**AIMS**

**Over the last 10 years, Veterans Health Administration (VA) invested in dissemination of evidence-based psychotherapies (EBPsy) and pharmacotherapies (EBPharm) or ‘EBPs’ in the outpatient mental health system based on substantial evidence of EBP effectiveness as compared to usual care.**1–5 EBPs are the most high-value treatments to meet Veterans’ mental health needs, and thereby, reduce chronic impairment, and prevent suicide6–8 or overdose.9,10 Yet access may not be timely, and EBP reach among the patient population for common, costly, high-risk concerns - depression, PTSD and opioid use disorder (OUD) – can be very low (3-28%).11 As a result, VA prioritizes high-value quality improvement (QI) strategies to increase timely Veteran access to effective mental health care.12,13

**[We piloted participatory system dynamics (PSD) for improving EBP reach based on 60 years of effectiveness in business and engineering***.*14Frontline staff evaluated QI tradeoffs via simulations of VA data guided by systems theory.15 Statistical process control analyses indicate pilot clinics demonstrated a three standard deviation increase in EBP reach (*Figure 1*), and maintained improvement for 12 and 8 months. During this period, the other VA clinics from the same regional health care system did not improve. From our R21 pilot, we developed a program entitled, *Modeling to Learn* (MTL) using participatory principles.

**Limited guidance is available to VA decision makers regarding effective, scalable and affordable QI strategies to improve EBP reach.**16 Our specific aims compare usual QI (facilitation + data) against MTL (facilitation + data + simulation) with frontline teams for improving EBP reach, and will inform Office of Mental Health and Suicide Prevention (OMHSP) leaders who must select QI strategies to improve quality (EBP reach). Second, we will evaluate MTL fidelity, assessing MTL fidelity for convergent validity with the participatory theory of change.17 If MTL can be delivered with fidelity to participatory principles at scale, we expect MTL clinics will achieve greater staff learning, which will explain improvements in EBP reach. Third, most cost analysis in implementation research focuses on EBP adoption, i.e., costs of EBP use.18 But, VA adopted EBPs and VA budgets facilitate/constrain QI activities to expand reach. Partnering with OMHSP, our trial evaluates costs to inform national scale, should MTL prove to be effective, scalable and affordable.**]**

**Via 12 hours of QI/MTL engagement with frontline teams, we will achieve the following specific aims**:

**We will compare usual QI against MTL for improving guideline consistent reach of 4 EBPsy and 3 EBPharm for depression, PTSD, and OUD,** each with quality measures. **We propose a two-arm, 24-clinic (12 per arm) cluster randomized trial to test for superiority of MTL over usual QI for increasing EBPsy/EBPharm reach.** Clinics will be from 24 regional health care systems (HCS) below the VA mental health quality median of VA measures known as Strategic Analytics for Improvement and Learning (SAIL), and below median on 3 of 8 SAIL EBP measures.19 Clinics will be notified of QI support via OMHSP memo with six clinics engaged per wave over four waves.20 Computer-assisted stratified block randomization will balance MTL and usual QI arms at baseline using Corporate Data Warehouse (CDW) data (see *Plan*).

**Aim 1 – Effective: Test superiority of MTL over usual QI 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 MTL clinics as compared to QI clinics in omnibus tests across EBPs using clinic 12 month pre/post period average EBP reach.

**[Aim 2 – Scalable:** (2a) **Evaluate QI/MTL fidelity (quality and dose).** (2b) **Test MTL fidelity for convergent validity (correlation) with participatory measures** using the R ‘psych’ package.21(2c) **Test the participatory theory of change.** Evaluate whether the effect of QI/MTL assignment on 12 month period EBP reach is mediated by 6 month team scores on validated participatory measures22–24 in ratio of mediator probability weight (RMPW) mediation analyses using the R ‘MultisiteMediation’ package.25–27

**Aim 3 – Affordable: Determine the budget impact of MTL.** (3a) Using staff activity tracking and payroll data, estimate and compare the budget impacts of MTL and usual QI implementation. (3b). **Calculate the average marginal costs per 1% increase in EBP reach.** Analyze the pattern of marginal costs as the number of patients treated in EBPs increases/decreases across MTL and QI arms.**]**

**Exploratory aim.** We contextualize aims 1-3 using *provider surveys* of team burnout (PACT),28–31 MTL/QI feasibility, acceptability and appropriateness (FIM, AIM, IAM),32 and MTL/QI co-facilitator engagement.33

**MTL Innovation – Enhanced QI for all VA Health Services, EBPs, Disciplines or Patient Populations.**

Consistent with VA as a learning healthcare system,12,13 the proposed IIR advances implementation science via study of theoretically grounded, systems science QI infrastructure that could be applied to most VA health service practices - not just the *high-priority area of mental health*. Our aims determine the value of MTL (relative to usual QI) for empowering VA staff, optimizing use of existing data resources to improve EBP reach, and expand timely access to the most effective treatments for meeting Veterans’ needs.

**RESEARCH PLAN**

**SIGNIFCANCE. Quality benchmarks have not led to system-wide reach of evidence-based practices (EBPs).** The VA aims for system-wide reach of evidence-based psychotherapy (EBPsy) among patients diagnosed with PTSD and depression, and evidence-based pharmacotherapy (EBPharm) for depression and opioid use disorders (OUDs). All are common, costly and frequently comorbid conditions, and are primary reasons Veterans seek care in VA.34,35 Meta-analyses of trials among thousands of patients indicate that the EBPsy and EBPharm selected for national implementation in VA (see *Table 1*), have positive effect sizes as compared to alternative treatments, usual care or waitlist-control, and lead to positive outcomes for patients, including reduced PTSD36,37 and depression symptoms,38–42 reduced opiate use,43,44 and thereby, reduced risk of death by suicide or overdose.6,9

**Background of the ‘Limited EBP Reach’ Problem: Ineffective Quality Improvement Strategies.** Based on the weight of evidence in support of EBPs, EBPs are recommended in VA/DOD clinical practice guidelines, mandated in the VA Uniform Mental Health Services Handbook,and assessed with VA quality measures known as Strategic Analytics for Improvement and Learning (SAIL).1,2,19,45 EBP resources include national EBP trainings/consultation and EBP note templates in electronic health records.46 EBP rollouts significantly improved the health and well being of Veterans. Patients who received cognitive behavioral therapy (CBT) for depression experienced a 40% reduction in depression symptoms4 and over 60% of Veterans who received prolonged exposure (PE) experienced a clinically significant improvement in PTSD.3 However, more work is needed to increase EBP reach.47

We define **reach** as the proportion of the outpatient population who *initiate* an EBP and complete a therapeutic *dose*. Too few VA patients receive EBPsy even in specialty programs.11,47 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 dose, 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*).

**Why hasn’t the VA quality improvement (QI) enterprise yielded a greater payoff?** Despite investment in SAIL, quality and EBP implementation gaps remain. In *Table 1*, the interrelated 5 health service quality and 7 EBP implementation gaps for depression, PTSD and OUD patients, reflect the complexity of identifying optimal health system improvements under typical local health system constraints. QI targets include different programs (e.g., general vs. specialty), meeting different patient needs (e.g., mental health vs. addiction), by multidisciplinary teams with varying capacities/expertise (e.g., EBPharm prescribers vs. EBPsy providers), under conditions that continuously change over time.

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| **Table 1. Study SAIL Health Services Quality Measures and EBP Reach Measures (Q1 2017)** | | | | | |
| **Definition** | **Study** | **Quality Target** | | **SAIL NAME** | **VA**  **50th %ile** |
| **Population Coverage - Denominator (*diagnostic* cohorts)** |  | **HS** | **EBP** |
| % OUD ***diagnosed*** patients receiving opioid agonist or antagonist | **A1**/recruit |  | **EBPharm** | SUD16 | 28.4 |
| % Depression ***diagnosed*** patients with depression psychotherapy visit | recruit | x |  | Psy32 | 38.3 |
| % PTSD ***diagnosed*** patients with psychotherapy visit for PTSD | recruit | x |  | Psy38 | 55.8 |
| % PTSD ***diagnosed*** patients receiving specialty PTSD outpatient care | recruit | x |  | PTSD56 | 21.7 |
| **Continuity of Care - Denominator (diagnosis + active *treatment*)** |  |  |  |  |  |
| % Patients on ***new antidepressant medication*** (84 days continuous) | **A1**/recruit |  | **EBPharm** | MDD43h | 73.0 |
| % Patients on ***new antidepressant medication*** (180 days continuous) | **A1**/recruit |  | **EBPharm** | MDD47h | 57.2 |
| % Depression ***treatment*** patients - 3 psychotherapy visits in 6 weeks | recruit | x |  | Psy33 | 30.4 |
| % PTSD ***treatment*** patients - 3 psychotherapy visits in 6 weeks | recruit | x |  | Psy39 | 44.0 |
| **EBPsy Reach Targets – Denominator (diagnosis/EBP template)** |  |  |  |  | **Reach %** |
| PTSD - EBP Template for PE or CPT Session 1 (Initiate) | **Aim 1** |  | **EBPsy** | PTSD 56 | 5.3 |
| PTSD - EBP Template for PE or CPT Completion (Dose) | **Aim 1** |  | **EBPsy** | PTSD 56 | - |
| Depression - EBP Template for CBT-D, ACT-D, IPT-D Session 1 (Initiate) | **Aim 1** |  | **EBPsy** | n/a | 2.6 |
| Depression - EBP Template for CBT-D, ACT-D, IPT-D Completion (Dose) | **Aim 1** |  | **EBPsy** | n/a | - |
| *Source.* OMHSP SAIL and CDW.HS = Health Services. EBP = Evidence Based Practice. A1 = Aim 1. EBPharm = Evidence-based Pharmacotherapy. EBPsy = Evidence-based Psychotherapy. PE = Prolonged Exposure. CPT = Cognitive Processing Therapy. CBT = Cognitive Behavioral Therapy. ACT = Acceptance and Commitment Therapy. IPT = Interpersonal Process Therapy. | | | | | |

**Preliminary R21 Research Guiding IIR [Revised] Specific Aims**

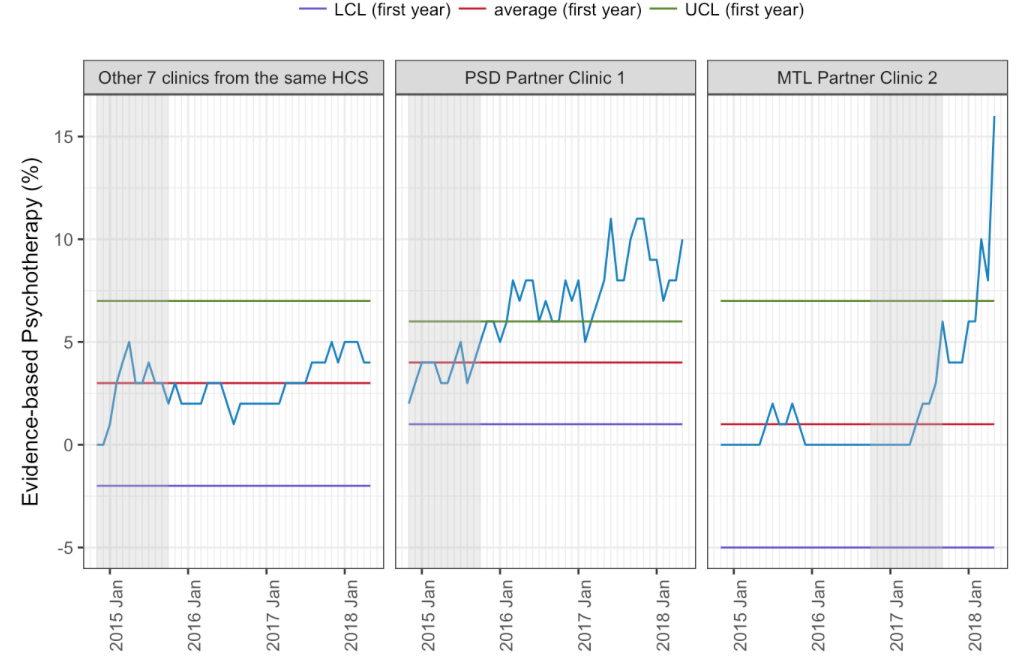
**Despite considerable investment in QI and EBP initiatives, significant quality gaps remain for prevalent, high-risk mental health and addiction needs** (*Table 1*). The proposed IIR was developed with Office of Mental Health and Suicide Prevention (OMHSP) partners who are engaged daily in the usual QI activities that continue to fall short of VA national quality goals. We find that local clinics can identify data informed gaps and set data-driven goals, but rarely formulate action plans that address underlying causes of limited EBP reach. *Modeling to Learn* (MTL) makes transparent the system causes of limited EBP reach, empowering frontline staff to maximize local EBP-specific capacities with existing staff and data resources.48,49

**Specific aims are summarized in *Table 2***. We will test whether MTL is superior to usual QI for improving EBP reach. Given the time and effort VA already spends on QI, we expect that QI enhanced by participatory simulation learning will better help frontline addiction and mental health teams to ensure the timely, continuous care, necessary to meet VA’s standards for quality. Due to parallel facilitation and online resources, we expect usual QI (facilitation + data) and MTL (facilitation + data + simulation) will have comparable costs.1,2,4–7,45,47

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| **Table 2. Summary of Proposed IIR QI/MTL CRT Design, Hypotheses, Tests & Measures for Specific Aims** | | | | | | | | |
| **Aim** | **Purpose** | | **Hypothesis** | | **Test** | | **Measure** | |
| **1** | **Effective** | | MTL will be superior to usual QI | | Cluster Randomization | | 6 & 12 month EBP initiation and course | |
| **2** | **Scalable** | | Effect of MTL/QI on EBP Reach mediated by Participatory Scales | | Multilevel Mediation | | 6 mo. Team Means (Mediator);  Existing Patient Data (EBP Reach Outcome) | |
| **3** | **Affordable** | | QI/MTL Costs are Comparable | | Budget Impact Analysis | | Staff activity tracking and payroll data | |

**Aim 1 – MTL is acceptable, feasible, and effective for quality improvement**. During our NIH R21 we observed high levels of staff participation and positive evaluations of PSD (demonstrating acceptability). We synthesized data, models and evaluated implementation scenarios (demonstrating feasibility).14 Statistical process control analyses indicate our two R21 pilot clinics each demonstrated a three standard-deviation increase above their pre-intervention EBP reach (*Figure* 1; α < .003). In *Figure 1*, purple = lower control limit (LCL); red = clinic 12-month pre-intervention EBP reach; green = upper control limit (UCL).

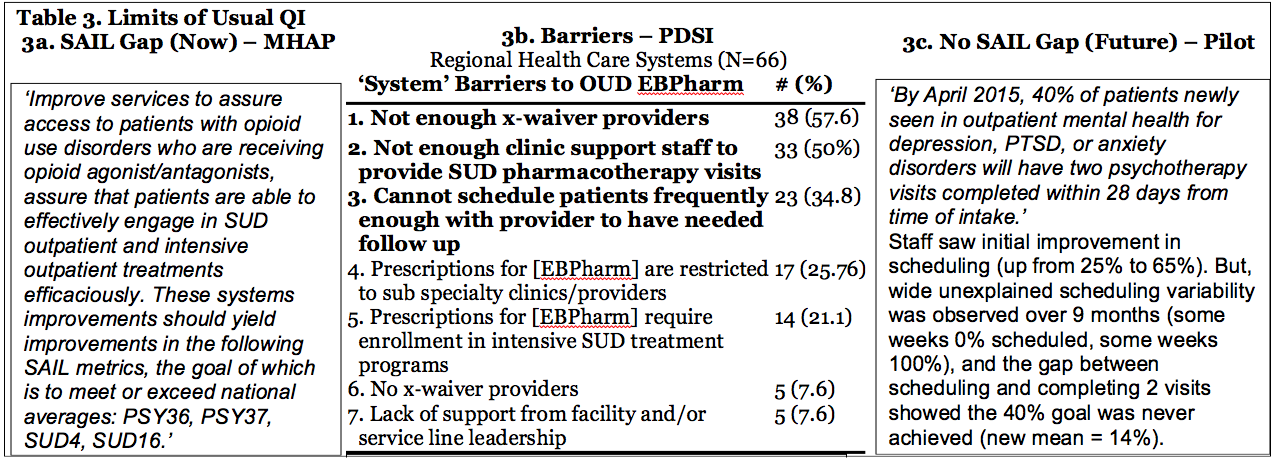
**Figure 1. R21 Effectiveness – Statistical Process Control of EBP Reach Improvement (+3 *SD*)**



Other VA clinics from the same regional health care system (HCS) did not improve EBP reach (left panel). But, our original PSD pilot clinic (center) has maintained improvement for 12 months, and our MTL pilot clinic (right panel) has been improving for 8 months. Moreover, we observed no secular trend toward improved EBP reach in VA national SAIL measures over this period. These R21 quasi-experimental findings support the proposed R01 effectiveness test: a cluster randomized trial (CRT) to evaluate for MTL superiority over usual QI.

**Why does participatory simulation learning (i.e., MTL) improve QI effectiveness?**

**Limited EBP reach persists in VA mental health care despite substantial investment in infrastructure to support quality improvement (QI).** Members of the IIR study team lead OMHSP QI programs including SAIL, National EBPsy Dissemination, and EBPharm via the Psychotropic Drug Safety Initiative (PDSI). Usual QI activities, with or without OMHSP technical assistance,50 require considerable staff time, even when unsuccessful. *Table 3* highlights usual QI activities including the *3a)* **Mental Health Action Plan (MHAP)** portal, *3b)* Psychotropic Drug Safety Initiative (PDSI) data, and *2c)* one of our R21 pilot clinics. Each illustrates the limits of usual QI for expanding EBP reach, due to inability to facilitate local team learning.

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**MHAP Gaps.** The MHAP is a website where HCS submit QI plans. We will use the MHAP to facilitate the usual QI arm in the proposed IIR. OMHSP team members lament how frequently submissions follow the formula shown in *Table 3*: ‘This is our SAIL gap now (3a). We will address the gap. And in the future, there will not be a SAIL gap (3b).’ The example plan in *Table 3a* is data-driven, but there are no claims about what explains the gap or how ‘systems improvements’ will be achieved. No local improvement actions are laid out.

**‘System Barriers.’** PSD posits that the MHAP entry is ‘black box’ (opaque), whereas system dynamics simulations are ‘white box’ (transparent), and show staff *how* the system operates.51 With MTL, we aim to shift from ‘black box’ QI plans, to ‘white box’ plans crafted with frontline staff who upgrade the mental models used to guide EBP decisions, by learning from experimentation with local drivers of EBP reach (i.e., simulation).51 For example, *Table 3b* displays the top seven barriers to OUD EBPharm delivery reported to the PDSI. Yet, review of MHAP submissions did not return any plans to address these barriers. Our experience suggests these barriers may be absent due to the notion that they are ‘system barriers,’ which HCS perceive as outside local control. As an alternative, our MTL medication management (MM) model addresses the top three EBPharm barriers in *Table 3b* *using local team data*. In our IIR proposal, we will use our MM/EBPharm model as an example to establish how MTL enables local decision-makers to handle these barriers.

**MTL Fidelity – Simulating System Behaviors to Find the Best *Local* Improvement Plan**.

***Six Lessons describing why usual QI doesn’t work better.*** Below we use frontline staff quotes from our pilot to set up the components of MTL fidelity, and put forward our hypothesis that ‘barriers’ to EBPsy/EBPharm are governed by generalizable system dynamics that providers can learn to locally manage.

**Lesson 1: *‘Our team is different.’*** A key component of PSD process is determining the appropriate level of aggregation for defining the system problem. We considered the decisional perspective of the modeling problem: Whose decisions will the model support? We wanted to aid multidisciplinary teams making decisions related to EBPs. We realized regional SAIL data may be too high a level of aggregation to be used meaningfully by frontline teams who weren’t sure it represented them or their patients.

**Lesson 2: *‘Where are these data from?’***Researchers, program officers and managers may consider data most objective for QI. We learned that many providers consider reviewing a single Veteran’s care as the most concrete indicator of quality.We developed our MTL data-user-interface to enable provider review of local team data, as well as drill down reports of individual Veterans before running simulations. *Table 4* displays model inputs drawn from the VA corporate data warehouse (CDW) that define the team, the supply of services, patterns of patient engagement, EBP reach, and patient cohorts. The ***Appendix 3***also includes an excerpt of the SQL logic that groups CPT encounter (visit) data to conform with OMHSP/SAIL standards.

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| **Table 4. Model Input** | **VA Data and Corporate Data Warehouse (CDW Data Source)** |
| **1. Team Selection** | User-selected collection of clinic/scheduling grids used by a team |
| **2. Service supply** | Clinic/Scheduling hours or availability (CDW VISTA/appointment table) |
| **3. Patient Engagement** | Visit/CPT encounters and missed appointment data (CDW visit table) |
| **4. EBP reach** | EBP templates attached to visits (CDW health factor table) |
| **5. Patient cohorts** | ICD diagnostic information from patient visits. (CDW visit table) |
| CPT = common procedural terminology. VISTA = Veterans Information Systems and Technology Architecture. ICD = International Classification of Disorders | |

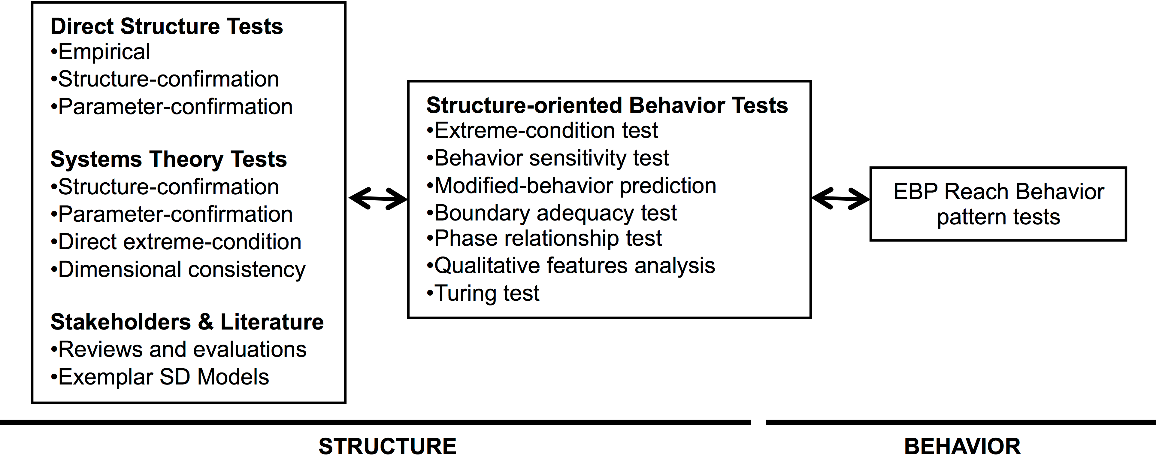
**Lesson 3: *‘Review data with our team not the clinic.’*** Were teams really different? Yes. Teams are established for different purposes (e.g., generalist vs. specialty teams) with different processes for making decisions. Teams have different staffing ratios (e.g., proportion of psychiatrists to social workers) and vary on a number of variables that constrain or facilitate EBPs. Providers requested that we work with teams during team meetings, rather than clinic staff meetings. We will meet with teams across both usual QI and MTL arms.

**Lesson 4: *‘How is this not just another way to ask us to do more with less?’*** All VA stakeholders are all interested in knowing when a team or clinic is doing the best they can with their limited resources. Showing how quality metrics vary as a function of team supply and demand is a key differentiator between MTL and usual QI. Unlike SAIL, which provides a comparison of regional health care systems (HCS) against the national VA median, MTL model parameters reflect *hyper local team conditions*. During iterative model validation (described below), we conserved supply of provider time in our models (e.g., appointments/week). As a result of this feature, OMHSP partners and frontline staff felt MTL is responsive to factors contributing to low morale, burnout, and intention to leave VA. Some providers even described MTL as ‘validating.’54

**Lesson 5: *‘I feel like I’m playing a game, but I don’t know the rules.’*** SAIL and PSD each require data review. But, staff told us they felt SAIL erected metrics that teams would not be able to meet due to factors outside their control. PSD research challenges the sufficiency of data for selecting effective changes and goes after QI via other means.54,55 Simulation illuminates causal dynamics that can be locally managed to improve EBP implementation through day-to-day decisions. Research on PSD learning indicates QI requires new ‘mental models’ that account for the causes of system behaviors when making decisions (see ***Aim 2*** *below*).56

**Lesson 6: *‘Just because it works in Cleveland, doesn’t mean it will work here.’*** Stakeholders may be reasonable to find imported QI solutions suspect. During our R21 pilot the best action plan for a given team varied as a function of the dominant feedbacks (described below) and their local resources/constraints. Options for local tailoring remain invisible to teams engaged in usual QI with data review alone.

**Model Structural-Behavioral Validity**. A strength of MTL is the ability to read team-specific parameters into general models of EBP dynamics. During the R21, we conducted several iterations of structural-behavioral validity testing to determine the soundness of our models. Developed over the last 60 years, tests of **structural-behavioral validity** assess the mathematical logic producing the model behavior against key historical trends to ensure accurate analytic formulation.51 *Figure 2* depicts the sixteen calibration and validity tests we used to verify our model dynamics across a range of teams.



**Figure 2**

**MTL Opioid Use Disorder Medication Management (EBPharm) Example.** PDSI data indicate the top two barriers to EBPharm reach for OUD are not enough X-waivered providers (#1) *or* non-waivered support staff (#2; see *Table 3b*). A Drug Enforcement Agency (DEA) x-waiver is required to prescribe OUD EBPharm. But, once the low-hanging fruit of completing the free VA 8-hour training to receive the x-waiver is accomplished teams need another options to provide more local patients OUD EBPharm. RVI was the third most common barrier reported to PDSI (see ***Table 3b***, #3 scheduling frequency) and is also an important causal influence on EBPharm reach. In ***Appendix 4***, we include an excerpt of the MTL Medication Management (MM) model, designed to locally optimize teams’ OUD EBPharm delivery to meet local patients needs. Teams can experiment up or down from their historical Appointment Supply and Return-to-clinic Visit Interval (RVI) decisions to better meet the MM needs (and VA SAIL measures) of different patient cohorts (e.g., depression, OUD, alcohol use disorder) who may require different follow-up intervals to meet EBP guidelines.

In ***Appendix 4*,** our MM modeldepicts the team values for CDW parameters in red font and calculated variables in black font. Slider icons denote simulations teams can run to find their team ideal, given their local patient demands. The arrows denote the direction of causal relationships between variables, and (+) and (-) signs express whether the variables are increasing together (+) or moving in opposite directions (-). The MM model is a ‘stock and flow’ diagram that represents causal system dynamics governing EBP reach as a function of stock or state variables in which units accumulate over time. Flow or rate variables (e.g., patients/week) influence and are influenced by the stocks. The interdependence over time among MM variables comprises a **balancing feedback loop***,* labeled, ‘Balancing Existing and New Patients.’ Like a thermostat that regulates heating/cooling to keep within a target, the RVI balancing loop creates homeostasis. Teams use scheduling to achieve steady equilibrium between new and existing patients. A balancing feedback like this, is a system resistant to change, because sustaining improvement in any one element will always be dwarfed by the more powerful balancing interplay among elements. This highlights how *real-time* MTL resources help teams to meet VA quality standards for multiple EBPs. A key MTL principle is that providers make RVI decisions several times a day and need mental models fine-tuned with simulation (see ***Aim 2*)**.

**[Real-time Simulation.** The MM model provides efficient experiential learning for improving local EBP decisions.*NOTE:* Because we know of no other instances of using real-time simulation to guide local team QI efforts at scale, we sought and received permission to submit a 2-minute video that demonstrates the MTL simulation user-interface (see ***Appendix 7***)**.**] ***Appendix 4*** *also provides a* subset of the system of equations for the Medication Management model.Equations are in plain English following PSD best practices.57–61

**Comparing System Behaviors**. The MM and four other MTL modules (Care Coordination, Psychotherapy, Aggregate Team Services and Measurement-based Stepped Care for Suicide Prevention) include emailed *Team Time* reports. [An example report for each MTL module is included in ***Appendix 5.*** Each reportincludes the simulated output from local team data for the series of experiments that teams run to identify local QI action plans from session 7 to session 10 of the MTL 12-session plan (see *MTL Fidelity Checklist* in ***Appendix 2***).] In MTL, teams can zoom in and out in real-time to see simulated output for any variable and identify changes with the greatest yield or best combination of critical tradeoffs across a range of clinical goals.

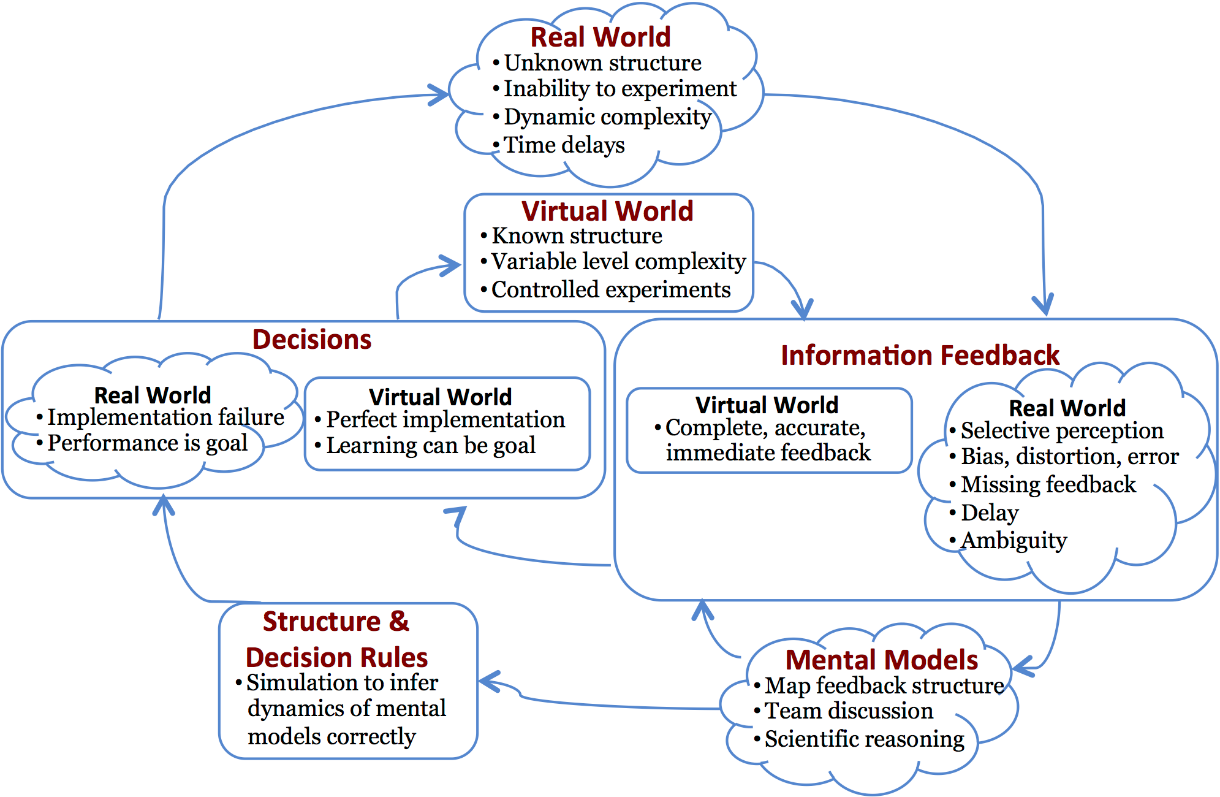
**Summary (Aim 1).** Usual QI and PSD research show data review is insufficient for effective change.61,62 QI effectiveness is diminished63 due to choosing ineffective strategies that leave system causes unaddressed.

**[Aim – 2. Participatory Learning as a Mediator of Change.]**

**We developed MTL using participatory modeling best practices from the field of system dynamics**.62 Systems are defined by feedback dynamics that are hard to see, understand, or improve without a simulation model.24,55,64 MTL models can be understood as ‘dynamic hypotheses’ of system capacity to provide EBPs as a function of patient demand and local system conditions. Synthesis of VA data in the enterprise-wide SQL Corporate Data Warehouse (CDW), virtual facilitation, and an online simulation user-interface make scaling MTL participatory learning feasible without compromising fit of action plans to local capacities and constraints.

**Engagement.** We emphasize empowering advantages of MTL that distinguish it from usual QI. *Table 2c* summarizes the unsuccessful QI effort undertaken by one our R21 pilot clinics. The plan is consistent with the common ‘black box’ MHAP formulation, but the clinic conceptualized it as a S.M.A.R.T goal. The clinic set a Specific, Measurable, Timebound goal. But, beyond being ineffective, PSD proposes that if the goal was never Actionable, because it was not Realistic in that Timeframe with the available resources, then the QI goal may do more harm than good by undermining psychological safety, or willingness to learn and try out new solutions, demoralizing staff and exacerbating staff burnout and risk for turnover.29,54

[*Figure 3* 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). 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 by modeling (42%).61,62



**Figure 3**

**Double Loop**

**Learning**

**Summary Aim 2: Usual QI identifies gaps, but doesn’t empower staff to resolve barriers.** We submit that PSD models make the underlying causal dynamics of ‘limited EBP reach’ transparent, and that participatory MTL sessions trigger locally actionable insights that newly equip frontline addiction and mental health teams to improve quality. MTL has an edge over usual QI in making causal system dynamics tractable, and in use of participatory research principles, including mutual learning, shared decision-making and equitable access to VA data and QI resources.49 We will evaluate our MTL Fidelity Checklist for convergent validity with measures drawn from Community Based Participatory Research (CBPR) and will evaluate the participatory theory of change by testing with participatory measures mediate QI/MTL effects on EBP reach.]

**Aim 3 – Costs of MTL and usual QI:**  **Why is participatory simulation learning likely to be affordable?**

**Simulation learning offers opportunities to safely examine dynamic ‘what if’ scenarios that backward-looking usual QI activities do not.39,40** PSD helps to manage trade-offs and reduce unintended consequences. Reducing and boosting QI time/resources, MTL engagement processes facilitate pre-change consensus68 and post-change resource optimization via system analysis and restructuring.48,69,70,71 Teams use simulation to 1) check assumptions, 2) resolve disputes, 3) examine change proposals, and 4) improve the quality and efficiency of collaborative learning.72,73 Because they do not uncover underlying causes, systems thinkers see accountability metrics as limited or potentially counterproductive for QI.74 Unlike static, retrospective SAIL observations, MTL endows frontline teams with necessary tools to test dynamic hypotheses about mechanisms underlying local quality gaps, to leveragemore effective change(s).75 MTL facilitates stakeholder alignment68 and makes local EBP-specific capacity transparent for optimizing limited VA resources.

**PSD comprises the theoretical and methodological basis for a ‘learning organization.’**76,77 As part of the VA Commission on Care, Institute of Medicine and Centers for Medicare and Medicaid Services identified 1) misaligned demand and resources, 2) uneven processes, 3) non-integrated data tools, and 4) lack of leader empowerment in VA, and recommended use of PSD to improve VA patient access.78 Prior effective uses of PSD in VA include a) reducing Veteran benefits claim delays,79 b) reducing Veteran homelessness by 47% over six years,80–82 and c) evaluating population impacts of alternative VA-wide EBP implementations for cardiovascular care.83 Despite calls for VA to become a learning healthcare system, Commission on Care recommendations, and diverse prior PSD application and success, PSD remains underutilized by VA.12,13, 84,85

**Summary Aim 3. We expect MTL simulation to be an affordable approach to QI learning for the reason other ‘high-stakes’ learning uses simulation** (e.g., surgery):66,67,83,86The costs of mistakes are too great to be learned in the ‘real world.’ Even at local VA division levels, system changes require coordination of dozens of staff serving thousands of patients. In the ‘real world’ of mental health, risks for suicide, overdose and chronic impairment are increased when quality gaps persist.8,10 Frontline decisions regarding scheduling, staffing, referrals, care coordination and continuity interact. MTL makes these interactions visible and accessible via safer virtual manipulation. We will track the costs of both usual QI and MTL, as well as costs associated with increasing the reach of EBPs in order to inform OMHSP decision-makers who are interested in implementing MTL as a substitute approach to addiction and mental health QI at national scale.

**RESEARCH DESIGN AND METHODS**

**Overview.** Five standards guided study design and will be followed for reporting (*Table 5*).

|  |  |
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| **Table 5. Design and Reporting Standards** | |
| Cluster Randomized Trial Design | **CONSORT\*** |
| Usual QI and PSD “Modeling to Learn” | **GREET** |
| PSD Simulation Model | **SIMULATE** |
| PSD Simulation Model Documentation | **SDM-DOC** |
| Budget Impact Analyses | **CHEERS** |
| Quality Improvement | **SQUIRE** |
| MH/Addiction Common Data Elements | **PHENX** |
| \* 2010 update for 'parallel group randomized’ trials. PSD = participatory system dynamics. MH = Mental Health. | |

**Design.** We propose a parallel two-arm, 24-clinic (12 clinics/arm) cluster randomized trial (CRT) to establish superiority of PSD over usual QI 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 (station).20 Number of clinics and number of patients per clinic define total CRT size. Our primary aim is to increase the proportion of the patient-population within PSD clinics that receives EBPs (reach: initiate/dose). Cluster size is defined by the eligible depression, PTSD, OUD patient cohorts, and clinic proportion (reach), as the sum of patient-level EBP reach in

usual care: patients receive (1) do not receive (0) an EBP (binary).

**Procedures for Stratified Block Randomization of Study Clinics.**

**Stratification.** Using baseline CDW data, computer-assisted stratified block randomization using the R package ‘blockrand’87 will balance QI/MTL arms for 5 factors expected to influence clinic-level EBP reach: baseline EBP reach, size (as total mental health patients and providers), urban/rural location35 and division/community-based outpatient clinic (CBOC). We stagger start dates every 6 months (3 MTL clinics/3 QI clinics per wave), making management of clinic relationships feasible and will help mitigate cohort effects.

**Randomization.** We will randomize clinics to usual QI or MTL. Clinics will be community-based outpatient clinics (CBOCs) or Divisions. Twenty-four eligible clinics (CDW sta6a) will be from 24 facilities/regional healthcare systems (CDW sta3n) below the overall SAIL quality median, and below the median on 3 of 8 SAIL measures associated with 4 EBPsy and 3 EBPharm for depression, PTSD, and OUD in *Table 1*. Inclusion criteria balance sensitivity and specificity in identifying lower performing clinics.Once identified via SAIL/CDW, OMHSP will notify clinics that they will receive 6 months of OMHSP TAS support.20 Given OMHSP partner support for running the proposed IIR through existing operations process, we expect that recruiting 8 facilities from these networks is highly feasible, enhanced by 18 months of total pre/post flexibility (see *Timeline*).

**[Usual QI Arm.** Study investigators and the advisory board will select and randomize (via the R ‘Blockrand’ package) regional health care systems based on the past year SAIL performance criteria. Half of the clinics (12 clinics from 12 health care systems) will receive an OMHSP memo notifying them that they will receive 12 sessions of online QI facilitation from the OMHSP TAS, which they will complete during their normal team meetings. Facilitated Data Review and Online Resources. Usual QI uses CDW/SAIL to for data review and the Mental Health Action Plan for developing local QI plans. In addition, to the usual QI 12 session plan, and the 24 standardized emails, the study team will support the co-facilitators in tracking QI activitiesusing the QI activity tracker (see *Usual QI Fidelity Checklist* in ***Appendix 2***).

**‘Modeling to Learn’ Arm.** Half of the clinics (12 clinics from 12 health care systems) will receive an OMHSP memo notifying them that they will receive 12 sessions of online QI facilitation from the OMHSP TAS, which they will complete during their normal team meetings. Facilitated Data Review and Online Resources. MTL uses CDW/BISL to host our team data user-interface. Team review of local data includes interactive filtering and drill down options to the patient level, as well as visualizations of aggregate team data over time. In collaboration with OMHSP, data are defined in the CDW backend to be consistent with SAIL. MTL has an online simulation user-interface and co-facilitators work with teams through a question, hypothesis, findings and decision process for improving QI decisions (see *Team Time* Reports in ***Appendix 5***). In addition, to the MTL 12 session plan, and the 24 standardized emails, the study team will support the co-facilitators in tracking QI activitiesusing the QI activity tracker (see *Usual QI Fidelity Checklist* in ***Appendix 2***).

**Usual QI and MTL 12-session Plans - Fidelity Protocols**

**Both usual QI and MTL team sessions are virtually co-facilitated** by co-facilitators from OMHSP and the study team (Drs. Zimmerman, Lounsbury and Rust).

**Team Engagement.**Virtually facilitated MTL sessions are designed for the existing multidisciplinary teams of addiction and mental health providers from each clinic.

**QI/MTL Fidelity.** We will track the resources, sessions and outputs in the parallel QI and MTL 12-session fidelity checklists in ***Appendix 2.***

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Table 6. Gantt Chart of Proposed Study Timeline** | | | | | | | | | | | | | | | | |
| **Year** |  |  |  | **1** |  |  |  | **2** |  |  |  | **3** |  |  |  | **4** |
| **Quarter** | 1 | | 3 | | 1 | | 3 | | 1 | | 3 | | 1 | | 3 | |
| **Block 1** |  |  |  | **1** |  |  |  |  |  |  |  |  |  |  |  |  |
| **Block 2** |  |  |  |  |  | **2** |  |  |  |  |  |  |  |  |  |  |
| **Block 3** |  |  |  |  |  |  |  | **3** |  |  |  |  |  |  |  |  |
| **Block 4** |  |  |  |  |  |  |  |  |  | **4** |  |  |  |  |  |  |
| **Data (CDW)** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **QI Activity/Cost** |  |  | **B** |  |  | **1** |  | **2** |  | **3** |  | **4** |  |  |  |  |
| **Participatory Mediator** |  |  | **B** |  |  | **1** |  | **2** |  | **3** |  | **4** |  |  |  |  |
| **Dissemination** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Phase 1** | IRB, Recruit, Computer-assisted Stratified Block Randomization – 24 Clinics (12 clinics per Arm; 6 clinics per wave) | | | | | | | | | | | | | | | |
| **Phase 2** | *QI/MTL Arms* – 6 Month Team Participatory Mediator | | | | | | | | | | | | | | | |
| **Phase 3** | *QI/MTL Arms* – Co-facilitated 12 Session Plans | | | | | | | | | | | | | | | |
| **Phase 4** | *QI/MTL Arms* – 6 months Post Technical Assistance | | | | | | | | | | | | | | | |
| **Phase 5** | *QI/MTL Arms* –Last 6 months of12-month EBP reach | | | | | | | | | | | | | | | |
| **Phase 6** | Final Analyses, Ongoing and Final *Dissemination*.  Post-IIR *Implementation* July 2022. | | | | | | | | | | | | | | | |

**Study Timeline and Feasibility**

We propose 16 quarters (48 total months) of study activities and 7.5 quarters (30 months) of active PSD facilitation or post-training assistance (phases 3 and 4). This leaves 4.5 quarters (18 months) of flexibility for delays or setbacks across pre (phases 1 and 2) and post (phases 5 and 6) activities (see *Table 6).*

**EBP Pre/Post Operationalization.** Our pre-measure is the 6 month period average of EBP reach before the first 6 clinics begin PSD, to avoid contamination effects and have a consistent baseline for all clinics. Post-measure is 6 month period average of EBP reach after PSD facilitation ends for that wave (PSD/QI).

**Project Communication and Management Plan**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Table 7. Team PSD Partners** | | | | | |
| **Name** | **Role** | **Organization** | **Study Relevant Expertise** | **Contributions** | | |
| Zimmerman\*+ | PI | OMHSP/NCPTSD | Mixed Methods, Implementation, PSD | Aims 1 & 2 | | |
| Lounsbury\* | co-I | Einstein | Participatory System Dynamics | PSD Model | | |
| Yu+ | co-I | HERC | VA Health Services Economics | Aim 2 (principal) | | |
| Rosen\*+ | co-I | OMHSP/NCPTSD | EBP Dissemination; VA Multisite Studies | Aims 1 & 2 | | |
| Kimerling\*+ | co-I | OMHSP/NCPTSD | Health Services Research | Aims 1 & 2 | | |
| Wiltsey Stirman+ | co-I | OMHSP/NCPTSD | Implementation Science/CRT | Aims 1 & 2 | | |
| Lindley\*+ | co-I | VAPAHCS | Frontline Management | Field Expertise | | |
| McGovern+ | co-I | Stanford | Large Scale Implementation Trials | Aims 1 & 2 | | |
| Collie | advisor | OMHSP | VA VISN and EBP MH Leadership | Clinic Engagement | | |
| Trafton\*+ | advisor | OMHSP | SAIL Measures; OMHSP Policy | SAIL Code | | |
| Rust\* | advisor | OSI/VERC | Systems Engineer/System Dynamicist | PSD Model/SAIL | | |
| Branscomb\* | advisor | GHPC | PSD Facilitation; Facilitation Training | PSD Trainings | | |
| Wiechers+ | Advisor | OMHSP | Psychotropic Drug Safety Initiative | EBPharm | | |
| Holbrook\* | key personnel | OSI/VERC | Industrial Engineer/CDW Programmer | CDW data/SAIL | | |
| Hong+ | key personnel | OMHSP/NCPTSD | Data Scientis1 | Aim 1 | | |
| VAPOR\*+ | key partner | VAPAHCS | Peer Specialists: Patient Perspective | PSD Trainings | | |
| Note: \* Co-investigators on R21 and partners in NCPTSD development. + Co-located at VAPAHCS = VA Palo Alto Health Care System. NCPSTD = National Center for PTSD. Einstein = Albert Einstein College of Medicine. HERC = Health Economics Resource Center. OMHSP = Office of Mental Health Operations. VERC = Veterans Engineering Resource Center. GHPC = Georgia Health Policy Center. VAPOR = Veterans Advisory Partnership for Operations and Research. PSD = Participatory System Dynamics. CRT = Cluster Randomized Trial. CDW = Corporate Data Warehouse. | | | | |

**NCPTSD-DT is ideally positioned to host MTL infrastructure and lead a multisite investigation of MTL effects.**46 NCPTSD-DT focuses on the technology/implementation science interface in research, and developed and supports dozens of mental health apps (iOS and Android) and websites for EBPs.88 NCPTSD-DT leads national virtual trainings in VA, including EBPsy dissemination of prolonged exposure (PTSD)3 and acceptance and commitment therapy (depression).39

**Study Team, Advisory Board and Stakeholders.** NCPTSD-DT principal investigator and co-investigators (*Table 6*)have collectively facilitated many, multisite implementation studies. IIR feasibility is further enhanced by our established partnerships. Eleven of 16 partners collaborated effectively as R21 co-investigators or NCPTSD-funded PSD development partners.14 New partners were added to our IIR team due to study relevant expertise with cost-effectiveness analyses (Yu), cluster randomized implementation studies (McGoven and Wiltsey Stirman) and national EBP QI efforts (Collie and Wiechers). We have collaborated effectively across our nationally distributed team through regular meetings on the Lucid Meetings platform, and project management via Basecamp 2.0. We also benefit from co-location of 10 of 16 partners at VA Palo Alto (NCPTSD, HERC, OMHSP and VAPOR; see included letters of support). NCPTSD and VAPOR trained facilitators will co-facilitate ‘Modeling to Learn’ workshops.

**Aim 1. Key Implementation Outcomes and Analysis**

**EBPs.** We selected EBPs for highly prevalent OUD, PTSD and depression89 based on demonstrated clinical efficacy and effectiveness36–44 and limited EBP reach (*Table 1*). We will study *five* **EBPsy** for *depression* (Cognitive Behavior Therapy [CBT-D], Acceptance and Commitment Therapy [ACT], Interpersonal Psychotherapy [IPT]), *PTSD* (Prolonged Exposure [PE], Cognitive Processing Therapy [CPT]), We will also improve reach of *four* **EBPharm** measures for *depression* (84 & 180 days therapeutic continuity at new antidepressant start), and *OUD* (methadone and buprenorphine).

**EBP Reach definition.** We propose to use PSD to improve reach of 7 EBPs in the outpatient system. We define reach as the proportion of patients diagnosed with OUD, PTSD, or depression (ICD-10 codes) who meet EBPsy and EBPharm *1a) initiation* and *1b) dose* measures (numerator) divided by the total number of patients with these diagnoses (denominator) at that location.*Initiation* of an EBP is indicated by EBPsy template or EBPharm prescription after intake. Adequate *dose* is based on receiving an adequate number of EBPsy sessions to be a “completer” (typically 8 sessions) or enough refills for a guideline-recommend adequate trial of each medication (varies by medication).

**Corporate Data Warehouse (CDW) Data, Definitions and Other Measures**

**EBPsy Measure.** Our **EBPsy** measure is completion of EBP templates during sessions with a relevant CPT code.90 EBP templates are underutilized and may *underestimate* overall EBP delivery, providing a conservative test for change. The templates confer advantages associated with use of existing CDW data, and integration with SAIL quality measures (PTSD 56) and EBP dissemination programs.

**EBPharm** **measure.** Our **EBPharm** measures follows SAIL definitions (SUD 16, MDD43h, MDD47h): a combination of prescriptions placed with the VA pharmacy and sessions with a relevant CPT code.

|  |
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|  |
| **Scale** | | **Aim** | **Time** | **Items** | **Valid** | **Factors** |
| **1**. Patient Aligned Care Team (PACT) Survey-Burnout | | Desc. | BL & 6 mo. | 5 | 0.89 | n/a |
| **2.** Context | | Desc. | BL & 6 mo. | 1 | - | 1 |
| **3.** Structural Values | | ***Aim 2*** | 6 mo. | 22 | 0.93 | 6 |
| **4.** Relationships | | ***Aim 2*** | 6 mo. | 15 | 0.94 | 3 |
| **5.** Synergy | | ***Aim 2*** | 6 mo. | 5 | 0.90 | 1 |
| **6.** Capacity-Building | | ***Aim 2*** | 6 mo. | 5 | 0.90 | 1 |
| **7.** Pragmatic Measures (AIM/IAM/FIM) | | Desc. | 6 mo. | 12 | 0.85 to 0.91 | 3 |
| **8.** Co-Facilitator Engagement | | Desc. | 6 mo. | 10 | n/a | 1 |

**[Aim 2. Team Survey Measures**

**Participatory Measure Selection and Evaluation Process.** The MTL participatory theory of change led us to review recent empirical and psychometric measurement research drawn from the recently validated test of the CBPR conceptual model. e will assess 1) burnout/morale, 2) Context asks who decided to participate. 2) Partnership Structural Values includes subscale measures of a) partner focus, b) core values, c) participation, d) cooperation, e) respect, f) trust. 3) Relationships includes subscale measures of a) participatory decision-making, b) leadership, and c) use of resources. And key proximal outcomes of 4) partnership synergy, and 5) capacity-building. We also will assess 6) pragmatic measures of QI/MTL implementation, and 7) ratings of co-facilitator use of engagement principles. We reviewed Society for Implementation Research Collaboration and Agency for Healthcare Research and Quality Measure Repositories, measures in *Implementation Science* and *System Dynamics Review,* and key IS review manuscripts,91–93noting measures validated with the VA staff. After identifying the most valid and reliable measures (see *Table 8*), our team of patients, providers, manager and program leads further reached consensus about the measures based on face and content validity, or factor structure. Higher weight was given to brief measures and measures preferred by providers, reaching a final survey items to be completed by staff pre/post QI/MTL.

**Measurement Schedule.** We willmeasure team burnout (PACT) and decision to participate at baseline (BL) and 6 months. At 6 months (75 items) we assess our participatory mediator and measures of QI/MTL practicality (AIM, IAM, FIM). The multiple rater co-facilitator engagement measure is added at 6 months to assess for convergent validity with both the MTL fidelity checklist, the participatory scales (see *Table 8).*

**Participatory Principles (Mediator).** We selected the 5 key constructs from the CBPR conceptual as mediator measure due to demonstration of criterion-validity. In addition to strong measures of internal consistency (Cronbach’s alpha) reported in *Table 8*, ***Appendix 2***reports evaluation of the R-squared effect size between each measure of scales #3-6 listed *Table 8* and distal health outcomes. Although only 37 items, the Structural Values and Relationships have strong measures of internal consistency for the nine subfactors that comprise these two dimensions, making these pragmatic scales conceptually strong evaluation of the MTL theory of change in this IIR (Aim 2).

**Convergent Validity Analyses. MTL Fidelity, Participatory Scales and Facilitator Engagement Principles**

**Facilitator Engagement Principles.** Developed by implementation scientists, the 10-item Engagement Principles measure assesses investigator readiness to conduct participatory implementation science research. We include it to assess team and co-facilitator self-ratings of co-facilitators’ use of engagement principles, such as building trusting relationships, knowledge of local conditions, and support for existing local capacities. Response options range from 1 (strongly disagree) to 5 (strongly agree). Items will be summed for analyses, and we will evaluate for convergence/divergence across facilitator and team ratings (see ***Appendix 2****)*.

**Exploratory Aim. Context Measures for Description of Study Clinics**

|  |  |  |  |
| --- | --- | --- | --- |
| **Table 9. Cost Methods** | | | |
| **Initial MTL Support** | | Track staff employment title and full-time effort (FTE) on model/data or interface, excluding training activities. The macro cost method records the FTE designated for this project. The micro method records the time a person spent for each activity. Using micro-costing, we will account for indirect labor costs, such as the time for general training, administrative activity, vacation and sick leave. Since staff salary varies within employment categories and by region, we will use a VA average salary to estimate staff cost. | |
| **QI/MTL Team En** | | Track attendance and duration of usual QI/MTL activities. The number of participants for each employment title will be matched to average VA employment pay categories. | |
| **Supplies** | | Estimate equipment, software, material and telecommunication costs of QI/MTL. | |
| **Equipment** | | Minimum equipment needed for PSD. If shared, estimate (%) used for QI/MTL. | |
| **System** | | Estimate MTL software and system maintenance cost considering economy of scale and marginal cost of adding MTL to the existing system. | |
| **Material** | | Record expenses for producing facilitation and learning resources. | |
| **Telephone/email** | | Estimate marginal equipment and utilization cost of MTL service use. | |
| **MTL recurrent costs** | | Staff time spent on MTL system/system operation/maintenance; estimated at the end of the study. | |

**Patient Aligned Care Team - (PACT).** From VA team-based primary care, this 4-item descriptive measure tracks 1) years of experience with the team, 2) working on more than one team, 3) turnover/change in team staff, 4) team overwork, and 5) self-reported burnout (sensitivity 83.2 % and specificity 87.4 %)28–31,52

**Measures of Feasibility (FIM), Appropriateness (IAM) and Acceptability (AIM)** will assess for differences in team perceptions of usual IQ and MTL on these three factors (12-items). Despite similarities, QI and MTL may be perceived differently in pragmatic terms. These scales have strong psychometric properties (*see Table 8*)for implementation research. Use in the IIR contributes to replication of reliability and dimensionality, and public release of data from the proposed sample of 720 providers adds to future measure norming.]

**Aim 3 Measures**

**Budget Impact Analysis Data Sources.** *Staff.* We will use the Managerial Cost Accounting (MCA) Account Level Budgeter Cost Center (ALBCC) data to assess staff cost. MCA ALBCC provides information on budgeted and actual expenses; hours of staff time are derived from VA financial management and VA payroll systems. MCA ALBCC data characterize costs by production unit, budget object code, location, and time frame.94 *Supplies.* We will track costs for supplies, software and system maintenance directly in the study.

**Design for Tests of Specific Aims**

**We propose a randomized, two-arm, parallel group CRT to test theoretical, *confirmatory* effectiveness (Aim 1), mediation (Aim 2) and cost (Aim 3) hypotheses.** To avoid inflating type I error for Aims 1 and 2 we will conduct two omnibus tests for improved EBP reach (initiate and course). Due to monthly fluctuations in EBP reach, we will calculate 12-month period pre/post EBP reach averages, which removes clustering of EBP reach observations *within* clinics over time in tests of specific aims.We seek to improve EBP reach for each diagnostic cohort (PTSD, depression and OUD) *to meet or exceed the national median* and we will be powered to assess this.

**Analyses for Tests of Specific Aims.**

***Aim 1.* Test for superiority of MTL over usual QI for increasing EBP initiation and course.** We will use R for tests of Aims 1a and 1b to establish MTL superiority. First, we will assess ICCs for within and between clinics. We will test for a significant difference between QI and MTL arms in increasing EBP reach using two (initiation and course) generalized estimating equation analyses for differences in proportions (reach).20,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 QI and MTL arms. We will report the effect size and 95% confidence intervals for the difference between arms at alpha = .05.20

**Average Clinic Cluster Size.** The median clinic/cluster size is 800 (monthly unique depression + PTSD + OUD patient cohorts).

**Intraclass Correlation Coefficient (ICC).** We used the ICC to estimate the variance inflation factor (or design effect) for clustered data in order to have an adequate number of clinics for our tests of specific aims. We describe steps to balance type 1 error (alpha), type 2 error (beta) and power below. We do not know of published ICCs for reach of our key EBP implementation outcomes: EBPsy reach for PTSD and depression, and EBPharm reach for depression and OUD. Using R and packages ‘ICC’ and ‘lme4’,95,96 we analyzed a database extracted from the corporate data warehouse (CDW) to estimate the intraclass correlation coefficients (ICC) for 1) clinics nested within facilities, and 2) repeated observations of clinics over time. Values ranged from low ICC (< 0.0001) for average correlation of station observations nested within facilities to high ICC (~ 0.006) for repeated within station observations. These ICC values are relatively low in CRT,97,98 and indicate near independence of between division/clinic observations within facilities and among within division/clinic observations over time. Note that in analyses for ***Aim 1*** and ***Aim 2*** we remove clustering of clinics within facilities/regional healthcare systems (HCS) by randomizing one clinic from each facility/HCS.

**Power analyses.** We used ‘CRTSize’97,98 in R to calculate the necessary number of clinics for our design. A two-tailed test using alpha = 0.05 and power = 0.80, average clinic/cluster size of 800 and an ICC = 0.02, requires 5 clinics randomized to each arm (10 clinics) to detect an increase from an average EBP reach of 5% to 15%. Using CRTSize, we examined a range of effect size estimates and ICC. With 12 clinics/arm we have power > 0.90 for to detect *5% improvement*. For most clinics, a 5% increase would represent doubling EBP reach. A 24-clinic trial confers several advantages, including the need to stratify and block randomize clinics in even numbers of clinics (i.e., not five), a) greater variation within arms, and b) improved balance across MTL and QI arms. Additional clinics improve intent-to-treat (ITT) analyses should any clinics fail to participate after randomization.

**[*Aim 2*. Participatory Measures Mediator: Multilevel Psychometric Analytic Plan**

**Baseline Measures and Descriptive Analyses***.* Participatory measure means, standard deviations, and correlations will be calculated for individuals and teams. Intraclass correlation coefficients (ICCs) will be calculated. ICC values represent team ‘traits,’ estimated as the proportion of total measure variance attributed to variance between teams. An ICC near zero indicates highly variable participatory constructs within teams.

**Multilevel Confirmatory Factor Analysis (MCFA)**. Factor analyses will be confirmatory. Psychometrics and factor structure for the participatory scales were determined in prior research (*Table 8*). Our unit of interest is teams. Teams are the unit for EBP implementation and PSD/AF training. As a result, we will use the team-mean across our participatory scales. MCFA will be used due to nested measurement (teams in clinics), and potential for differential measure performance across arms in Aim 2 analyses due to QI/MTL assignment. MCFA with R package ‘lavaan,’99 will determine whether the same covariance (factor) structure holds for clinics in each arm (QI/MTL) via closeness of fit (CFI), root mean squared error (RMSEA) and information criteria (BIC/AIC). MCFA reduces risk for inflated error variance associated with non-independent measures (teams in clinics), which is known to inflate type I errors in association tests (mediation). MCFA ensures valid reliability and validity estimates of theorized constructs, and ensures valid tests of Aim 2 mediation hypotheses. We will use confirmatory factory analyses to assess for the six subfactor structure will be specified in prior CBPR psychometric validation studies and results reported.

**Convergent Validity**. We expect the participatory measures to correlate highly with our MTL fidelity checklist scores and with our Co-Facilitate Engagement Scale to be sensitive to change and discriminate between our PSD/AF arms at 6 and 12 months. We expect to observe R2 effect sizes consistent with CBPR validation research between the participatory measures and our distal outcome of EBP reach (R2 *= .78*).17

**Reliability. Measurement Invariance** will be examined with generalizability coefficients (GC)100 in R package ‘lavaan,’99 which extend tests of internal consistency to designs with multiple sources of error. GC values measure the true variability of participatory team-means in each arm as a proportion of total variance to determine the reliability of the scales across teams within arms (Factor loadings and 95% confidence intervals). A standard set of increasingly constrained SEM Models will assess factor loadings, intercepts and residual variance for equivalence101 and will detect the magnitude of measure non-invariance to obtain correct mediation inferences. Variance- covariance matrices of within- and between-arm latent factors will be plotted.

***Aim 2.* Test the MTL theory of change that increased EBP reach is via team participatory learning.**22–24We hypothesize that the effect of QI/MTL

Participatory Measures

EBP Reach

QI/MTL Assignment

a

b

**c = c’ + ab**

c’

**Figure 4**

on 12 month period EBP reach will be explained by 6 month team participatory scale scores, adjusting for baseline covariates using the ratio of mediator probability weight (RMPW).25–27 Our CRT design uses QI/MTL assignment (independent variable) to experimentally manipulate team participatory learning (mediator) on clinic-level EBP reach (outcome) in each arm. But, participatory principles 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 participatory measures through unhypothesized mechanisms (confounders) using multilevel mediation analyses in R package ‘MultisiteMediation’27a 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 (participatory measures), to outcomes (12 months), where ***a*** = the standardized beta coefficient of QI/MTL assignment on participatory measures, ***b*** = the effect of articipatory measures on EBP reach, ***c*** = the total effect of QI/MTL assignment on EBP reach, ***c’*** = the direct effect of QI/MTL on EBP reach, and ***ab*** = the indirect effect of QI/MTL on EBP reach through team participatory learning (hypothesized mediation). We will use a bootstrapping, asymmetric confidence interval approach to balance power and type I error.

**[*Aim 3*. Budget Impact Analysis.] MTL & usual QI.** We will use the quality improvement activity form adapted from a current VA operations-focused, implementation facilitation trial by the VA Team-Based Behavioral Health QUERI Program.102 Four strengths of this measure apply to our study: 1) assessment of activity costs readily comparable to other another VA multisite trial, 2) measure from Behavioral Health Interdisciplinary Program (BHIP) Enhancement Project, team-focused MH care, like PSD, 3) emphasis on quantifying a) staff and b) facilitator time, rather than categorizing content, 4) prior use in VA. Following Bauer et al., at baseline and in the first month *after* the 6-month PSD Workshop or usual QI, we will choose random weeks to have a) local managers log all QI activities during.

**[Usual QI/MTL Cost Measurement.** We will estimate QI/MTL cost from VA’s perspective, generating a cost impact on a HCS’s budget (*Table 9*). We will use ***micro-costing*** to measure costs of using usual QI or MTL to implement EBPs for patients diagnosed with PTSD, depression and OUD.16,18 For each division, we will estimate PSD costs for model development and operation. PSD development occurs only at the initial stage, whereas PSD operation costs are recurrent. Staff time will be separated into initial PSD Support and PSD staff training. Staff training will be considered separately to assess economy of scale, should PSD training be provided in VA nationally. We will record additional time on model development/refinement and designate the cost impact on budget during proposed IIR activities.103]

**Alternatives to Proposed Study Design and QI Strategy Considered.**

**Design Limitations and Data Exploration.** Our procedures rely heavily on existing CDW data. This is a strength in that the proposed IIR is stays as close to typical mental health operations as possible, maximizing the potential for PSD scale and sustainment. We aim to reduce data quality issues by focusing on EBPs and quality measures with significant infrastructure support represented by partners on our team.

We will complement our primary test of aim 1a and 1b using exploratory alternatives that mitigate potential limitations**.** To guard against threats from secular trends104,105 (overall patient demand or VA EBP adoption may be increasing), and regression to the mean (given these are lower performing clinics), we will also track national trends in EBP reach and estimate the percentage of regression towards the mean. *Autoregressive integrated moving average (ARIMA).*106 We will evaluate ARIMA models to detect and correct for autocorrelation-biased residuals in time-series observations. We will also describe and graphically display the 6 month period average 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 proportions of patients who receive each EBP. SPC is a standard, healthcare quality tool robust for non-normal data and unbalanced samples.107 The p-chart centerline corresponds to the mean proportion of patients who meet EBP criteria, controlling for the number of patients in each observation.108 Within a particular clinic, SPC charts indicate whether Aim 1a and 1b are successful if serial observation (average run line = 8 data points) of a new mean after PSD is outside initial control limits indicating improvement beyond 3 SD (alpha = .0027).72,108 When 80% of data points fall within 1 SD of this new mean, improvement is stable.72,108 We will follow SQUIRE reporting standards for SPC.72

***PSD Models.*** We will document our models using SDM-DOC and report findings using SIMULATE.49,50

**Alternatives to PSD Strategy Considered**. Better QI strategies can reduce potential for delays, waste, and thereby, costs of improving quality. Without QI enhancement from theoretically and empirically sound simulation tools and systems thinking, it is hard to resolve disputes about changes, and easy to pursue ineffective or counterproductive strategies, even when time-intensive external facilitation or resource-intensive data review (e.g., lean) are available.56 Stakeholder experimentation with theoretically and mathematically sound simulationtools, encourages safe prototyping of ideas, experiential learning, and accumulates in new staff QI capacity over time, maximizing limited QI resources when defined by staff activity costs.

We propose that improvement of ‘limited EBP reach’ among the eligible patient population will emerge from changes to dynamics that determine interdependent clinic states and flows. If so, SD models, and participatory modeling, are more appropriate for guiding change, than models to identify rules governing individuals’ behaviors (agent-based models) or changing network relations (social network analysis).49

‘Modeling to Learn’ focuses on improving everyday QI decision-making among frontline teams. When models or algorithms are opaque and do not have the confidence of staff, they do not guide these decisions to improve quality.109 Other exemplars, such as the VA Quality Scholars program, focus principally on leaders.But, frontline staff make decisions related to quality (aided or unaided) everyday. Provider QI competencies are now prioritized across medical education and interface with health informatics, and providers spend considerable time entering data (charting). But, VA data are typically geared toward QI management, not QI learning.12,77 Without participatory staff engagement and experimentation to improve frontline decisions, current gaps between QI resources and quality are likely to remain (*Table 1*).

**Dissemination and Implementation Plan.**

**Broad Aim:** If IIR findings favor MTL, OMHSP leadership may consider substituting MTL with activities of current facility, VISN, OMHSP and other QI activities.

**Timeline for Scaling MTL *Implementation*: Concurrent with IIR/Ongoing** If preliminary trial effectiveness data are promising, we will begin to train MTL facilitators to facilitate MTL immediately after IIR end (~July 2023). Readiness for **implementation** is enhanced by 1) focus on QI/operations, 2) use of existing CDW data, 2) ‘usual QI’ comparator, 3) OMHSP operational partners, 4) online/virtual resources/platform, 5) cost estimates. We anticipate VA-wide scaling will be enabled by 1) downloadable/reproducible a) learner, and b) facilitation resources on GitHub, 2) data review on CDW/BISL and OMHSP quality metric dashboards (i.e., with SAIL), and 3) partnership with EES to offer continuing education credits (see *Letters of Support*).

**Mechanisms for *Dissemination*:** *Clinical/operations*. Our OMHSP partners direct VA addiction and mental health QI. We will present updates regularly to OMHSP workgroups on national webinars/calls (EBP Coordinators & VISN MH leads). At NCPTSD, we will coordinate with a) PE, CPT and ACT EBP dissemination leads, b) the PTSD Mentorship Program for all PTSD Special Program Directors, and c) the Practice-based Implementation Network. *Research.* HSRD/QUERI updates through cyberseminars/conferences.

**Budget Based on Cost Summary.** We will have strong estimates of a) staff and b) technology requirements to scale MTL. *Barriers:* Beyond established partnerships and integration with existing VA data and program infrastructures, we anticipate two primary scaling costs (constraints) outside IIR scope/budget: a) hosting many more concurrent user-interface users, and b) training more MTL facilitators. Costs depend on **scaling the MTL QI infrastructure** in terms of access to online resources and training of co-facilitators. *Sustain MTL at IIR size:* Support for up to 1000 unique staff users/month for $4770. *Scale:* Support for 5000 staff users/month for $9770/year.

**INNOVATION**

**PSD is innovative meeting several needs for advancing *science of EBP implementation*** (*Table 10*). Learning from investments to promote EBP adoption and QI infrastructure, VA is at the vanguard of implementation science, recognizing the need for generalizable implementation strategies, applied at the local, setting level. Health care data systems are now ubiquitous, and lessons learned in VA outpatient mental health can be translated to many other VA health services, and health care systems.13

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| **Table 10. PSD or ‘Modeling to Learn’ Innovation for Advancing Implementation Science** | |
| **Theoretical/Empirical mechanisms** | Stakeholders make theory-based, causal attributions about the system and QI plans that are structured in a model, and validated with calibrated parameters from health system data.110,111 A significant advance beyond self-report of implementation ‘barriers and facilitators’ alone. | |
| **Generalizability** | A primary innovation of PSD is generalizability of one systems change approach to tailor EBP implementation to any local healthcare setting. PSD can be applied to any EBP that requires coordination among multidisciplinary providers and multiple visits, and is responsive to clinic/ system needs to improve implementation of multiple evidence-based practices in one system. | |
| **Local Engagement** | Participatory by-design, PSD responds to calls for practice-based research and pragmatic implementation knowledge. PSD is consistent with a learning health care organization, promoting leadership and systems thinking among staff.76,77 Modeling to adapt or make ongoing improvements increases sustainability of QI efforts amid ongoing change.71 | |
| **‘Fit’ and ‘capacity’ formally specified** | Eliciting stakeholders’ ‘mental models’ is necessary, but not sufficiently precise for improved alignment of EBP implementation to meet patients’ needs.48,64 | |
| **Simulation** | Rather than guesswork, wasted resources or unintended consequences, stakeholders’ ‘dynamic hypotheses’ about system impacts are tested before changes. Without simulation, implementation strategies can only be improved via trial-and-error in the real world. | |
| **Existing Data to Examine Dynamics** | Traditional statistical evaluations omit important variables when data are unavailable. PSD models estimate these ‘missing parameters’ formally in real-time from other data. Unlike linear statistics, PSD addresses non-linearities, such patient accumulations and service delays. | |

**The IIR addresses *critical crosscutting VA priorities* for improving VA health care** (*Table 11*). This study is innovative for emphasizing use of existing VA resources and data that empower frontline staff to reach greater consensus and specificity regarding system organization to implement EBPs. We found no studies evaluating participatory system dynamics in a randomized trial (see ***Appendix 6*).** Identifying the best ways to allocate limited resources is critical in VA and all healthcare systems. Without methods to improve QI and system procedures, health systems will make ineffective use of their resources to provide evidence-based mental health care, and fall short of goals to provide high-quality, patient-centered care,12,78 that reduces risk of suicide and overdose death, andsignificantly increases patient well-being.3,4,8,10

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| **Table 11. Proposed Research Aims and Design Address Critical Cross-Cutting VA Research Priorities** | | |
| **Veteran, provider, stakeholder engagement in research** | Preliminary research, development and proposed IIR based on multi-stakeholder partnerships with local frontline staff and managers, Veterans, and OMHSP, HERC and VERC VA partners |
| **Employee engagement to improve decision making and team functioning** | Increasing *and* standardizing team-based quality improvement activities and professional continuing education for six frontline mental health disciplines to improve access and quality |
| **Mental and Behavioral Health** | Focus on patient populations at higher risk for suicide or overdose |
| Leverage existing VA programs: National EBP training and quality improvement programs |
| Focus on multiple provider disciplines and EBP practices across generalist and specialty care in the modal form of treatment (outpatient care) |
| Enhancing clinical operations through the complementary PSD innovation coordinated with existing SAIL quality measure infrastructure |
| **Patient Centered Improvements to Deploying Best Practices** | Improving care management to improve patient flows through care, care coordination across multiple providers/teams and provide continuity of care to patients |
| **Cost Comparison, Budget Impact, Cost-Effectiveness** | Budget impact of multi-clinic intervention that can be applied in VA outside of mental health |
| A randomized cost comparison/cost effectiveness estimate for achieving quality, focused on national scaling of quality improvement integrated with existing VA programs |
| **Implementation Science** | Design and testing of strategies to implement effective practices and improve quality across multiple evidence-based mental health practices with explicit focus on employee engagement |
| **Systems Change Approaches to Promoting High-value Care** | Use of health systems engineering *and* operations research to improve coordination/processes to maximize VA EBP investments and increase access to this high-value care among Veterans |

**HUMAN SUBJECTS**

1. **Risks to Subjects:**

*Human Subjects Involvement and Characteristics*

*Patient participants.* Electronic data from the VA Corporate Data Warehouse (CDW) will be used to evaluate specific aims and comprises the *first of two* human subjects components to our study. We will use existing data during this project. Therefore, risks associated with this study to individual patients who use addiction and mental health services are minimal.

*Staff/Provider participants.* Comprising the *second of two* human subjects components of our study, addiction and mental health staff will be engaged in 12 hours of quality improvement activities, randomized to either usual quality improvement (QI arm) or the participatory system dynamics program entitled, ‘*Modeling to Learn’* (MTL arm). Across the two randomized conditions, both usual QI and MTL will include approximately two hours per month of engagement with external co-facilitators for six months with optional self-directed learning. During usual QI, frontline teams of providers will evaluate VA quality measures known as Strategic Analytics for Improvement and Learning (SAIL) and select improvement strategies in their teams, which they will enter in the online Mental Health Action Portal (MHAP). During MTLsessions, frontline teams of providers will review data and evaluate improvement scenarios via simulation using the online question/hypothesis/findings/decisions (QHFD) simulation user-interface dialogue to identify new quality improvement decisions in their clinics/teams.

Providers will be invited to complete brief online surveys at baseline and 6 months. Across both measurements, providers will be asked to respond to 75 total items, which should take approximately 15-20 minutes.

*Office of Mental Health and Suicide Prevention (OMHSP) Co-Facilitation/Team Engagement.* This project is a collaboration between the Principal Investigator and Co-Investigator team, and operational partners of the VA Office of Mental Health and Suicide Prevention (OMHSP). The OMHSP Technical Assistance Specialists (TAS) will comprise the study co-facilitators, in pairs with co-facilitators from the study team (Drs. Zimmerman, Lounsbury and Rust). Across both arms, staff will participate in their existing multidisciplinary care teams, and will review the same VA data in relation to the same VA quality standards (e.g., data drawn from the same records and defined the same way). However in usual QI, staff and co-facilitators will review existing VA dashboards, whereas in MTL staff and co-facilitators will review the data user-interface of MTL. Across both arms, providers will receive the same number and duration (6-months) of email engagement related to local quality improvement goals, and will have the same co-facilitators for virtual/online facilitation during usual team meetings (see usual QI fidelity and MTL fidelity in *Appendix*).

*Participatory Research Methods with Stakeholder Partners.* Over the last three and a half years of partnership, OMHSP leaders and frontline staff of the outpatient service system helped to shape the goals of this study. Along with these OMHSP partners, 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. These certified peer specialists from the Veteran Advisory Partnership for Operations and Research (VAPOR) complete Collaborative IRB Training Initiative (CITI) Training.

*Sources of Materials*

*Sources of Materials – Patient Human Subjects.* Administrative data and VA information systems will be used to evaluate VA quality metrics known as Strategic Analytics for Improvement and Learning (SAIL), and quality improvement activities will compare staffing allocations, patient referral flows, appointment timing and type, and pharmacy records. These electronic data will be drawn from the VA CDW.

*Sources of Materials – Staff/Provider Human Subjects*. Both usual quality improvement and Modeling to Learn quality improvement activities will collect anonymized, qualitative and quantitative data from addiction and mental health staff in the Mental Health Action Plan (MHAP) portal and in the Modeling to Learn simulation user-interface. Routine data about team care patterns, and information about staff decisions regarding change will be collected throughout the project as part of both usual QI and MTL activities.

*Potential Risks*

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 VA quality measure data and the focus of the survey questions on the quality improvement activities of their teams.

**2. Adequacy of Protection Against Risks:**

*Recruitment and Informed Consent*

*Patients.* The research involves no more than minimal risk to the patient participants. No new data will be collected beyond data generated during routine care. There will be no interaction with current patients for the purposes of research. Patients will not be asked to sign a consent form. 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.

*Provider team engagement.* This research involves no more than minimal risk to the provider participants. Usual QI is standard practice in VA. MTL is an augmented version of usual QI for achieving greater improvements in quality. Eligible VA regional health systems will be below the overall VA national quality median. Providers will be informed of the goals of the usual QI or MTL engagement with OMHSP.

*Provider survey informed consent.* Providers will be invited to complete brief online surveys at baseline and 6 months. They will be informed of possible risks, such as discomfort being asked about quality issues and team care coordination issues. Providers will also be informed of potential benefits, such as the ability to improve patient care and provider quality of work-life based on the findings from the proposed trial.

Providers will have the option not to participate in the survey measures or withdraw their participation in surveys at any time. Across both measurements, providers will be asked to respond to 75 total items, which should take approximately 15-20 minutes. Providers will be informed of the potential knowledge to be gained from the surveys. Providers will be informed of the opportunity to stop survey participation at any time without penalty.

*Clinic Recruitment/Randomization.*

Clinics will not have the option to decline participation in OMHSP-led quality improvement activities during the project period. The 24 clinics from the 24 independent regional health care systems will receive an OMHSP/VA Central Office memo from OMHSP Executive Director, Dr. David Carroll, indicating that they will receive OMHSP assistance with improving addiction and mental health care quality. OMHSP Technical Assistance Specialists (TAS) are each responsible for facilitating clinics and health care systems from their assigned VISNs to achieve VA quality metrics, known as SAIL. Underperforming VA regional health care systems and clinics are required to meet VA quality standards, and would typically receive assistance from OMHSP TAS to improve without the proposed IIR trial. During the proposed multi-site IIR, OMHSP TAS will continue this usual quality improvement approach in half of the clinics, and will test the Modeling to Learn approach in the other half. Although non-optional clinic QI activities conducted during the trial will facilitated by OMHSP, staff will retain the right to decline to provide survey data for the purposes of research.

Over the course of the proposed study, this research project expects to involve 24 clinics, with one clinic drawn from 24 separate regional health care systems randomized to either usual QI or MTL (12 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. Usual QI/MTL sessions with staff will be held during regularly scheduled staff meetings or team huddles. Participation will occur during work hours. Since randomization occurs at the VA regional health system level, with one participating clinic from each health care system, quality improvement activities and facilitation opportunities will not vary among co-workers from the same clinic. Local staff will either all receive usual QI or all receive MTL.

*Protections Against Risk including Data Security and Sharing*

*Protection against Breaches of Confidentiality.* Patient information in the VA administrative data systems will not be transported. Real-time aggregate data reports will be extracted from existing quality assurance algorithms leaving the data on VA servers in existing VA dashboards/platforms for data review. Individually identifiable patient data will not be synthesized in models in the MTL arm. All files related to study data will be password protected and will only be accessible by those working directly on the study.

*Protection against Staff Discomfort.* Addiction and mental health staff are required to meet VA quality standards and are expected to participate in quality improvement efforts (usual QI or MTL) as directed by OMHSP leadership. Review of health system data to improve evidence-based practice implementation and overall mental health and addiction service quality is a typical staff professional activity. During meetings staff may decline to discuss topics without penalty and withdrawing from the team meetings will in no way impact access to OMHSP consultation or VA data services routinely made available to staff and incorporated as primary foci for this study. Based on past research collaboration with outpatient stakeholders, we expect that staff will appreciate the opportunity to share their experiences, challenges, and concerns. However, should they experience distress as a result of participating in this research partnership, we will refer them to a member of our VA Office of Research and Development, and will notify the IRB. Co-Investigators and advisors on this grant have extensive experience working with and addressing the problems of VA staff (Drs. Lindley, Rosen, Kimerling, Collie, Iwamasa, Wiechers, Rust, and Trafton). Staff may decline to participate in online surveys or decline to answer any particular item from the survey measures.

**3. Potential Benefits of the Proposed Research to the Human Subjects and Others:**

The purpose of this project is to test for the superiority of MTL against usual QI. Based on large bodies of usual QI and MTL research, we expect MTL to enable frontline mental health staff to better identify improvements to mental health delivery that increase the proportion of the patient population who receive high-quality, evidence-based care. We will learn about causes of limited evidence-based practices (EBP) reach, the explanation for findings regarding usual QI/MTL effectiveness, and we will track costs of usual QI/MTL across a wide range of clinics/regional health systems. This project should improve Veterans’ health and well-being by improving the quality of their care. It is possible that MTL/usual QI activities will also improve providers’ quality of work-life on their teams as improvements are identified. Findings from tests of specific aims will enable VA OMHSP to prepare to expand this benefit more widely beyond VA through future research through online public dissemination of models, code and training resources. Finally, this project is designed to maximally support and increase the capacities of stakeholders in outpatient services delivering care via mental health, and therefore we aim to build the skills and knowledge of staff who are participating.

**4. Importance of the Knowledge to be Gained:**

We’re proposing a Phase III Clinical Superiority design with falsifiable hypothesis tests. We’re testing the most commonly used VA quality improvement strategy as ‘usual QI’ – SAIL data review and external implementation facilitation from VA Central Office Leadership (OMHSP) – against a very rigorous theory-based approach (MTL: participatory system dynamics) with a 60-year track record of effectiveness for improving organizations/business. Confirmatory effectiveness (Aim 1) and causality (Aim 2) hypotheses are relatively rare in the field of implementation science. We will complete these analyses with budget impact analyses (Aim 3) to inform VA quality improvement efforts in the high priority area of addiction and mental health care. The ultimate anticipated benefit of this project lies in its potential to identify consistent ways to increase the reach of EBP’s to patients in need of services. Toward this end, study aims are designed to inform replication of the use of MTL should IIR findings warrant further study. Our project activities are the first step toward creating an improved learning healthcare system paradigm for ongoing quality improvements in health service delivery. Due to our use of VA nationwide data extraction approaches, this method can be scaled and applied to other VA health specialties beyond mental health. Use of standard data definitions for coding patient diagnoses or patient-provider encounters (visits) makes the study ready for replication in other VA services. This program of research could improve the quality of care in the future for large populations of patients and help the VA and other health systems to make better use of existing resources (i.e., staffing) to provide highly effective treatments.

**5.** **Data and Safety 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 Dr. Trafton, Director of the Office of Mental Health and Suicide Prevention (OMHSP) Program Evaluation Resource Center (PERC) and will regularly review data management procedures.

**Inclusion of Women and Minorities:** 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 IIR 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). Our trial plans are inclusive for both patients and providers.

The IIR 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, 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 primary trial outcome measure is drawn from existing health care records.

Prior studies neither support nor negate the potential for significant differences in usual QI or MTL 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, fidelity to participatory principles (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.

**Targeted/Planned Enrollment:** Analyses to test specific aims include 24 months of observation (12 months pre-/12 months post-intervention) across all 24 sites (12 MTL sites/12 usual QI sites). See enrollment table.

***Patients.*** By VA policy, all VA patients should have equal access to EBPs.Existing health system data (e.g., means/median number of patients receiving specific services, means/median of scheduled clinic appointments) will be reviewed with frontline staff in order to achieve higher quality care (usual QI arm), or available for review by frontline staff and synthesis in participatory system dynamics models for simulation testing (MTL arm). Analyses to test specific aims include a 24-month observation of health services delivery (12 months pre-/12 months post-) across 24 clinics.

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| **Enrollment - Unique Patients in Multisite Mental Health Cohort** | | | | | | | |
|  | **Not Hispanic or Latino** | | | **Hispanic or Latino** | | | **Total** |
| **Racial Categories** | **Female** | **Male** | **Female** | | **Male** |  | |
| American Indian/Alaska Native | 314 | 3,157 | 50 | | 504 | 4,025 | |
| Asian | 64 | 649 | 10 | | 104 | 827 | |
| Native Hawaiian or Other Pacific Islander | 35 | 351 | 6 | | 56 | 448 | |
| Black or African American | 291 | 2,929 | 46 | | 468 | 3,734 | |
| White | 1,039 | 10,455 | 166 | | 1,670 | 13,330 | |
| More than One Race |  |  |  | |  |  | |
| **Total** | 1,743 | 17,541 | 278 | | 2,802 | 22,364 | |

***Providers.*** Teams (typically 4-6 staff) of frontline multidisciplinary mental health and addiction staff from 24 participating clinics will be randomized to six months of team usual QI or six months of team MTL, each designed for improvement in delivery of high-quality, evidence-based care. Pre-post provider survey measures will be collected at baseline and at the end of the improvement strategy (six months). All addiction and mental health providers mapped to a care team in our study clinics will have the opportunity to participate.

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| **Provider Demographics** | | | | | | | |
|  | **Not Hispanic or Latino** | | | **Hispanic or Latino** | | | **Total** |
| **Racial Categories** | **Female** | **Male** | **Female** | | **Male** |  | |
| American Indian/Alaska Native | 8 | 5 | 1 | | 1 | 15 | |
| Asian | 32 | 20 | 3 | | 2 | 57 | |
| Native Hawaiian or Other Pacific Islander | 8 | 5 | 1 | | 1 | 15 | |
| Black or African American | 78 | 52 | 9 | | 6 | 145 | |
| White | 245 | 163 | 27 | | 18 | 453 | |
| More than One Race | 19 | 13 | 2 | | 1 | 35 | |
| **Total** | 390 | 258 | 43 | | 29 | 720 | |

**Inclusion of Children:** All participants will be 18 years of age or older. There will be no children involved. This is a study of adult outpatient mental health and addiction services in the VA. The purpose of the study is to understand how to expand the reach of evidence-based psychotherapies and evidence-based pharmacotherapies determined to be effective for adult diagnosis with depression, PTSD, alcohol or opioid use disorder. The study will take place in the national VA health care system, which serves adult male and female patients. Therefore, due to the trial target to expand the reach of adult treatments (i.e., evidence-based practices), and due to the focus on intervention with professional health care staff, participation of children in this trial is not scientifically or ethically justified.