDW.

**Qualitative Interviews (Summative Evaluation)** – The summative evaluation of implementation efforts will also be assessed using key informant interviews. We will conduct qualitative interviews with CBOC and VAMC staff identified in the excel spreadsheet. These staff will be emailed to invite them to participate in the interviews. Staff will include clinical and administrative leaders in their organization. **The qualitative interviews will be voluntary, anonymous and confidential.** Interviews are expected to require 30 minutes and with the verbal permission of the interview will be audio-recorded and transcribed. During the interviews, we will ask about the success of the implementation as well as barriers and facilitators to adoption, including their perceived benefits and weaknesses of the TOP model.

**Data Analysis** – The Adaptive Stepped Wedge design allows us to estimate the effectiveness of the implementation strategy by comparing adoption and reach between groups of VAMCs randomized to standard or enhanced implementation and by comparing adoption and reach over time within the same VAMC as it is transitioned from standard to enhanced implementation. The adoption regression will be estimated using providers as the unit of analysis and the reach regression will be estimated using patients as the unit of analysis. With 500 patients (accounting for attrition), we will have 80% power to detect an increase in reach from 15% to 26%. The explanatory variable will be whether the VAMC was randomized to standard VA implementation or enhanced implementation during the time period. Likewise, by collecting PCL-5 scores pre-baseline and again throughout each implementation step, we will be able to compare the clinical outcomes of patients between VAMCs successfully implementing TOP to those not successfully implementing TOP and by comparing clinical outcomes over time within the same VAMC as it is transitions to successful implementation. **This will allow us to estimate the clinical effectiveness of the TOP promising practices as implemented in routine care.** Following intent to treat principals, we will estimate the clinical effectiveness of TOP for the entire sample regardless of whether they were reached to generate a measure of **population level effectiveness.** Generalized linear models will be used to account for the clustering of patients within VAMCs. VAMCs will specified as random effects. Patients will be specified as the unit of analysis and data from all VAMCs not achieving benchmarks will be included. No casemix variables will be included.

#### **D. Impact**

The proposed project will have two major impacts. First, it will help ORH identify the most effective and cost-effective implementation strategy for rolling out promising practices that involve virtual care teams, along with the budget impact. Second, it will improve rural Veterans access to and engagement in evidence-based PTSD treatments and strengthen VA’s reputation as the healthcare system of choice for rural Veterans.