r01\_protocol

Trial registration: The trial is registered at ClinicalTrials.Gov: \_\_\_\_\_\_\_\_\_\_\_\_\_\_#. Registered MONTH, DAY, YEAR, [https:// clinicaltrials.gov/INSERT](https://clinicaltrials.gov/ct2/show/NCT02675777) LINK.

Abstract

Background: In Veterans Health Administration (VA), alcohol and opioid use disorders (AUD/OUD), depression and PTSD comprise the majority of outpatient addiction and mental health needs (Elbogen et al., 2013; Hermes et al., 2014; Mott et al., 2015). Highly effective treatments for these conditions, such as evidence-based psychotherapy (EBPsy) and evidence-based pharmacotherapy (EBPharm) reach only 3-28% of patients (Fulton et al., 2015; Hankin et al., 2014; Hoggatt et al., 2015). National evidence-based practice (EBP) dissemination programs (Eftekhari et al., 2013; Karlin et al., 2012; Karlin and Cross, 2014; Ruzek et al., 2012; Watts et al., 2014), policies,(Department of Defense and Department of Veterans Affairs, 2009, 2009; Veterans Affairs, 2014) incentivized quality measures, (Harris et al., 2009; Lemke et al., 2017) and EBP-focused electronic health records (Rosen et al., 2016) have been insufficient for greater EBP reach, (Harpaz-Rotem and Rosenheck, 2014; Mott, Mondragon, et al., 2014; Seal et al., 2010) key to preventing chronic impairment, relapse, overdose, (Degenhardt et al., 2010; Harris et al., 2015; Kaplan et al., 2007; Lin et al., 2015) and suicide (Desai et al., 2014; Gradus et al., 2013) among Veterans. Using the Participatory System Dynamics (PSD) theory of change as a framework, the specific aims of this R01 are to define EBP reach as a system behavior and to engage VA frontline staff in systems thinking to improve EBP reach.

Methods/Design:

Discussion:

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**Background**

Providers, patients, policy makers and scientists each have a stake in ensuring all patients with alcohol use disorder (AUD), depression, PTSD and opioid use disorder (OUD) receive timely, evidence-based care. In Veterans Health Administration (VA) these common, costly conditions comprise the majority of outpatient addiction/mental health needs (Elbogen et al., 2013; Hermes et al., 2014; Mott et al., 2015). But, highly effective treatments, such as evidence-based psychotherapy (EBPsy) and evidence-based pharmacotherapy (EBPharm) reach only 3-28% of patients (Fulton et al., 2015; Hankin et al., 2014; Hoggatt et al., 2015). National evidence-based practice (EBP) dissemination programs (Eftekhari et al., 2013; Karlin et al., 2012; Karlin and Cross, 2014; Ruzek et al., 2012; Watts et al., 2014), policies,(Department of Defense and Department of Veterans Affairs, 2009, 2009; Veterans Affairs, 2014) incentivized quality measures, (Harris et al., 2009; Lemke et al., 2017) and EBP-focused electronic health records (Rosen et al., 2016) have been insufficient for greater EBP reach, (Harpaz-Rotem and Rosenheck, 2014; Mott, Mondragon, et al., 2014; Seal et al., 2010) key to preventing chronic impairment, relapse, overdose,(Degenhardt et al., 2010; Harris et al., 2015; Kaplan et al., 2007; Lin et al., 2015) and suicide (Desai et al., 2014; Gradus et al., 2013) among Veterans.

We define reach as the proportion of the outpatient population who initiate an EBP and complete a therapeutic course. Implementation gaps for depression, PTSD, AUD and OUD patients (Table 1), reflect the complexity of identifying optimal health system improvements. Too few VA patients receive EBPsy even in specialty programs (Shiner et al., 2013; Watts et al., 2014). Improving reach involves interdependent fixes within and across programs (e.g., general vs. specialty), meeting a variety of common, and often comorbid patient needs (e.g., mental health/addiction), by multidisciplinary teams with varying capacities/expertise (e.g., EBPharm prescribers vs. EBPsy providers). What generally causes limited EBP reach under these conditions?

Current strategies are insufficient for improving reach of evidence-based practices (EBPs). Ten years of VA nationwide programs to disseminate, train, track and incentivize evidence-based psychotherapy (EBPsy) for PTSD and depression patients, and evidence-based pharmacotherapy (EBPharm) for patients with depression, opioid use disorders (OUDs) and alcohol use disorders (AUDs) has been insufficient for reaching adequate proportions of these patient populations (see Table 1). Opiate and alcohol misuse, depression and PTSD, are the primary reasons Veterans seek outpatient VA addiction and mental health care (Elbogen et al., 2013; Hermes et al., 2014; Mott et al., 2015). Yet, at the median (see Table 1),less than 60% of PTSD patients, and less than 40% of depression patients, start psychotherapy of any kind. Only 28% of depression patients starting EBPharm receive a therapeutic course, and 71% of OUD patients do not initiate EBPharm. Among depression and PTSD patients who start psychotherapy, only 30-44% are retained for at least 3 visits. Only 3-5% of depression and PTSD patients start EBPsy (see Table 1).

**Table 1. VA SAIL Quality Measures & R01 Study EBP Reach (Q1 2017)**

Audit and Feedback (AF) *strategies have been insufficient to* maximize EBP reach. VA/DOD clinical practice guidelines, national EBP training and consultation programs, EBP note templates in electronic health records, and VA quality measures known as Strategic Analytics for Improvement and Learning (SAIL) (Department of Defense and Department of Veterans Affairs, 2009; Department of Veterans Affairs, 2008; Lemke et al., 2017; Rosen et al., 2016; Veterans Affairs, 2014) were all developed, due to the efficacy of EBPsy and EBPharm (see Table 1) for reducing PTSD (Bradley et al., 2005; Powers et al., 2010) and depression (Cuijpers et al., 2011; Fournier et al., 2010; Powers et al., 2009; Stewart et al., 2014; Walser et al., 2013), alcohol (Anton et al., 2006; Knudsen and Roman, 2016a, 2016b; Pettinati et al., 2006) and opioid misuse (Barnett et al., 2001; West et al., 2001) and reducing risk of death by suicide or overdose (Degenhardt et al., 2010; Gradus et al., 2013). VA dissemination programs also demonstrate EBPsy/EBPharm effectiveness. Patients who received cognitive behavioral therapy (CPT) for depression experienced a 40% reduction in depression symptoms and over 60% of Veterans who received prolonged exposure (PE) experienced clinically significant improvements in PTSD (Eftekhari et al., 2013). VA’s multicomponent strategy of: 1) setting guidelines, 2) providing training/resources to meet guidelines, 3) tracking performance, and 4) providing feedback to identify gaps or progress, form the chief principles of AF benchmarking in any health system (Harris et al., 2009; Ivers et al., 2012; Lemke et al., 2017). But, AF systemic reviews show AF must also provide actionable insights to gain increases in EBP reach (H. L. Colquhoun et al., 2017; Hysong, 2017, 2009; Hysong et al., 2006, 2012; Ivers et al., 2014).

Proposed Theory of Change

The Participatory System Dynamics (PSD) theory of change is that participatory stakeholder co-learning from modeling enables new capacities for managing system dynamics or mechanisms of change (Forrester, 1985; J. D. Sterman, 2006a). Informed by 60 years of PSD research, this R01 aims to define EBP reach as a system behavior, and test the PSD theory of change that grasp of system dynamics (mechanisms of change) is not just for scientists. Rather, systems thinking by frontline staff, is the basis for improving EBP reach. We briefly highlight limits of extant implementation science (IS) theories of change, and tests of mechanisms of change, focusing on what a PSD paradigm adds to IS, and its advantages over audit and feedback (AF).

PSD posits that participatory learning from modeling can build new capacities for managing systems change and build systems thinking skills (Andersen et al., 2007; Vennix, 1996) (Bendoly, 2014; Rouwette et al., 2002). PSD learning occurs through real-time visual emergence of local causes of EBP reach in virtual experiments (Forrester, 1985; Hirsch et al., 2014; Lich et al., 2014). Simulations are a safe way to build systems thinking in to EBP decisions (Bendoly, 2014; Derickson et al., 2015; Edmondson, 1999). Based upon the premise that EBP reach in health service delivery is a function of local resources (Oliva, 2003; Zimmerman et al., 2016), a set of SD models were built and tailored to four types of VA health services: Care Coordination, CC; Medication Management, MM/EBPharm; Psychotherapy, Psy/EBPsy; and Aggregate, Agg.

**Aims**

Our primary aim is to increase the proportion of the patient-population within PSD clinics that receive EBPs (reach: initiate/course). Using PSD and AF with outpatient mental health teams, this study will achieve the following specific aims:

**Aim 1.** Test superiority of PSD over AF for increasing EBP initiation and course. The proportion of patients (1a) initiating EBPsy/EBPharm, and (1b) completing an adequate EBPsy/EBPharm course, will significantly increase in PSD clinics as compared to AF clinics, in omnibus tests across EBPs for (1a) initiation, and (1b) course, using clinic 12 month pre/post period EBP reach averages.

#### Aim 2. Test PSD theory of change that increased EBP reach is via systems thinking (Forrester, 2009, 1994; Rahmandad et al., 2009). The effect of PSD/AF on 12 month period EBP reach will be explained by 6 month team systems thinking (STS), in ratio of mediator probability weight (RMPW) mediation analyses using the R ‘MultisiteMediation’ package (Hong, 2010; Hong et al., 2015; Qin and Hong, 2014).

#### Aim 3. Test the generality of mechanisms of change in EBPsy/EBPharm PSD models. Structural-behavioral validation tests (Barlas, 1996; Homer, 2012; Rahmandad and Sterman, 2012) of causal dynamics formulated in our Psy/EBPsy and MM/EBPharm models will generalize to explain EBP reach as a function of local data across PSD and AF clinics (in Plan).

We contextualize aims 1-3 using provider surveys of the clinic-level learning organization survey (LOS-27)(Singer et al., 2012) team-level decision-making questionnaire (TDMQ) (Batorowicz and Shepherd, 2008) and burnout (PACT) (Dolan et al., 2015; Helfrich et al., 2014, 2017; Nelson et al., 2014), and PSD/AF feasibility, acceptability and appropriateness (FIM, AIM, IAM) (Weiner et al., 2017). We enlist qualitative/observational coding of PSD/AF fidelity, systems thinking (Sweeney and J. D. Sterman, 2000a) during team decision-making, and online PSD/AF use and sustainment (Landis-Lewis et al., 2015; Liberati et al., 2017).

**Methods**

**Study design**

We propose a parallel two-arm, 24-site (12 clinics/arm) cluster randomized trial (CRT) to establish superiority of PSD over usual AF for increasing EBP reach. CRTs are best for complex interventions like PSD, with many interacting components, and in which the unit of intervention and observation is the clinic (Campbell and Walters, 2014). The number of clinics and number of patients per clinic define total CRT size. Cluster size is defined by the eligible AUD, depression, PTSD, OUD patient cohorts. Clinic proportion (reach), is the sum of patient-level EBP reach in usual care: patients receive (1) or do not receive (0) an EBP (binary).

Computer-assisted stratified block randomization with the R package ‘blockrand’ (Snow, 2015) will balance arms (6 clinics/wave over four waves) at baseline using VA data. We stagger start dates every 6 months (2 rounds of 5 small PSD clinics/5 small AF clinics, followed by 1 large PSD clinics/1 large AF clinic), to mitigate cohort effects, making management of multi-site relationships feasible.

Virtually facilitated AF/PSD workshop sessions (see Table 9) are designed for teams of providers (typically 5-10/team) from each clinic, with no cap on total providers (typically ~20-40 staff). Frontline leadership and one ‘champion’ from each service delivery team will receive additional PSD resources to operate as an internal facilitator for their team. Mental health staff will be eligible to receive continuing education credits for AF (2 credit hours) and PSD (12 credit hours) workshops from VA Employee Education Service (EES) for six primary frontline disciplines: psychiatry, psychology, social work, counseling, nursing and certified peer-support.

We propose 60 total months of study activities and 30 months of active PSD facilitation or post-training technical assistance (phases 3 and 4). This leaves 24 months of flexibility for delays across pre (phases 1 and 2) and post (phases 5 thru 8) activities (Table 10).

AF participants will engage during two regular team meetings in 1 month (2 hours), and receive weekly emails for 6 months; PSD participants will engage during two regular team meetings over 6 months (12 hours), with weekly emails for 6 months (Strategy AF/PSD Workshop Training and AF Dynamic Data Tools). AF/PSD will occur during normal meetings, substituting only the activities used to improve quality objectives.

For each wave, we use 12-month period average of EBP reach before AF/PSD start (pre-measure) and 12-month period average of EBP reach after AF/PSD end (post-measure).

#### Inclusion/Exclusion Criteria for Study Clinics.

We will randomize and complete the PSD ‘Modeling to Learn’ virtual workshop with VA divisions (VAMCs) and community-based outpatient clinics (CBOCs) or ‘clinics.’ Eligible clinics will be from regional VA health care systems (HCS) below the overall SAIL quality median, and 3 of 8 SAIL measures associated with 4 EBPsy and 3 EBPharm for AUD, depression, PTSD, and OUD in Table 1. Inclusion criteria balance sensitivity and specificity in identifying clinics from lower performing HCS.

Once identified via SAIL/CDW, recruitment will occur via OMHSP, NCPTSD, EBP Coordinator, and VISN Mental Health Lead networks (see Section 2.5 - Recruitment and Retention Plan). Clinics must have HCS director assent to randomization. Each clinic will be from a separate health care system (1 clinic/health care system). Analyses will control for clinics nested within VA (Campbell and Walters, 2014). Given known PSD interest, and R01 partner support, recruiting 12 clinics from these networks should be highly feasible, enhanced by 18 months total pre/post flexibility (see Table 10).

#### Intraclass Correlation Coefficient (ICC).

Intraclass Correlation Coefficient (ICC) was used to estimate the variance inflation factor/design effect for clustered data, a parameter for determining the number of clinics needed for tests of specific aims. Using R and the ‘ICC’ package (Bates et al., 2017; Wolak, 2015) we analyzed a 2-year database extracted from the CDW to estimate the ICC of EBP reach for clinics nested within the VA health care system, and repeated observations of clinics over time. Across EBP initiation and course, values were low (Rotondi, 2015; Rotondi and Donner, 2012) ranging from low ICCs (< 0.0001) between clinics, to higher ICCs (~ 0.006) for repeated within-clinic observations. These ICC values indicate near independence (Rotondi, 2015; Rotondi and Donner, 2012), and are consistent with pilot work identifying significant differences between clinics, and high within-clinic variability in EBP reach over time (Zimmerman et al., 2016).

#### Mediation analyses.

Tests of Aim 2 are assessed on same between-clinic level: Clinics are assigned randomly to AF or PSD. We will use the clinic observation of team-means across arms as our mediator, and the clinic EBP reach as our outcome. Our mediator is adequately powered (d = .78) (Moore et al., 2010).

#### Average Clinic Cluster Size.

ICC and average cluster size are key to determining CRT power, accounting for variance inflation due to clustering. Our pre/post EBP reach measure is the 12-month period average of 12 monthly EBP reach observations. In our 2-year CDW database, median clinic size was ~800 unique patients/month summed across diagnostic cohorts (AUD + depression + PTSD + OUD diagnoses).

#### Power analyses.

We used ‘CRTSize’ (Rotondi, 2015; Rotondi and Donner, 2012) in R to calculate the number of clinics necessary to balance type 1 error (alpha), type 2 error (beta), and power, for a CRT with a binary outcome (difference in proportions). Omnibus EBPsy/EBPharm initiation (Aim 1a) is the limiting power analysis (Rotondi, 2015; Rotondi and Donner, 2012). Effect size: We expect a 5% initiation increase in PSD clinics (from ~5 to 10%), which would meaningfully double omnibus EBP reach to exceed the national median. We expect little/no change in AF clinics (~ 5 to 5%). Thus, we expect PSD intervention will to lead to a 5% difference in EBP reach between PSD and AF arms. With 11 clinics/arm we have power = 0.80 to detect a 5% difference in EBP initiation (two-tailed test, alpha = 0.05, average clinic/cluster size of 800, and ICC = 0.02). However, we will use an even 12 clinics/arm, better for stratified block randomization (Snow, 2015). Power analyses used ICC = .02, because our STS team-mean measures should become more similar after PSD/AF, leading to higher ICC values than in our CDW clinic population database (Campbell and Walters, 2014).

#### Attrition.

Attrition of providers or patients will not impact analyses for specific aims. Provider PSD participation will be tracked as a PSD fidelity check, but patient attrition is included by definition in EBP reach measures, and use of provider attrition in team-average (mean) survey measures means the only loss of data would be due to loss of an entire clinic team. Our R21 pilot testing indicates it is unlikely that care teams will attrit. Should clinics attrit after randomization, they will be included in intent-to-treat analyses using CDW data.

## Research Plan

### Implementation Science (IS) - Determining what works, why and under what conditions

Understanding causes of limited EBP reach is critical to our stakeholders and to our field. IS seeks to determine why and under what conditions a strategy increases EBP reach (Brownson et al., 2012; Glasgow et al., 1999; Proctor et al., 2011). Over 61 IS frameworks elaborate multiple domains (Damschroder et al., 2009; Powell et al., 2015) and doing so, underscore limited knowledge of their underlying dynamic, multi-causal premises (Chambers et al., 2013).

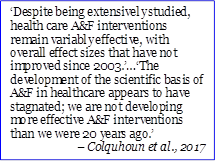
#### Mechanisms of Change (MOC)

MOCs are targets that will explain findings and accelerate research progress. Many implementation strategies produce no effect (Powell et al., 2014). Review of multilevel mechanisms of implementation strategies in controlled trials, found nine tests of mediation, all unsupported (Williams, 2016). Again, there are challenges; Confirmatory hypotheses require a strong theoretical and empirical base, as inclusion of multicollinear variables, and/or use of multiple tests both inflate error. Without a resource-intensive experimental design, use of mediating associations to infer causality is debated; ‘Mediators differ from mechanisms which invoke a higher level of specificity and describe the precise sequence of operations or underlying causal processes through which an effect occurs’ (Williams, 2016; p. 784) (Williams, 2016). Finally, multilevel mediation is in the expert domain and inaccessible to most stakeholders, with limited utility for guiding local change. Is there an alternative?

### Preliminary Research – Two Causal PSD Theories for Improving EBP Reach – AF versus PSD (Aim 1)

Based on our R21 pilot (Reference?, PSD is well suited to the need for improving EBP reach and need for IS progress in defining and testing TOC and MOC. The PSD paradigm sees the status quo ‘limited EBP reach’ as a function of the mental models that teams use to guide decisions, which are inadequate for redesigning EBP-related system dynamics [ (Cronin et al., 2009; Diehl and Sterman, 1995; Rahmandad et al., 2009; Sterman, 1989). PSD shows how ‘today’s problems come from yesterday’s solutions.’(Senge, 1990). PSD simulation learning to make system causes transparent and analyzable, increases systems thinking enabling more effective ongoing change. PSD enlists two ‘classic’ causal theories: decision theory (Aim 2 - TOC) and systems theory (Aim 3 - MOC). Distinct from IS determinant frameworks and process models, ‘Classic theories originate from fields external to IS, e.g., psychology organizational theory, which can be applied to provide understanding and/or explanation of aspects of implementation’ (Nilsen, 2015; p.8) (H. L. Colquhoun et al., 2017; Nilsen, 2015; Sales et al., 2006).

AF is central to VA EBP implementation (Lemke et al., 2017; Trafton et al., 2013) and is one of the most common IS strategies used around the world (Flottorp et al., 2010; Ivers et al., 2012). AF and PSD each require data review [Landis-Lewis et al. (2015);(Hysong, 2017). But, PSD research challenges the sufficiency of data for selecting effective changes (Sterman, 2010; Sweeney and J. D. Sterman, 2000b). AF reviews have found variability in effectiveness could be traced to the complexity of the EBP (with AF more effective for simple practices91) and the feedback audience (with AF for team practices, more effectively delivered to teams (Hysong et al., 2014, 2015). AF must be frequent, in writing, and include a correct solution (Hysong, 2009; Ivers et al., 2012). PSD agrees with need for timely, actionable feedback (Richardson, 2013, 2011). But, without systems thinking and modeling, PSD doubts the ability of policy makers to provide correct solutions for the myriad local issues that trouble EBP delivery (Garcia et al., 2014, 2011, 2015). PSD cautions, ‘The cure can be worse than the disease.’(Meadows, 2012; Senge, P.M., 2006). How might AF be counterproductive?

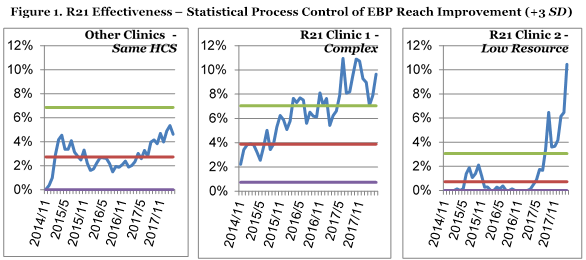


PSD uses the term policy resistance (Meadows, 2012) to describe the need for holism when making changes, represented in aphorisms such as ‘The harder you push, the harder the system pushes back’ (Senge, 1990, 1999), and ‘There are no side effects in systems. There are only effects’(J. D. Sterman, 2006a, 2006b; Sterman, 2000). System resistance does not refer to stakeholders’ attitudes; it refers to powerful dynamics of the system.

#### Preliminary Pilot

For example, prior to our R21 pilot study, our pilot partners invited us to try PSD after a previous SMART goal effort failed. The clinic set the following Specific, Measurable, Timebound goal: ‘By April 2015, 40% of patients newly seen in outpatient mental health for depression, PTSD, or anxiety disorders will have two psychotherapy visits completed within 28 days from time of intake.’ Staff saw initial improvement in scheduling (up from 25% to 65% scheduled), but wide unexplained scheduling variability was observed over 9 months (some weeks 0% scheduled, some weeks 100%), and the gap between scheduling and completing 2 visits showed the 40% goal was never achieved (new mean = 14%). In SMART terms, PSD proposes that if the goal was never Achievable, because it was not Realistic in that Timeframe with the available resources, then it may do more harm than good by 1) generating further instability of the EBP-related system behaviors (see Aim 3 Background), and 2) undermining psychological safety, or willingness to learn and try out new solutions (Bendoly, 2014; Edmondson, 1999; Singer et al., 2012) exacerbating staff burnout and risk for turnover (see Aim 2) (Derickson et al., 2015; Garcia et al., 2015; Helfrich et al., 2017).

### Preliminary R21 Data in Support of Aim 1 – PSD Effectiveness

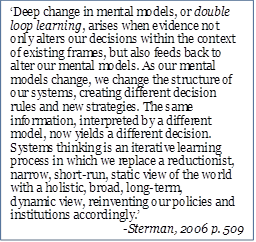
Our statistical process control analyses indicate our two R21 pilot clinics each demonstrated a three standard-deviation increase above their pre-intervention EBP reach using PSD (Figure 1; α < .003). In Figure 1, purple = lower control limit; red = clinic 12-month pre-intervention EBP reach; green = upper control limit. Control limits are three standard deviations above and below the pre-intervention mean. These clinics have maintained this improvement for 12 months and 8 months respectively, whereas the other seven VA clinics from the same regional health care system (HCS) did not improve EBP reach over this period. Moreover, we observed no secular trend toward improved EBP reach in VA national AF measures over this period. These R21 quasi-experimental findings support the proposed R01 effectiveness test: a cluster randomized trial (CRT) to evaluate for PSD superiority over standard AF. 

#### Summary (Aim 1). AF and PSD research show data review is insufficient for effective change (Rouwette et al., 2002; Rouwette and Vennix, 2006). AF effectiveness is diminished (H. L. Colquhoun et al., 2017) due to choosing ineffective strategies that leave system causes unaddressed.

### Partnering to Define EBP Reach using Systems Thinking – PSD Theory of Change (TOC) – Aim 2

Why else doesn’t AF work better? PSD explains that AF learning is also attenuated by delays between making changes and observing their real-world effects (Rahmandad et al., 2009). A recent scoping review of ‘Healthcare Learning Organizations’ found the majority principles outlined by System Dynamics (the field coined ‘Learning Organization’) (Senge, P.M., 2006; Senge, 1999) including the central idea, in which systems thinking coheres mental models, shared vision, and team learning (Akhnif et al., 2017). But, narrowed down from 263 keyword- identified articles, only 2 published studies measured systems thinking, the cornerstone of PSD research on change.

The PSD TOC defines learning as a system feedback process in which mental models are formed from feedback in the real or virtual world, which shape the rules used for decision-making, which then shapes the real world. In other words, ‘Seeing is believing and believing is seeing,’ (J. D. Sterman, 2006a) especially as we act to change the real world. This learning process is more effective with PSD modeling, called ‘double loop learning’ (Argyris and Schön, 1997; Morecroft J and Sherman J, 1994; Sterman, 2000). From the first writings of the discipline (Forrester, 1961), PSD practices are guided by decision science (Simon, 1991, 1957). PSD research identifies several cognitive biases and limitations that lead to poor decisions when facing complexity: use of heuristic mental models that seek minimally satisfying solutions rather than optimal solutions (bounded rationality) (Simon, 1957), rules of thumb that wrongly attribute the state of a system solely to inflows rather than outflows (correlational heuristic)(Sterman, 2000), and inability to solve accumulation or delay problems (stock-flow failure) (Huz et al., 1997; Powell et al., 2014; Sterman, 2000). A PSD insight is that in a complex system, cause and effect may not be closely related in time and space (Senge, 1990), rendering learning from AF alone unlikely.



#### Systems Thinking as a Mediator of Change. Figure 2 depicts the difficulty of learning from the complex, real world, as compared to the virtual world of modeling. PSD recommends simulation to improve mental models with systems thinking. Without PSD, defective causal decision rules impact explicit, effortful implementation planning (system 2 cognition) and implicit, automatic day-to-day decisions about EBP coordination and continuity (system 1 cognitions) (Evans, 2003, 2008; Evans and Stanovich, 2013). An effectiveness review of 107 PSD projects, identified more efficient improvements (33%), increased consensus (49%) and commitment to change (33%), including systems change guided and evaluated by modeling (42%) (Rouwette et al., 2002; Rouwette and Vennix, 2006). A recent mediation study showed increases in systems thinking due to PSD, that led to increased psychological safety, which increased information sharing, explaining performance improvements (Bendoly, 2014).

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### Preliminary PSD Mixed-Methods Facilitation Data in Support of Aim 2 – Systems Thinking Mediator

#### Systems Thinking during PSD model development. We used PSD best practices, including nominal group technique to generate 12 categories of (Huz et al., 1997) ‘limited EBP reach’ related issues (Andersen and Richardson, 1997; Hovmand et al., 2012). Over a period of six months of modeling we used several rounds of ‘dot voting’ to converge on PSD priorities: ‘issues’ were translated into ‘variables’ and ‘decisions’ in models (Hovmand, 2014; Hovmand et al., 2013). Our purpose was to build models that explain ‘limited EBP reach’ using providers’ new systems thinking skills. Our prompt question was: ‘What simulation will help teams within the VA learn to manage the tradeoffs in how to provide evidence-based care to Veterans?’ Four Focus areas, ‘Care Coordination,’ ‘Management Concerns,’ ‘Provider Capacities and Constraints,’ and ‘Provider Quality of Work Life’ were narrowed to 9 specific priorities (Table 2).

#### Summary (Aim 2). Systems thinking is the ability to recognize, understand, and synthesize interactions and interdependencies, including how actions and components can reinforce or counteract each other (Moore et al., 2010). Simulation learning upgrades mental models guiding daily system 1 (fast) and strategic system 2 (slow) EBP decisions in multidisciplinary teams, overcoming AF limits for learning how to improve local EBP reach (Forrester, 1994; Simon, 1957).

### Partnering to Define EBP Reach as a System Behavior – PSD Mechanisms of Change (MOC) – Aim 3

The ability to infer general principles from observations (generality) is foundational to scientific development. The ability to infer general principles from observations (generality) is foundational to scientific development. Use of PSD in Mayo Clinic identified substantial savings in the treatment of renal disease by recognizing that oscillating hemoglobin measures were caused by a mismatch between the measurement and its use in guiding clinician medication decisions (Gallaher et al., 2011; McCarthy et al., 2014). Although hired to develop an AF system, use of PSD with a multidisciplinary team recognized the problem was across hematology and nephrology. Based on the measures available, clinicians were administering a second dose before the first took effect, causing clinically acute adverse effects. Identification of this underlying biophysical dynamic was generalizable and led to Mayo Clinic-wide implementation of PSD to guide individualized dosing, which brought population-level hemoglobin within range, increased well-being of patients, and reduced costs (Gallaher et al., 2011; McCarthy et al., 2014).

Aim 3 will test whether R21 models have potential to replicate this type of advance in addiction and mental health. We hypothesize the structural-behavioral validity of our R21 models will generalize across AF/PSD arms.

In common with Community Based System Dynamics (Hovmand, 2014) we locate PSD within the continuum of participatory research (Minkler and Wallerstein, 2008; Zimmerman et al., 2016). PSD is a partnership approach that equitably involves all stakeholders’ expertise, in all aspects of the research development process, using shared decision-making activities that are designed to produce system change (Case et al., 2014; Israel et al., 2010; Minkler and Wallerstein, 2008; Wallerstein, 2006). We committed to equitable PSD resource development, valuing local staff knowledge in PSD models and activities. Unlike most AF systems, we co-created our new shared PSD assets with frontline staff (Zimmerman et al., 2016). PSD activities elicited stakeholders’ mental models about how they think EBP implementation works, with those interconnections made explicit in PSD models.

A system is set of elements interconnected in such a way that they produce their own internal dynamics (Meadows, 2012). The dynamics of a system problem cause its behavior. Many IS frameworks, and stakeholders, view a system as an external setting or organizational context (exogenous) (Aarons, 2005; Aarons et al., 2014, 2016; Brimhall et al., 2016; Damschroder et al., 2009) PSD does not. EBP reach behavior emerges from internal causes (Meadows, 2012; Sterman, 2000). Using AF, these system dynamics are hidden ‘black boxes.’ With simulation, PSD makes causal dynamics transparent in real-time. The PSD endogenous theory of ‘limited EBP reach’ is qualitatively refined with stakeholders and rigorously assessed for structural-behavioral validity (Barlas, 1996; Oliva, 2003; Rahmandad and Sterman, 2012; Senge and Forrester, 1980). The PSD endogenous view is empowering, proposing that local teams engage in mutual learning to co-create solutions that change the dynamics of EBP reach.

PSD Model Structural-Behavioral Validity is present when the model represents its purpose defining ‘limited EBP reach,’and the accuracy of its formulation is rigorously confirmed using reliable data (Barlas, 1996; Homer, 2014; Oliva, 2003; Rahmandad and Sterman, 2012; Sterman, 2000). All of these conditions were present in our R21 model validation using VA data (Lemke et al., 2017; Trafton et al., 2013; Zimmerman et al., 2016). Tests of structural-behavioral validity show how PSD reconciles the equifinal/multifinal IS paradox. The equifinal and multifinal columns in Table 3 display explanatory causal operators (structure of the equation), accounting for specific numerical values to derive the result.

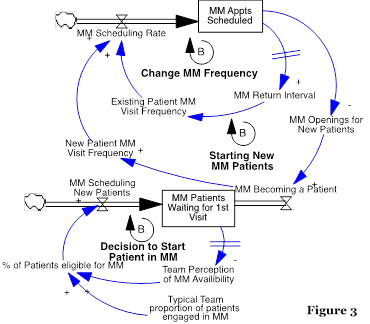
In the equifinal column of Table 3, mathematical operators demonstrate different causal relationships sometimes achieve the same result (2 out of 4 times), and sometimes don’t, even with the same numerical values. The multifinal column demonstrates the same cause achieving different results as a function of different numerical values. These mathematical facts demonstrate the key import of understanding causes.

PSD formulates generalizable feedback and stocks-and-flow equations that produce EBP reach according to system theory, when parameterized with local data to guide change. The fundamental insight of PSD, ‘Dynamics (equations) before details (specific parameter values),’ is drawn from the fundamental theorem of calculus.

### Preliminary PSD Structural-Behavioral Validity Data in Support of Aim 3.

#### Causal Stock and Flow Dynamics. We found that although stakeholders may disagree about details, rarely did they disagree about dynamics. For example, several insights are visual and clear in Figure 3, which shows how changing the ‘Medication Management (MM) Appointment Frequency’ and ‘MM Return Visit Interval’ are related, and influence the interdependent ‘New and Existing Patient Services,’ and how the units of appointments (‘MM Appts scheduled’), ‘MM New Patient’ start rate and ‘MM Patients waiting for 1st visit’ are all related. Before calibration, these interdependencies were refined qualitatively to ‘saturation.’ After several iterations with multiple teams and stakeholders no new key dynamics were identified. These issues are generic across a variety of clinical teams.

Improving team understanding of these dynamics was deemed critical by staff, particularly with regard to OUD EBPharm, which requires a very strict return, visit interval for an adequate dose among existing patients. This tradeoff with ‘Decision to start Patient in MM’ is typically managed with mental heuristics, which staff agreed would be better optimized with PSD modeling. NOTE: Figure 3 is static, but PSD simulations are temporally dynamic and show the impact of decisions in 1) real-time, on 2) EBP reach over a variety of future time horizons. We noted intent to submit a video for the R01 to show how these causal dynamics are displayed in the ‘Modeling to Learn’ Team Training (described below).



#### Calibration and Validation of PSD Models. PSD models are calibrated against existing EBP reach time-series data for each decision-making team, using Kalman Filtering and Monte Carlo methods for optimization (Oliva, 2003). Sensitivity analyses test the structural-behavioral validity of the model, which also was formulated to be consistent with seminal service system PSD models (Oliva and Sterman, 2010). Estimates for key model parameters were derived from team-specific VA health systems data, using standard definitions for diagnoses, appointments, visits, and service (Lemke et al., 2017; Trafton et al., 2013).

Figure 3 and Table 4 and Table 5 (on the next page) show PSD model dynamics and the associated parameter inputs are expected to be generic across a variety of services, patient populations and EBPs. But, parameter values are team-specific to guide local decision. Like the Mayo Clinic example, this enables participatory ‘modeling to learn’ activities at scale.

Table 5 displays example model inputs, feedback dynamics represented as provider decisions, and model equations. In addition, based on feasibility and acceptability of PSD in the R21, NCPTSD funded the development of ‘Modeling to Learn.’ This workshop and user-interface enables this specification and sophistication under the hood, and real-time causal learning simulations to frontline EBP decision-makers. NOTE: Demonstration of real-time dynamic interface used in team training is available in the 2-minute ‘Modeling to Learn’ simulation video.

#### Summary (Aim 3). PSD effectiveness of improving reach in a variety of settings is enhanced by the use of standard data definitions for model inputs and the generality of using mathematical principles to identify the common dynamics of EBP services systems. Based on the multiple iterations of stakeholder engagement and structural-behavioral validity testing, we expect that our four PSD models will explain reach in any R01 study clinic.

### Study Team and Stakeholders

Serving more than 8.9 million Veterans each year, VA is the largest health care system in the U.S., providing care at 1,053 outpatient clinics. Due to our participatory system dynamics (PSD) philosophy of science, interdisciplinary PSD application, and the scale of VA, a large team with a range of investigator, methodologist, and advisory expertise, ensures R01 success. The NCPTSD principal investigator and co-investigators have collectively facilitated many, multi-site implementation studies. R01 feasibility is further enhanced by our established partnerships. Eleven of seventeen partners collaborated effectively as R21 co-investigators or NCPTSD-funded PSD development partners (Zimmerman et al., 2016). Three new partners were added to our R01 team due to study relevant expertise with implementation science in addiction and mental health (McGovern), cluster randomized implementation studies (Wiltsey Stirman) and scaling system dynamics trainings (Snyder). In addition to our VAPOR partners, four study advisors lead national VA improvement initiatives: VA system organization (Rust), SAIL audit and feedback quality measures in mental health (Trafton), national evidence-based psychotherapy coordinator program (Collie) and the national evidence-based pharmacotherapy program (Wiechers). Rust and Trafton (R21 co-investigators) worked with us to develop Modeling to Learn at scale in VA. The study relevant expertise and contributions of each R01 study team member or partner is listed below in Table 8.

During the R21, we collaborated effectively across our nationally distributed team through regular meetings on the Lucid Meetings platform, project management via Basecamp 2.0, an open data science workflow on GitHub, and an integrated set of servers behind the VA firewall. We also benefit from co-location of NCPTSD, Office of Mental Health and Suicide Prevention (OMHSP), Veterans Advisory Partnership for Operations and Research (VAPOR), and Stanford partners at VAPAHCS (see included letters of support). NCPTSD, Georgia Health Policy Center (GHPC) and VAPOR staff will co-facilitate ‘Modeling to Learn’ workshops. NCPTSD staff will provide post-workshop technical assistance.

### Outcomes and Analysis Plan

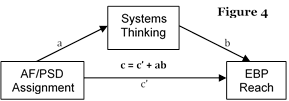
### Analyses for Tests of Specific Aims

#### Aim 1.

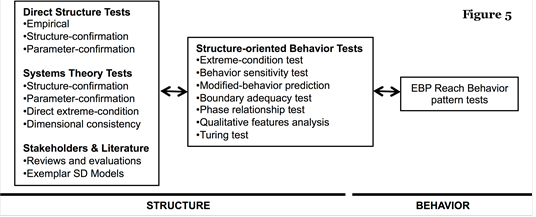
Test for superiority of PSD over AF for increasing EBP initiation and course. We will use R for tests of Aims 1a and 1b to establish PSD superiority. First, we will assess ICCs for within and between clinics. We will test for a significant difference between PSD and AF arms in increasing EBP reach using two (initiation and course) generalized estimating equation analyses for differences in proportions (reach) (Campbell and Walters, 2014). We will estimate two (initiation and course) generalized linear models that account for clustering. We will assess distribution of EBP reach to identify the appropriate link function for robust standard errors, and test for a significant difference in EBP reach between the PSD and AF arms. We will report the effect size and 95% confidence intervals for the difference between arms at alpha = .05 (Campbell and Walters, 2014).

#### Aim 2.

Test the PSD theory of change that increased EBP reach is via systems thinking (Forrester, 2009, 1994; Rahmandad et al., 2009). We hypothesize that the effect of PSD/AF on 12 month period EBP reach will be explained by 6 month team systems thinking (STS), adjusting for baseline covariates using the ratio of mediator probability weight (RMPW) (Hong, 2010; Hong et al., 2015; Qin and Hong, 2014). Our CRT design uses AF/PSD assignment (independent variable) to experimentally manipulate STS (mediator) on clinic-level EBP reach (outcome) in each arm. But, STS is not randomized. RMPW uses sensitivity tests to address potential bias due to an interaction between the intervention and the mediator, or due to the operation of systems thinking through unhypothesized mechanisms (confounders) using multilevel mediation analyses in R package ‘MultisiteMediation’ (Qin and Hong, 2014) a confirmatory hypothesis test using multilevel mediation with partial variance in 6 month STS and 12 month period EBP reach across arms. Figure 4 displays the mediation model from strategies (baseline), to mediators (Baseline to 6 month STS change), to outcomes (12 months), where a = the standardized beta coefficient of PSD/AF assignment on systems thinking, b = the effect of systems thinking on EBP reach, c = the total effect of PSD/AF assignment on EBP reach, c’ = the direct effect of PSD/AF on EBP reach, and ab = the indirect effect of PSD/AF on EBP reach through STS (hypothesized mediation). We will use a bootstrapping, asymmetric confidence interval approach to balance power and type I error.



#### Aim 3.

Test the generality of mechanisms of change in EBPsy/EBPharm SD models. We will use structural-behavioral validation tests (Barlas, 1996; Homer, 2012; Rahmandad and Sterman, 2012) to evaluate whether causal mechanisms formulated in our Psy/EBPsy and MM/EBPharm models generalize to explain EBP reach as a function of local data across PSD and AF clinics. Figure 5 displays the analytic plan we will use to establish the Structural-Behavioral validity of the two models against observed 12 month EBP Reach in both arms (AF and PSD), using the Theil Statistics module in Vensim DSS49 (Ventana Systems Inc, 2014). 

#### PSD Models.

We will document our models using SDM-DOC and report findings using SIMULATE (Oliva, 2003; Trafton et al., 2013).

### Limitations and Alternatives

#### Limitations.

Random assignment to usual AF or PSD is the best comparator for guiding decisions about scaling/sustaining PSD infrastructure. However, clinics in our ‘usual AF’ comparator will likely engage in highly variable AF activities. We take steps to address this with CDW-based stratification.

#### Alternatives.

We will complement our primary tests of Aim 1a and 1b using autoregressive integrated moving average (ARIMA) to mitigate potential limitations (Hyndman et al., 2017, 2017). This helps to guard against threats from secular trends (overall patient demand or VA EBP adoption may be increasing), and regression to the mean (given these are lower performing clinics). We will track national trends in EBP reach and estimate the percentage of regression towards the mean (Mott, Hundt, et al., 2014; Oliva et al., 2013). We will also graphically display 12 month period averages of EBP reach related to Aim 1a and 1b at the clinic level, using statistical process control (SPC). SPC p-charts will display the pre/post intervention EBP reach proportions for all PSD and AF clinics. SPC is a standard, healthcare quality tool robust for non-normal data and unbalanced samples (Diaz, 2005). The p-chart centerline corresponds to the mean proportion of patients who meet EBP criteria, controlling for the number of patients in each observation (Duclos and Voirin, 2010). We will use SQUIRE standards for reporting SPC (Ogrinc et al., 2008).

## Statistical Design and Power

## Data Safety and Monitoring

We propose an implementation trial focused on the comparative effectiveness of two health care quality improvement strategies (participatory system dynamics vs audit and feedback). Two strategies will be compared to test their relative effectiveness for increasing the proportion of the outpatient addiction and mental health patient population that receives the highest quality, evidence-based standard of care. The focus is on changing provider care decisions to expand evidence-based treatments in routine care and improving the reach of evidence-based practices as measured in the VA electronic health record system. Therefore, although our proposed R01 meets criteria for a phase III clinical trial, it is low risk with regard to patients and providers as there will be no patient interaction for the purposes of research. This is a large national implementation science trial, but we are not examining the effectiveness of evidence-based practices. We are focused on expanding their reach among patients. There is no prior data to suggest that audit and feedback or participatory system dynamics approaches to quality improvement have significant adverse effects for patients or providers. Given this, we will take the following steps to ensure adequate data safety and monitoring.

### Data Safety and Monitoring Plan

All investigators and project staff will complete necessary coursework regarding protection of human subjects and will receive certification from the Collaborative IRB Training Initiative (CITI). All investigators and project staff will remain current on VA privacy and information security trainings. We will also submit all procedures and documentation/definitions for electronic health record data collected to the relevant IRB (Stanford University) and VA Offices (VHA National Data Systems, VA Informatics and Computing Infrastructure, VA Office of Research and Development) for review and oversight.

We will maintain ongoing communication with our data safety and monitoring board and will regularly review data management procedures to identify and address unintended problems, and address any unlikely, but possible, adverse events.

### Data Safety and Monitoring Board

Commensurate with the low risk of the trial, and commensurate with the size and complexity of our trial, our advisory board of VA quality improvement leaders in VA will comprise our data safety and monitoring board. One member runs the VA national audit and feedback program for the VA Office of Mental Health and Suicide Prevention (OMHSP) as the Director of the Program Evaluation Resource Center. A second member runs the national VA OMHSP quality improvement program for evidence-based pharmacotherapy as director of the Psychotropic Drug Safety Initiative. A third member runs the national VA quality improvement program for evidence-based psychotherapy as an OMHSP Quality Improvement Implementation Consultant. A fourth member runs national VA systems engineering quality improvement programs using EHR data. Finally, the Veterans Advisory Partnership for Operations and Research (VAPOR) provides ongoing input in study plans and evaluation from the Veteran patient perspective. This advisory board, will help to provide oversight and monitoring of the trial through the independent activities of their programs, and through regular communication with the study team.

We will meet regularly with our advisory board and will perform data safety and monitoring activities every six months. Monitoring activities will include review of study data in light of overall VA quality improvement data with our complete multidisciplinary R01 study team. Our advisory board will provide assessments of trial progress based on the input of their independent teams of multi-disciplinary program evaluators, and will advise the R01 study team accordingly.

In addition to the advisory board, the R01 study team includes clinical trial experts, VA health services research experts, and clinicians who are experts in the evidence-based psychotherapies and pharmacotherapies that this trial seeks to make accessible to more VA patients.

## Recruitment and Retention Plan

#### Continuing Education Licensure Credit.

All frontline addiction and mental health disciplines will have the opportunity to participate for licensure credit provided by VA Employee Education Services. This includes psychiatrists, psychologists, social workers, nurses, counselors and certified peer support specialists. Providers randomized to the audit and feedback arm will have the opportunity to receive two hours of licensure credit for two facilitated team meetings. Providers randomized to participatory system dynamics will have the opportunity to receive twelve hours of licensure credit for twelve facilitated team meetings over six months.

#### Attrition.

Attrition of providers or patients will not impact analyses for specific aims. Provider PSD participation will be tracked as a PSD fidelity check, but patient attrition is included by definition in EBP reach measures, and use of provider attrition in team-average (mean) survey measures means the only loss of data would be due to loss of an entire clinic team. Our R21 pilot testing indicates it is unlikely that care teams will attrit. Should clinics attrit after randomization, they will be included in intent-to-treat analyses using CDW data.

## Inclusion of Women, Minorities, and Children

The proposed research will be open to adult men and women of all ethnic and racial backgrounds. Women and members of minority groups from two populations will be included in the proposed R01 study: the VA patient population served in outpatient mental health and addiction services (existing VA health system data) and the VA outpatient mental health and addiction provider population (survey data; see second page). Our trial plans are inclusive for both patients and providers.

The R01 patient and provider samples will be representative of VA patient and provider populations. The VA patient population skews male. We address sex/gender, race, and ethnicity in our proposed trial design with inclusive eligibility criteria. All VA addiction and mental health patients with a primary diagnosis of depression, PTSD, alcohol use disorder and opioid use disorder are eligible. All VA addiction and mental health providers mapped to a care team in a study clinic are eligible. We will randomize provider participants to each arm. Our evaluation of the trial outcome measure is drawn from existing health care records (see Patients below).

Prior studies neither support nor negate the potential for significant differences in participatory system dynamics or audit and feedback effectiveness for improving the reach of evidence-based practices among sex/gender, racial or ethnic subgroups. Our plans for valid analysis include reporting results by subgroup, and exploring for significant differences in our outcome of EBP reach (patients), and our mediator, systems thinking (providers). The targeted/planned distribution of subjects by sex/gender, racial, and ethnic groups for each proposed sample is provided in two Targeted/Planned Enrollment Tables below.

## Study Timeline

### Timeline and Feasibility.

We propose 60 total months of study activities and 30 months of active PSD facilitation or post-training technical assistance (phases 3 and 4). This leaves 24 months of flexibility for delays across pre (phases 1 and 2) and post (phases 5 thru 8) activities (Table 10).

Table 10. Timeline of Proposed Study Activities

## Protection of Human Subjects

This Human Subjects Research involves an NIH-Defined Phase III Clinical Trial.

Human Subjects Involvement and Characteristics. Electronic data from the VA Corporate Data Warehouse (CDW) will be used to evaluate specific aims and comprise the first of two human subjects components to our study. Due to our proposal using existing data during this project, risks associated with this study to individual patients who use mental health services are minimal. There will be no interaction with current patients for the purposes of research. Patients will not be asked to sign a consent form. No new data will be collected beyond data generated during routine care. All individual patient data will stay on servers behind the VA firewall to prevent any potential risk for loss of confidentiality of protected health information. Data inputs in the models will be de-identified team aggregates and will not be individually identifiable.

Staff/Stakeholder Involvement. This project is a collaboration between the Principal Investigator and Co-Investigator team, and the leadership, front-line providers, and staff in the VA outpatient service system. Comprising the second of two human subjects components of our study, Mental Health staff will be engaged in the Audit and Feedback (AF) ‘Team Feedback’ and Participatory System Dynamics (PSD) ‘Modeling to Learn’ team trainings (i.e., they will participate in their actual team/workgroup) for no-cost, with continuing education credits provided by VA Employee Education Services toward licenses in psychiatry, psychology, social work, nursing, certified peer support specialty, and counseling. These educational trainings are commonly provided in VA and are necessary for maintenance of state licensure and VA hospital privileges. During workshop sessions, frontline teams of providers will partner to evaluate improvement scenarios via simulation and identify quality improvement changes in their clinics/teams.

*Over the course of the proposed study, this research project expects to involve eight regional health systems randomized to either AF or PSD, in which the Medical Director has identified at least three clinics for participation in training (4 regional health systems/12 clinics per arm; 24 clinics total)*. We expect approximately 30 staff to participate in each outpatient clinic. Across 24 clinics that will include 720 staff. AF/PSD workshops with staff will be held during regularly scheduled staff meetings or team huddles. We anticipate that participation in PSD will include approximately two workshop hours per month for six months with optional self-directed learning. Participation in AF activities will include two hours in the first month, and less than one self-directed hour per month during months two through six. Participation will occur during work hours and require clinic manager workload credit approval to staff for participation. Staff will receive 12 continuing education credit hours for PSD and two continuing education credit hours for AF. Since randomization occurs at the VA regional health system level, the training opportunity will not vary among co-workers. Local staff will either all receive AF or all receive PSD. The leaders and staff of the outpatient service system helped to shape the goals of this study. Veteran staff with lived experience using the mental health and addiction service systems, who now work as VA patient navigators, will continue to participate and shape the development of the project through all phases, including their role as workshop co-facilitators. These certified peer specialists from the Veteran Advisory Partnership for Operations and Research complete CITI Training.

The primary risk to human subjects/mental health patients is associated with potential breaches of confidentiality of patient health records. In addition, staff who participate may feel uncomfortable about the review of data and our focus on the performance of the mental health delivery system.

## IRB Plan

Our local IRB is the Stanford University IRB and the Office of Research at VAPAHCS.

The study team at the National Center for PTSD will manage the R01 trial protocol from the campus of the VAPAHCS. All clinics enrolled in this R01 study will complete the same randomization protocol and participate in either audit and feedback (AF) or in participatory system dynamics (PSD). These interventions and all trial records and data will be managed centrally from one lead site at NCPTSD/VAPAHCS.

## Dissemination Plan

### Data, Facilitation Guides and Code

A central component of each arm of this participatory research project is to increase data transparency and accessibility among local frontline providers. Should participatory system dynamics prove to be superior and/or effective for improving reach of evidence-based practices, then dissemination of system dynamics modeling scripts, code, and models will be made available for use in other implementation contexts, and for replication by other implementation researchers.

Data. Datasets meeting VA standards for disclosure to the public will be made available within 1 year of publication. A de-identified, anonymized dataset will be created and shared. Final data sets underlying all publications resulting from the proposed research will be shared publicly.

Prior to distribution, a privacy officer will certify that all datasets contain no PII/PHI. Final data sets will be maintained locally, until VA and NIH enterprise-level resources become available for long-term storage and access. The VA Office of Research Development (ORD) will provide guidance on request and distribution processes. Those requesting data will be asked to sign a Letter of Agreement regarding use.

Publicly Available Participatory System Modeling Resources. In addition to these datasets, model SQL code for retrieving data from generic health record systems will be made publicly available online. The system dynamics model files and group modeling scripts used in the “Modeling to Learn” workshop series will be posted online for transparent, public use.

### Publications

Publications from this research will be made available to the public through the National Library of Medicine PubMed Central website within one year after the date of publication, in accordance with guidance provided by NIH and VA ORD.

## Resource Sharing Plan

### Data and Code

A central component of each arm of this participatory research project is to increase data transparency and accessibility among local frontline providers. Should participatory system dynamics prove to be superior and/or effective for improving reach of evidence-based practices, then dissemination of system dynamics modeling scripts, code, and models will be made available for use in other implementation contexts, and for replication by other implementation researchers.

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