Study Protocol and Statistical Analysis Plan

Evaluation of Implementing FLOW in VISN 19:

Transitioning Stabilized Mental Health Patients to Primary Care

PEX 19-004

8/15/2023

Specific Aims

Adequate access to mental health treatment is one of the highest priority problems facing the Veterans Health Administration (VHA) and VISN 19. Chronic staffing shortages exist for both psychologists and psychiatrists.[1,2] Our clinical partner, VISN 19, notes that access to mental health clinics impact their performance on SAIL access and quality metrics. Poor access to care can contribute to suicide and disability, and long wait times contribute to patient dissatisfaction and disengagement from care.[3,4,5]

Common mental health conditions are expected to remit in many cases[6] or to be substantially improved with treatment[7] such that patients no longer need intensive specialty mental health services. International clinical guidelines encourage the use of stepped care, in which patients should be treated at the least intensive level of care that is appropriate to their condition[8,9] and VA has embraced stepped care.[10] As part of this, VA has rolled out primary care mental health integration (PCMHI) programs at every VA.[11] Primary care, in partnership with PCHMI, provides access to maintenance treatment (e.g., ongoing psychotropic prescriptions). VA mental health manuals encourage the transition from specialty mental health to primary care for patients whose mental health has stabilized and can be addressed in the primary care.[11,12] Unfortunately, VA manuals do not provide clear guidance on which patients are appropriate for transition back to primary care or how the transition should take place.[11] In the absence of guidance, few patients are appropriately transitioned and specialty mental health panels remain full, contributing to access problems.

To address these issues, our team partnered with VISNs 16 & 17 to pilot a demonstration project called FLOW. **This program consists of an algorithm to identify patients who are potentially appropriate for transition, a user-friendly online report to communicate this information to providers, materials to explain this process to patients and providers, and an electronic medical record (EMR) note template to document care transitions**. In cases where providers believe continued specialty mental health treatment is warranted or patients object to the transition, patients remain in specialty mental health. This approach has high acceptability to remitted patients because of perception of less stigma and reduction in appointment burden when care is managed in primary care.[13] The FLOW program fits with VA national priorities to 'focus resources more efficiently' and 'improve timeliness of services.' To implement FLOW, external facilitators work with site-based internal facilitators and providers in specialty mental health and primary care using evidence-based implementation facilitation strategies and feeding back data to individual sites to guide implementation.

FLOW was first implemented at 4 sites in VISNs 16 and 17 and is now being implemented at all VISN 17 sites. Data from the first site indicates that 424 unique patients transitioned from specialty mental health to primary care and of those, only nine (2.1%) returned to MH after that transition, suggesting that the majority of transfers were successful. Implementation success differed dramatically across the original pilot sites but data collected did not offer an explanation for this or allow examination of implementation factors associated with success. To maximize timely access for new mental health patients, VISN 19 is embracing the FLOW program. **Given that VACO is moving towards implementing this program nationwide (personal communication from Dr. Marsden McQuire in OMHSP and Dr. Timothy Dresselhaus in Office of Primary Care),** it is essential to examine the impact of this program on VA patients and clinics and understand the factors that facilitate implementation success. We are partnering with VISN 19 to evaluate this program using **a cluster-randomized stepped wedge design with 9 sites randomly allocated to receive the intervention in one of 3 steps.** This provides an ideal opportunity to conduct rigorous evaluation of FLOW's clinical impact and the implementation factors affecting success at each site.

Specific aims for this proposal, co-developed with VISN 19, are:

1. To evaluate the impact of FLOW on patient care, relative to standard care, using the evaluation framework RE-AIM, including:
   a. Reach of the program: % of clinic patients transitioned to PC
   b. Effectiveness: % of patients with successful transition to primary care and impact on clinic access and provider time for incoming SMH patients
   c. Adoption: % of providers in the selected clinics transitioning patients to primary care
   d. Implementation: use of all FLOW components, based upon the implementation checklist (see Appendix)
   e. Maintenance: sustainment of FLOW after withdrawal of external facilitation
2. To evaluate the relationships between successful FLOW implementation and implementation factors as aligned with the Consolidated Framework for Implementation Research model (CFIR)[14], including intervention characteristics, inner and outer context (e.g., staffing, resources, readiness to change), characteristics of individuals (e.g., leadership, facilitators and providers), and the process of implementation (e.g., the process of implementation facilitation).

A. Background and Significance

Access is a priority problem. Improving access and timeliness of services is one of the five priorities in the 2018 VA Strategic Plan. Our clinical partner, VISN 19, notes that access to mental health impacts their performance on SAIL access and quality metrics. Unfortunately, chronic staffing shortages exist in specialty mental health (SMH)[1,2] and inefficiencies and poor coordination of care combine to reduce mental health access and impact wait times and frequency of visits. Poor access to care contributes to suicide and disability, and long wait times lead to patient dissatisfaction and disengagement from care.[3,4,5]

To make the most efficient use of existing SMH providers, patients who are improved or remitted should be transitioned from intensive SMH treatment to a less intensive setting, primary care (PC). For our purposes, transition to PC is defined as an intentional, planful discharge from SMH and transfer of any prescription and monitoring responsibilities to the PCP, when the patient has sufficiently recovered such that they no longer need intensive SMH care. This will increase availability in specialty providers' panels and provide faster access for new patients referred to SMH. This approach also has high acceptability to remitted patients because of perception of less stigma and reduction in appointment burden in PC.[13] This creates little burden on PC physicians to renew medications of patients already in their panel. VISN 19 notes that their SMH providers face barriers to transitioning patients, including lack of guidance on whom to transition, a method to identify candidates, a lack of processes and incentives to support this practice, and lack of coordination across clinics.

Clinical Guidelines Encourage Recovery and Transition out of Mental Health. Many mental health conditions are expected to remit.[6] Others may be dramatically improved with evidence-based prescribing and psychotherapy,[7] such that patients no longer need intensive SMH services. International clinical guidelines and VA practice guidelines encourage stepped care, in which patients are treated at the least intensive level of care appropriate.[8,9,13] VA has embraced stepped care[10] and rolled out primary care mental health integration (PCMHI) programs at every VA.[11] Primary care, in partnership with PCHMI, provides access to maintenance treatment (e.g., ongoing psychotropic prescriptions). VA mental health manuals encourage the transition from SMH back to PC for patients who have stabilized and can be addressed in the primary care setting.[11,12] Having a mechanism for transition back to PC is consistent with the VA and SAMHSA-supported Recovery Model,[15,16,17,18] which facilitates recovery rather than continued dependence upon treatment. In contrast to this guidance, however, lack of a way to 'graduate' successfully sends patients the message that continued dependence upon SMH is expected.

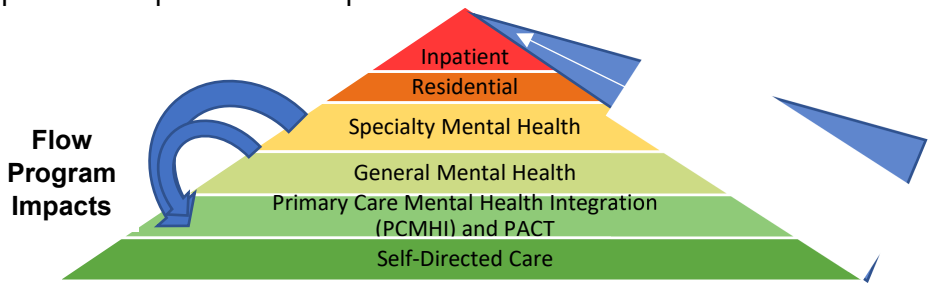


Figure 1. FLOW fits with OMHSP's Mental Health Continuum of Care Model

Recently, VA's Office of Mental Health and Suicide Prevention (OMHSP) has embraced the Mental Health Continuum of Care Model (CoC; Figure 1).[19] It incorporates stepped care, the recovery model, and measurement-based care to determine when to step up or step down in care intensity. According to OMHSP's Continuum of Care workgroup report, "Within stepped care, the basic tenet is to start with the least resource-intensive, yet likely to be effective, treatments, only 'stepping up' to more intensive/specialist services as clinically indicated and 'stepping down' once maximum clinical benefit has been obtained from the higher level of care." Further, it indicates that "discussions regarding stepping down should occur when Veterans have met their treatment goals or are stabilized as demonstrated by validated assessment of their symptoms and functioning."[19] The processes for stepping up care are already well defined in clinical practice guidelines and policy manuals, but there is very little to determine when or how to step down. The FLOW program will assist VA providers and clinics in making this clinically important decision and implementing processes to facilitate it.

There is no current solution for the problem of care transitions. In the absence of processes to facilitate discharge, patients who recover and no longer need SMH are left with 3 options: 1) stay in SMH and continue attending multiple unneeded yearly visits; 2) disengage from SMH by no-showing and discontinuing medications without supervision; or 3) ask their SMH provider to transition them to PC. Given the current poor coordination, lack of agreements between SMH and PC, and lack of experience with these transitions, option 3 is unlikely to be easy or seamless. VA Central Office indicated that electronic medical record (EMR) templates for transition to PC exist in only a few facilities nationwide and are rarely used.[19]

The FLOW program assists facilities with transitions. The FLOW program was created to address this need. FLOW consists of EMR-based criteria to identify patients who may be eligible for transition to PC and a user-friendly online report to communicate this information to clinicians. The criteria were developed by the FLOW team in consultation with stakeholders and a Veteran community advisory board. Current criteria are that patients must be taking three or fewer psychotropic medications, not be taking antipsychotics, lithium, or a mood stabilizer when bipolar disorder is present, had no new psychotropic medications in the past 6 months, no psychiatric inpatient or psychiatric ER visits in the past 12 months, and have no suicide risk flag. Recent refinements of these criteria added that the patient must not be taking Suboxone and must not be high risk for suicide based upon REACHVet score. Because these criteria rely upon information available in administrative databases, they may miss subjective signs that the patient is not ready for transition such as milder suicidal ideation or near-hospitalization episodes. As such, provider clinical judgment based upon the individual patient's current functioning, strengths, and resources, is the final determination of eligibility. The process of transition starts first with identification of potential eligibility via the online FLOW report. SMH providers review the list and determine which patients they believe are clinically appropriate, and discuss this with the patient at their next appointment to determine if the patient feels ready to transition. If yes, the SMH provider contacts the PCP to facilitate transition. If a patient is reluctant to transition, the SMH provider may make a plan for what level of functioning would indicate recovery sufficient to transition. FLOW materials discuss how measurement-based care can be used to guide decisions about transition and education materials for providers in SMH and PC about how to have therapeutic conversations with patients about transition. It also contains education materials for patients about the transition, how to address service-connection concerns, what to do if they have a resurgence in symptoms, and an EMR template to document transitions and facilitate communication to PCPs.

Implementation of FLOW begins with weekly meetings between the external facilitator, Dr. Smith, and the identified local champion at a site. Local champions are selected by sites based upon a list of criteria including interpersonal characteristics (e.g., strong communicator) and role and tenure at an organization. The FLOW external facilitator meets with the local champion weekly to feed back data on transitions, provider adoption, transition success, process data, and to problem solve barriers that arise. VISN 19 believes that having an official channel with processes, coordination, and support for these transitions will enhance the Veteran's experience with transition to PC and encourage a focus on recovery, all while increasing access for future patient referrals to SMH (personal communication, Dr. Herbert Nagamoto, 10/5/18).

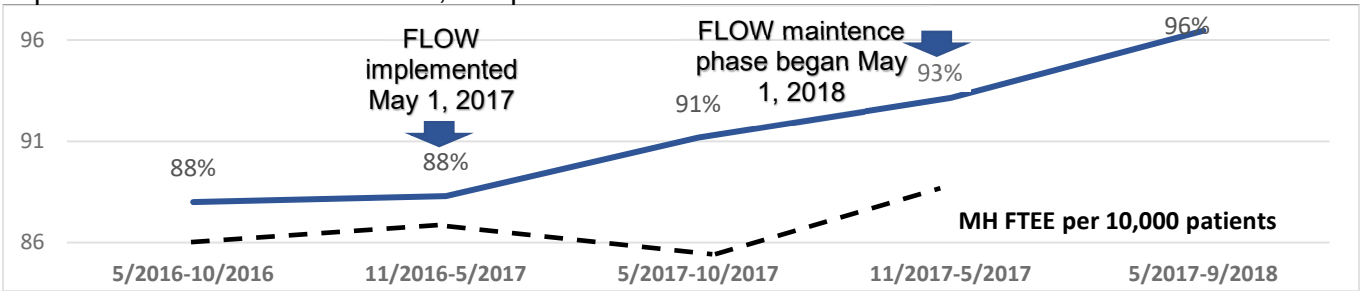
FLOW is effective in pilot programs. We piloted FLOW in VISN 16 and 17. The process began with meetings with leadership and provider stakeholders. Formative qualitative interviews were conducted with providers in SMH, PCMHI, and PC before implementation. Qualitative data indicated that providers from all settings noted several strengths, including an increase in access to care for newly referred Veterans, less appointment burden on recovered patients, and signifying to recovered patients that they were better. Providers were concerned that PC could not offer the same level of care as SMH and that some Veterans may be reluctant to transition due to concerns about symptom reoccurrence, loss of service connection, or alliance with their SMH provider. To address these concerns, provider and patient brochures were altered where necessary to allay concerns. After multiple meetings with VISN and local facility operations partners, providers in the various clinics, and stakeholders, FLOW was implemented.

Evaluation Framework. Guiding the evaluation of FLOW was the Reach, Effectiveness, Adoption, Implementation, Maintenance framework (RE-AIM).[20] RE-AIM provides a way to assess outcomes in five facets: reach, or % of the population affected by a program; effectiveness, or the impact of the program upon the patients and clinics; adoption, or the proportion of providers who use the program; implementation, whether the program was implemented as intended; and maintenance of the program over time after implementation.

FLOW increases access. During implementation, 1,566 patients in participating clinics were identified as potentially meeting criteria for transition and 411 unique recovered MH patients transitioned from MH to PC. Of those, only nine (2%) returned to MH for care after the transition. The patients transitioned represented 16% of all unique patients (n=2,504) treated in the clinics implementing FLOW, suggesting that FLOW had a significant impact on workflow and access. After our team left the site, they continued using FLOW to transition a further 205 patients and independently implemented the program at a nearby CBOC. Initial data suggests that FLOW increased access and timeliness for new patients to obtain a SMH appointment (Figure 2). This increase was not due to an increase in mental health staffing, as MH FTEE per 1000 patients decreased during the initial implementation of FLOW in 2017. At 12-months post-implementation, qualitative data indicated that providers felt FLOW increased access for patients, increased communication among providers, and for SMH providers, decreased their own stress related to workload, although they reported that sometimes

the transition process was not as smooth as they would have liked. Qualitative patient interviews suggested that many patients felt ready for transition, although some were surprised by being asked to transition and recommended that patients be prepared earlier, which is incorporated in FLOW.

Figure 2. % patients who received a SMH appointment within 7 days of the preferred date before and after implementation of FLOW at site 1, compared with MH FTEE.



Other sites. FLOW is being piloted at 3 other sites in VISNs 16 and 17. Initial data suggest substantial variability in uptake of FLOW. Sites 2 and 3 have transitioned 7 and 8% of unique MH patients. At site 4, implementation is paused due to inability to enact project tasks. Substantial variation also exists in provider adoption (100% and 92% at sites 1 and 2, 33% at site 3). Sites differ significantly in readiness to implement and more work is needed to understand key barriers and facilitators to refine implementation methods.

Need for further evaluation. FLOW has recently been disseminated to other V17 sites through a passive implementation strategy--providing sites with FLOW materials and a monthly consultation call. Of the 5 sites receiving the passive implementation strategy, 3 sites have transitioned 0 or 1 patient in the year since receiving FLOW materials, 1 site has had minimal success, whereas 1 site has achieved rates roughly similar to that in the official pilot. Given the wide variation in program success and evidence that passive implementation is generally insufficient, it is clear that successful implementation depends heavily on context, local implementation efforts, and internal facilitators. As VACO is moving towards implementing this program nationwide, it is essential to examine the impact of this program on patients and clinics and understand what facilitates implementation success. Further evaluation in a new VISN-wide setting will a) indicate effectiveness in a larger scale evaluation effort and b) allow us to understand which implementation factors are influential and provide insights that can shape the implementation strategies used in a later national rollout.

With approximately 1.8 million Veterans receiving specialty mental health care nationally (Clinic Practice Management Dashboard [CPMD], data extracted 4/18/19), a national rollout of FLOW has the potential to dramatically increase access. If sites achieve the same transition rate as in the pilot (7%), an estimated 126,000 to 288,888 patients would transition. Given that the average SMH patient has 7.5 SMH visits per year (including assessments, medication management, therapy, groups, and social work visits (CPMD, data extracted 4/18/19), this translates into nearly 1 to 1.4 million freed up appointment slots in SMH per year.

B. Research Overlap

We searched the suggested websites using the search terms ‘mental health’ and ‘access,’ ‘transition,’ ‘discharge,’ ‘stepped care’ and ‘coordination of care’ and found no similar studies. Existing studies of care transitions focus on transition into MH treatment, or from inpatient treatment to outpatient SMH. VACO indicated that no similar program exists and reported that only a few sites nationwide had EMR notes for formalizing the transition from SMH to PC but that these were rarely used, had little impact on transitions, and that no incentives or guidance exists to facilitate use. Clinical Practice Guidelines discuss the importance of using stepped care to intensify treatment but do not discuss when or how to transition to less intensive care.

C. Methods (Evaluation Plan)

Partnership process. Partners in VISN 19 originally approached the FLOW team after hearing about the success of FLOW in VISN 17. Initial champions of FLOW in VISN 19 were Dr. Edward McPhee, Deputy ACOS in Eastern Colorado, and Dr. Lisa Smith, Mental Health Director at Rocky Mountain Regional VA. With their enthusiasm about FLOW, they connected our team to the VISN 19 Deputy Chief Medical Officer, Dr. Herbert Nagamoto, and Dr. Lisa Noe, who oversees mental health programs throughout VISN 19. Through a series of calls and emails facilitated by Dr. Nagamoto, we discussed the mental health priorities of VISN 19 and their current status on SAIL measures and VISN leadership performance metrics. Dr. Nagamoto assisted us with obtaining support of VISN leadership, Dr. Ralph Gigliotti. VISN 19 leadership noted that many of their large facilities struggle with access, with many patients waiting until 14 days or more after their desired date to obtain an appointment. At their request, we provided them with data on how FLOW impacted these metrics when

implemented at Site 1 and provided data on current access metrics in their VISN for comparison. Although all sites expressed interest in participating, 7 sites were able to promise 4 hours per week of protected time for a provider to be the internal facilitator at their sites, with two more tentatively committing. Our partners noted that they were willing to commit to this because they were certain that the financial and time investment "would be returned many times over in freed up FTEE to see new patients in MH" (personal communication, Dr. Herbert Nagamoto, 10/5/18). Project aims were developed in collaboration with VISN 19 to align with their priorities, and methods were tailored to fit their preferences, such as the use of a stepped wedge design.

At the request of VISN 19 we will also provide a less intensive implementation approach to the remaining VISN 19 sites, not included in the 7-9 sites in this project. The other sites will receive a toolkit for implementing FLOW and optional monthly calls for support. This may provide supplemental data regarding whether the intensive implementation approach at the primary 7-9 sites is necessary, or how many sites receiving the scaled down approach are able to implement FLOW. Because the EMR template will be implemented at all VISN 19 facilities, we will obtain data on the number of patients transitioned to primary care throughout VISN 19, regardless of their participation in this program evaluation process. Exploratory, descriptive analyses will compare implementation of FLOW at the 7-9 primary sites to the less intensive implementation sites.

Study Design Overview. A cluster-randomized stepped wedge design[21,22] will examine implementation of FLOW in VISN 19. We chose a stepped wedge (see Table 1) because VISN 19 requested that all participating sites receive the FLOW program, and this design allows balancing of practical considerations with statistical considerations and randomization. This design is also appropriate because we expect the intra-class correlations in sites to be large. We will use the new CONSORT extension for cluster-randomized stepped-wedge trials to report methodological considerations and outcomes.[23] Sites will be matched on resources and staffing ratios and simultaneously randomized to the time in which they begin the intervention (i.e., step 1, 2, or 3) on the basis of matching. Implementation of the program will be examined in three phases. First, data will be collected about the frequency of patient transition during the baseline phase. Next, FLOW will be implemented for 1 year with external and internal facilitation, and program evaluation will be guided by RE-AIM (see Table 1). Finally, there will be a minimum of a 1-year maintenance phase during which only data collection will occur.

Sites. Seven to nine VAMCs and very large CBOCs (>10,000 unique patients) from VISN 19 will participate, depending upon final leadership commitment at that time. VISN 19 is the geographically largest in the nation.

Randomization. Sites will be randomized based upon balancing relevant characteristics across cohorts. We propose to match upon: facility complexity, staffing ratios in SMH and PC, and PCMHI penetration rate. We will create a composite variable based upon each site's performance compared to the average participating site. A z-score will be created for each selected variable and averaged to create a final composite variable. Based upon FY19 data, it appears that the three larger VAMCs would be in the higher resource group whereas the smallest VAMC and the 3 very large CBOCs would be in the lower resource group. These calculations will be repeated with the newest data when the study commences and the final number of sites is determined. We will ensure that each cohort in the stepped wedge has 1-2 higher resource sites and 1-2 lower resource sites. If 9 sites participate, we will use a tertile split for matching. A random number generator will be used to assign sites to the step in which they receive the intervention. Sites will be randomized to receive FLOW implementation immediately in sequence 1 or to wait until steps 2 or 3 (see Table 1 for timeline) but will not be informed of their randomization until it is time for the site to begin implementation.

Table 1. Project timeline.

	Year 1				Year 2				Year 3			
Months	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Startup	X											
Cohort 1 (2 sites)		Implementation				Maintenance						
Cohort 2 (3 sites)			Implementation				Maintenance					
Cohort 3 (2 sites)				Implementation				Maintenance				
Assessment timepoints	●	●	●	●	●	●	●	●	●	●	●	
Data analysis, papers										X	X	X
Report to VISN leaders	X	X	X	X	X	X	X	X	X	X	X	X

Pre-implementation data-collection. Before implementation (i.e., Q1, Q2, or Q3), baseline rates of patient transition from SMH to PC will be examined. Some sites currently have an EMR note template for discharge or transition out of specialty mental health; others document this as needed in medication management session EMR notes. We will use VA administrative databases to identify the pre-FLOW discharge rate. We will also collect assessments of implementation factors tapping the five CFIR domains: intervention

characteristics, outer setting, inner setting, characteristics of individuals, and process.

Implementation of FLOW. Implementation of FLOW will occur by implementation facilitation, an evidence-based strategy to change clinical practice, guided by the VA-based implementation facilitation manual.[25] Facilitators partner with key stakeholders to plan change strategies, adapt them to the local context, and address barriers to implementation. Implementation facilitation is a flexible strategy that has been used effectively to create change in VA mental health services.[26,27] Our multifaceted implementation strategy will use both external facilitation provided by Dr. Smith, who has received training in facilitation from Dr. Kirchner, and internal facilitation provided by a local champion at each site.

As in the pilot, each site will receive FLOW materials and internal and external facilitation, in partnership with a local champion. The process starts with meetings with clinic leadership and identification of a local champion, typically a SMH provider. Sites will be given a list of ideal Internal Facilitator (IF) characteristics (e.g., strong communicator, opinion leader, prior QI or PE experience, well-established in their current position) and will nominate a provider who fits these. Next, the FLOW implementation team meets with providers from the affected clinics: SMH, PCMHI, and PC, to explain the rationale and procedures and answer any questions or concerns. With the input of providers and the local champion, local processes are identified to support communication between different clinics about patients transitioning. Sites are given access to the online FLOW report identifying patients who meet criteria for transition, provider and patient materials to explain the process of transition, and an EMR template with a progress note title to document the transition. The project team initially holds weekly meetings with the local champion to troubleshoot implementation, and implementation is flexibly differentiated to meet each site's identified barriers (see Table 4 for information about strategies employed by facilitators). Data will fed back to the internal facilitator on a monthly basis, including information about both the process of implementation and implementation success. Process data will include barriers and facilitators, types of actions or interventions the IF enacted to overcome barriers or leverage facilitators, assistance from the FLOW team, and local climate and context information arising that affects implementation. Implementation success metrics include the number of patients eligible and transitioned, which providers are engaging in FLOW and which providers have yet to transition any patients, etc. The internal facilitator is responsible for local implementation activities guided by regular calls with the FLOW team.

Although the implementation strategies used are more resource intensive than passive implementation, they are nevertheless more resource efficient than other mental health program implementation efforts in VA such as the evidence-based psychotherapy rollouts[28] and thus likely to be scalable for future national implementation. The primary 'cost' to each facility implementing FLOW is 4 hours per week of one provider's time in the early stages of implementation, with smaller time investment as time goes on. Based upon pilot data, this provides a return on investment of freeing up many hours of specialty mental health provider time to see new mental health patients and substantial improvements in SAIL access metrics.

Measures/Data Sources

Outcomes. Program effectiveness outcomes were developed with VISN 19 leaders and aligned with the RE-AIM framework. VISN 19's priorities are to 1) increase access to timely mental health services for new patients, and 2) ensure that patients who are transitioned back to primary care have a clinically appropriate transition. Considering these priorities, we developed the outcomes discussed in detail in Table 2.

Assessment of implementation factors/determinants and their relationship to FLOW implementation success is guided by the consolidated framework for implementation research (CFIR),[14] which is composed of five major domains: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and process. Table 3 shows the proposed implementation factors as aligned with CFIR constructs.

Table 2. RE-AIM outcomes measured during implementation and maintenance phases (Specific Aim 1).

RE-AIM Domain	Project Outcome	Measured by:	Level of Analysis	Timepoint
Reach	Patient transition to PC, before and after FLOW implementation	Administrative data for EMR template	Patient	Baseline; quarterly
Effectiveness	Successful patient transition to PC, defined as PCP renews psychotropic prescriptions and patient does not return to SMH within 1 year	VA administrative data for FLOW EMR template use	Patient	Baseline; quarterly in impl. phase
	Patient satisfaction with FLOW	Qual. interviews	Patient	Post-transition
	Provider satisfaction with FLOW	Qual. interviews	Provider	Post-implementation
	Impact on access, measured as (1) gain in provider hours available and (2) gain in % of	CDW Completed Appointments	Provider	Baseline; quarterly

	patients who receive appointments within 7 days of desired date	Cube		
Adoption	Providers who use FLOW for >2 patients Providers' average % of patients engaged If turnover exists, new provider use of FLOW	VA administrative data for FLOW EMR template use	Provider	Quarterly in impl. phase
Implementation	Fidelity in implementation of FLOW components	Implementation checklist	Facility	Monthly
Maintenance	Sustainment, including all RE-AI metrics Continuing facilitation activities taken over by the local facility	All metrics above Assessment of IF behavior	Patient & provider	Quarterly during maintenance phase

Table 3. Assessment of implementation factors guided by CFIR (Specific Aim 2).

CFIR Domain	Construct measured	Measured by	Timepoint(s)
Intervention characteristics	Attitudes about FLOW	Qualitative interviews	Baseline; Implementation
Outer setting	Facility resources	Facility complexity	Baseline
Inner setting	Readiness to change	Organizational Readiness for Implementing Care	Baseline
	Facility staffing	Staff to patient ratio in SMH; PCMHI penetration rate; PCP mean panel size; Turnover in staffing	All phases
	Facility organization	Degree with which PCMHI is integrated in PC; Existence of active Behavioral Health Interdisciplinary Program teams	All phases
	Facility climate	VA Clinical Practice Organizational Survey Provider qualitative interviews	Baseline; Implem. phase
	Inter-service clarity of roles	Existence of MOU between SMH and PC outlining roles and how patient care responsibilities are divided	All phases
Characteristics of the individuals	Provider support for change	Provider qualitative interviews	Implem. phase
	Leadership support	Provider survey and qualitative interview data regarding leadership support	Baseline; Implem. phase
Process	Facilitator behaviors	% of FLOW meetings attended; IF's documentation of their activities; Actual protected time; Provider interview questions re: IF behaviors; Qualitative interviews of Ifs	Implementation phase

Implementation phase data collection. The majority of data during the implementation phase will be collected via VA administrative databases. Use of the FLOW EMR template, extracted from administrative databases, will provide information on reach (% of patients transitioned pre vs. post FLOW implementation), effectiveness (% of patients who receive follow up MH care in PC, based upon filled prescriptions, and % of MH patients who return to SMH, based upon consult and appointment data), and adoption (% of providers using the template at least three times, average rates of transition by provider). We will also track demographic characteristics of transitioned patients to examine whether transition rates differ by gender and ethic/racial background. CDW clinical/administrative data will also be used to collect information on the impact of FLOW on access by tracking the percentage of all SMH clinic patients who receive an appointment within 0 to 7 days of the preferred date. A second measure of effectiveness will be the expected gain in provider time for new patient appointments as a consequence of transitioned patients. This will be calculated for each provider as # of patients discharged multiplied by the average yearly minutes spent in appointments with a patient. We will also examine impact on provider time available for new patients by tracking the number of completed new patient appointments by provider from pre-post implementation of FLOW.

Brief qualitative interviews will assess the satisfaction of Veterans and providers (see interview guides in Appendix). Veterans will be recruited via 'opt out' letter sent to those who transitioned, stratified by site. Final n will be determined by saturation, but we propose 45 Veterans across the seven sites. Veteran qualitative interviews assess satisfaction, perception of appropriateness of the transition and the transition process, and satisfaction with care post-transition. Veterans will complete the interview via phone and receive compensation of $30. Provider qualitative interviews will assess perceptions of clinical appropriateness, effectiveness, implementation barriers and facilitators such as leadership support and local champion actions that facilitated implementation (see Appendix for draft interview guide). Providers will be recruited by email and will not be compensated. We will interview at least 3 providers at each site (n = 27) to enable understanding of differences across sites. All interviews will be audio recorded, transcribed by a professional transcription service (see revised budget), and coded by two experienced qualitative coders using rapid qualitative analysis.[29]

To assess implementation, the FLOW implementation team, in collaboration with the local champion, will continuously update, at least once per month, each site's FLOW checklist to monitor which aspects of FLOW

are being implemented with fidelity. Local champions will also be asked to document their time spent in various activities (for example, logistical support vs. influencing providers) in order to understand the key ingredients of facilitation in the local context. We will also examine the number of FLOW meetings the local champion attended (% of scheduled meetings) and their actual protected time, to understand whether the champion's availability and time influence implementation.

Maintenance phase data collection. After a 1-year implementation phase, the FLOW team will phase out external facilitation and the facility will be encouraged to continue using FLOW locally. Maintenance phase data will continue to be collected on all reach, effectiveness, adoption, and implementation outcomes.

Power analysis. Power calculations were conducted for the reach and effectiveness outcomes using the Steppedwedge command in Stata Version 14.[30] Although between 7 and 9 sites will participate, power calculations were estimated conservatively, assuming only 6 facilities (clusters) with 2 randomized into each of the 3 steps of the predominately open cohort (i.e., different patients at different timepoints) complete design. Calculations assume a two-tailed alpha of 0.05. VISN 19 leadership reports that few patients are currently being transitioned from MH to PC. Transition rates are <1% of patients in facilities who do not receive the FLOW intervention and between 1-16% of patients in facilities who do receive the FLOW intervention. Given an average of 1000 patients per quarter per facility based upon the Clinic Practice Manager data for VISN 19, a sample size of 6 clusters (24,000 patients in total) achieves 80% power to detect a difference in transition rates from 1% at baseline to 1.65% upon receiving FLOW. Power is >99% to detect a two-fold increase in patients who transition from SMH to PC. Reach, effectiveness, and most maintenance outcomes are binary variables at the patient level (e.g., whether one was transitioned to PC). These outcomes represent an open cohort trial, as different patients will be included at each timepoint within a given site. Adoption outcomes are both binary (e.g., whether a provider engaged in the FLOW process for at least 3 patients) and continuous (e.g., % of patients engaged in FLOW for each provider) at the provider level. These outcomes represent a closed cohort trial, as the same providers will be included at each timepoint. Adequate effectiveness will be declared if at least 90% of transitioned patients successfully transition without return to SMH in the 1 year follow-up period. Given a very conservative estimation that 4% of SMH patients transition from SMH to PC, an average of 40 patients per quarter per facility (4% of 1000 = 40), a sample size of 6 clusters (960 transitions in total) will allow for 80% power to detect a difference in the percentage of patients who successfully transitioned to primary care from 76.50% to 90% upon receiving FLOW.

Downstream effectiveness, or impact upon access, will be measured as increase in appointments within 7 days of requested date from pre-implementation to post-implementation. Data extracted from the Clinic Practice Manager suggests a fairly high baseline rate of clinic patients receive appointments within 7 days of desired date in VISN 19 (~75 to 80%). Given an average of 1000 patients per quarter per facility, a sample size of 6 clusters (24,000 patients in total) achieves 80% power to detect a difference in the percentage of patients receiving appointments within 7 days of desired date from 80% at baseline to 83% upon receiving FLOW. Power calculations are consistent with ICC values of .10, .15, .20, and .25 and would be similar to what is described above for the maintenance phase.

Quantitative data analysis. We will begin by describing the number of participants, providers, and sites (clusters) who were randomly assigned to each sequence and the numbers included at each quarter. Intervention conditions will initially be compared using generalized linear mixed models (HGLMs) for binary outcomes and hierarchical linear mixed models for continuous outcomes. Each model will include intervention (yes/no) and quarter as fixed predictors and models for reach, effectiveness (except for gain in provider hours), and maintenance will also include the value of the outcome during the baseline quarter as a fixed predictor. Site will be included in all models as a random effect. As we expect the intervention effect may be delayed and reach its peak at the end of the implementation period or that the effect may plateau or even decay during the maintenance period, we will also conduct a set of models where the treatment by time interaction is included as a fixed effect. Furthermore, given the sequences have different lengths of maintenance we will be able to examine whether maintenance varies with time since removal of external facilitator.

Qualitative analysis. We will examine associations between the proposed implementation factors (e.g., staffing levels, leadership support) and outcomes. To do so, we will use a mixed-methods comparative case study approach,[31] a method that has been used to examine determinants of successful implementation of evidence-based practices in integrated healthcare systems.[32,33] In this method, patterns of similarities and differences in relationships between implementation factors and outcomes are examined qualitatively and quantitatively across sites. This method is particularly suited for understanding why program implementation fails and succeeds at sites and is an appropriate evaluation design choice when it is not feasible to randomize sites or to have a large enough number of participating sites to determine statistical associations.[34,35] We will

follow the steps of QCA, including: 1) operationalize the metric of success (example: successful implementation of FLOW leading to high reach), 2) identify which sites are classified as high implementation success vs. low implementation success, 3) Identify key conditions theoretically affecting implementation success (e.g., our implementation determinants), 4) create a matrix of scores signifying whether each site was high or low on each determinant, 5) analyze which implementation determinants in the matrix appear to be associated with high implementation success, 6) use freely available software (e.g., fsQCA 2.0) to analyze all possible configurations of selected implementation determinants, and 7) examine the results and resolve contradictions (e.g., if a contradictory result is potentially explained by a third, unmeasured variable or by the combination of variables) and re-run analyses if necessary. QCA can appropriately handle mixed methods data because the potential implementation determinants included in the analyses can be quantitative data such as staffing ratios, or can be qualitative data, such as presence or absence of a theme arising from qualitative interviews at each site. Outcomes produced from QCA will be information regarding whether a particular implementation determinant or combination of implementation determinants can be used to successfully distinguish between sites with high implementation success vs. low implementation success. This method has successfully been used for small n implementation studies such as the currently proposed study.[32,33]

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