I. Project Goal

The overarching goal of this study is to develop an adaptive implementation strategy involving previously established implementation strategies: Replicating Effective Programs (REP) and External/Internal Facilitation (EF/IF) to further disseminate an evidence-based clinical program for mood disorders (Life Goals- LG) in community-based routine care settings.. This study is designed to implement promising ways to improve health care operations through Facilitation.

II. Project Aims

It often takes years if not decades to translate evidence-based practices (EBPs) into community-based settings. This research-to-practice gap is especially pronounced for psychosocial EBPs for mental disorders. Despite the availability of psychosocial EBPs, they are not getting into the hands of frontline providers in community-based practices and ultimately, improving care for persons with mental disorders. Implementation strategies, which are highly specified, operationalized approaches, involve educating and supporting frontline providers and clinical managers in promoting the use of EBPs. Notably, Replicating Effective Programs (REP) is a previously established implementation strategy that includes standardized EBP toolkits, training and limited technical assistance focused on supporting frontline providers in implementing EBPs in their care settings. REP is a low-intensity strategy with minimal costs from the site's and provider's perspective. However, more enhanced implementation strategies might be needed especially when sites and providers face competing demands or when the EBPs require additional support from higher-level organizational leadership. Hence, we enhanced REP to include **Facilitation,** a previously established implementation strategy that provides more personalized coaching to frontline providers and clinical managers in promoting the use of clinical EBPs in routine care that addresses site-level organizational barriers to EBP adoption. Specifically, there are two Facilitation roles: External and Internal Facilitators. External Facilitators (EFs) resided outside the clinic and provided technical expertise to providers in adapting EBPs. Internal Facilitators (IFs) resided within each site with designated time to support EBP implementation through day-to-day provider engagement. REP in combination with EF and IF **(REP+EF/IF)** versus standard REP alone when applied to implement LG improved patient outcomes, notably mental health quality of life. However, IF requires additional time from sites, and not all sites may need IF. Therefore, an adaptive implementation strategy approach is necessary, whereby the REP implementation may need to be augmented if sites are not responding (i.e., not adopting EBP). In contrast to simply measuring correlates of implementation non-response, adaptive implementation strategies are augmented, or stepped, in direct response to limited uptake of EBPs among specific sites based on circumstances that may not be observable at baseline.

The overarching goal of this study is to build the most cost-effective adaptive implementation strategy involving REP and Facilitation to enhance the update of an EBP for mood disorder and subsequent changes in patient outcomes using clinical assessments available in routine care. The EBP, Life Goals (LG), is an evidence-based psychosocial treatment shown to improve outcomes among patients with mood disorders and will be implemented as part of routine clinical care at each organization. In this study, sites initially receiving REP that have not fully implemented LG (e.g., <10 patients receive the LG EBP) will be randomized to receive additional External Facilitation **(REP+EF)** or External plus Internal Facilitation **(REP+EF/IF)**. At 12 months, sites that are non-responsive to External Facilitation **(REP+EF)** will be re-randomized to receive **REP+EF** or **REP+EF/IF** and then followed for another 12 months to determine whether longer-term exposure to Facilitation is needed. Because sites and not patients will be randomized, the EBP (LG) is already an established evidence-based clinical practice that will be implemented as part of routine clinical care, and because all sites will receive some additional state-of-the-art

implementation support through Facilitation, this project involves health care operations improvement within select healthcare systems.

Primary Study Aim. To determine whether sites that do not exhibit response to REP alone after 6 months (e.g., <10 patients receiving LG), the effect of adding an External and Internal Facilitator **(REP+EF/IF)** versus adding an External Facilitator alone **(REP+EF)** on use of the EBP (LG) and changes in routinely collected patient clinical assessments (health-related related quality of life and mood symptoms).

Secondary Aim 2. To estimate the costs of REP+EF/IF compared to REP+EF at the sites.

Secondary Aim 3. To describe the implementation of EF and EF/IF, including interaction between the two roles and the specific strategies EFs and IFs use to facilitate LG uptake across different sites.

Results from the project will be used to inform activities designed to implement promising ways to improve clinical care and healthcare operations.

III. Background and Significance

Persons with mental disorders are not getting adequate care, leading to poor outcomes: In particular, mood disorders (depression, bipolar disorders) are common, undertreated, represent the top ten causes of disability according to the World Health Organization, and are associated with significant functional impairment, high medical costs, and preventable mortality. For many patients, pharmacotherapy is not enough to improve outcomes, and psychosocial treatments in addition to pharmacotherapy are recommended.

Evidence-based implementation strategies are needed to promote uptake of psychosocial EBPs & improve mental health outcomes: Despite the availability of evidence-based psychosocial treatments, they rarely leave the academic shelf and get translated to community-based practices. As a result, quality of care and outcomes for persons with mental disorders remain suboptimal. This research-to-practice gap can lead to millions of dollars of funded research being wasted when the evidence-based practices themselves never reach the populations in need. New health care initiatives including medical home models, bundled payments, and health care exchanges that are designed to improve efficiency and value will substantially impact publically-funded community-based sites that serve a disproportionate number of persons with mental disorders. For EBPs to make a difference under these emerging models of care, they need to be implemented with fidelity, yet be flexible in responding to organizational changes so that they are also used effectively to improve patient outcomes. Hence, improving the uptake of EBPs will require evidence-based implementation strategies that promote the rapid deployment of EBPs.

Replicating Effective Programs improves uptake of psychosocial programs: There have been few rigorous trials of implementation strategies in community-based practices. Among the frameworks that guide implementation efforts, few have been operationalized for use as strategies to improve EBP uptake and patient outcomes. Study investigators have used Replicating Effective Programs (REP) to promote the uptake of psychosocial EBPs. REP is based on the Centers for Disease Control and Prevention's (CDC's) Research to Practice Framework project, and includes 1) translation of the EBP's scientific protocol into non-technical, user-friendly language ("packaging"), 2) formal training in implementing the package, and 3) supporting the

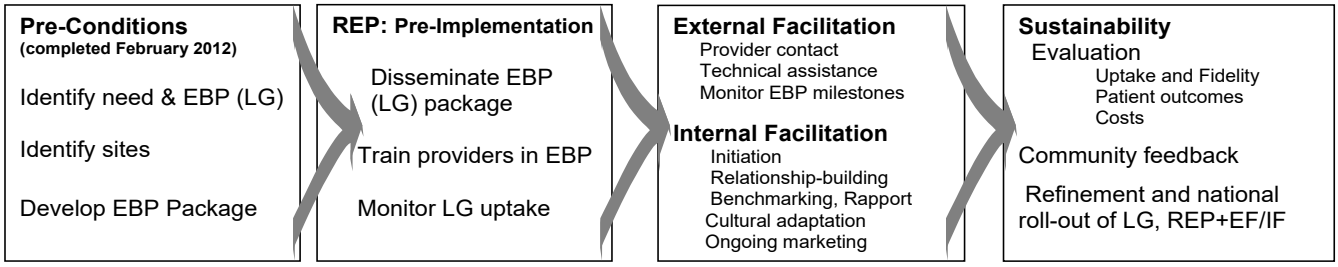
implementation through six months of brief, structured technical assistance. The concepts underlying REP include diffusion of innovations and social learning theory. In a national study of implementation of HIV prevention EBPs, AIDS service organizations receiving the REP package dissemination, training, and brief technical assistance were more likely to adopt HIV EBPs than sites receiving the package and training alone in 6 months (54% vs. 31%).

Facilitation is needed to address organizational barriers: REP uses key tactical strategies that can promote effective EBP adoption in community-based practices. However, many sites face multiple organizational barriers including staff turnover, lack of leadership support, competing priorities, or lack of guidance regarding supervision that are beyond the scope of technical assistance. Addressing these barriers may require additional strategic thinking and multilevel organizational alliances that are tailored to the site's unique circumstances, especially with the advent of new healthcare initiatives. Moreover, while support in EBP adoption from leadership is important, involvement and buy-in from frontline clinicians may lead to a greater likelihood of EBP uptake and sustainability. Hence, REP needed to be augmented to address these organizational barriers to adoption, to ultimately show value of the EBP through the triple aim (improving patient outcomes, experience, lowering costs).

Consequently, study investigators enhanced REP to include Internal and External Facilitation, based on the Promoting Action on Research Implementation in Health Services (PARiHS) Framework. Facilitation is defined as the process of interactive problem solving and support that occurs in the context of a recognized need for improvement and a supportive interpersonal relationship. Study investigators (R01 MH79994, MH QUERI) operationalized Facilitation into two roles: External (EF) and Internal Facilitators (IF). EFs are off-site and provide technical assistance on EBP implementation (akin to REP technical assistance). IFs reside within each site to support the use of the EBP through strategic thinking and relationship-building, notably by incorporating provider input to support the adoption of the EBP, and aligning the EBP with organizational priorities via a direct reporting line with leadership. The EF/IF strategy proposed in this study extends the work of other programs such as the National Demonstration Project and the Evidence-Based Quality Improvement Model, whereby the EF and IF roles used in this study emphasize inter-organizational relationships across mental health and general medical care.

Adaptive implementation strategies can determine how best to augment REP using Facilitation in routine clinical care: An adaptive implementation strategic approach is needed to more efficiently improve EBP uptake and patient mental health outcomes using Facilitation, whereby REP is augmented given early signs of site non-response. While REP might be sufficient for some sites in adopting EBPs, our preliminary studies and prior research suggest that the majority needed additional assistance (see below). Moreover, sites initially not responding to REP (i.e., limited adoption of EBPs) were unlikely to do so in the future. Adaptive implementation strategies are analogous to the concept of stepped care strategies, which have been applied for the treatment of mood disorders in a sequential fashion. In such strategies, care is augmented if the patient does not initially respond to treatment. In contrast to simply measuring correlates of implementation non-response across sites, adaptive implementation strategies allow for immediate augmentation at individual sites. For this proposed study, more intensive implementation strategies (e.g., EF/IF) are offered sequentially to sites that demonstrate limited EBP uptake under REP. In a preliminary study by the investigators (Figure 1, see below), REP in combination with EF and IF **(REP+EF/IF)** versus standard REP alone when applied to implement LG improved patient outcomes, notably mental health quality of life (R01 MH 79994).

Figure 1: Replicating Effective Programs (REP) & Internal/External Facilitation (EF/IF)



EBP for community-based practices (Life Goals) improves outcomes in mood disorders: The EBP to be implemented using REP and Facilitation in this proposed study is Life Goals (LG). LG is an evidence-based psychosocial treatment that has been shown to improve medical and psychiatric outcomes in patients with mood disorders (including bipolar disorder or depression) from primary care and community mental health practices. LG is based on social cognitive theory and delivered in four two-hour weekly group sessions and six brief tailored contacts that encourage active discussions focused on individuals' personal goals that are aligned with healthy behavior change and mood symptom management strategies. **As LG is an EBP, it will be implemented in this project as part of routine clinical care by existing providers using established implementation strategies (REP + EF/IF).**

In five randomized controlled trials across mental health and primary care settings, LG improved outcomes, including mental and physical health-related quality of life, and reduced impaired functioning and mood symptoms. LG has also been shown to be equally effective across patients with co-occurring substance use and general medical comorbidities. LG was originally developed for bipolar disorder, and in partnership with community-based providers (R34 MH74509), expanded to include patients with any mood disorder (unipolar depression or bipolar disorder) as both are common, contribute to substantial functional limitation, and are considered the most expensive mental disorders in primary and mental health care settings. As with many psychosocial EBPs, LG has not been widely implemented across different community-based practices. LG has already been manualized for REP based on feedback from community partners. It is an appropriate choice in EBP to conduct an adaptive implementation trial of Facilitation, given that group sessions and follow up provider contacts require the support of frontline providers and leaders to implement.

IV. Preliminary Work:

REP and REP+EF applied to LG implementation for mood disorders. Study investigators defined and assessed variation in LG uptake and outcomes in patients diagnosed with unipolar depression or bipolar disorder using REP across primary care practices from three states. A provider (MSW) from each site was trained in LG based on REP in July 2010 and began implementing LG in August 2010. Each provider was asked to provide LG to 20 patients during a six-month period. Non-response was defined as <10 out of 20 patients receiving at least one LG session within the three-month period after REP training. Overall, three of the four sites (75%) were non-responsive to REP. Sites unable to implement LG faced organizational barriers that were observed during REP, notably lack of awareness of LG among the other providers and competing demands of the LG provider. EF technical assistance was then offered to non-responsive sites, and included strategies to facilitate patient recruitment and tips on marketing the value of LG. Subsequently, two additional sites were responsive (50%) when EF was added.

While preliminary, these findings suggest that most sites will be initially non-responsive after REP, and some but not all improved LG uptake through EF.

REP+EF/IF versus REP alone improved patient outcomes & LG fidelity, with additional IF costs: The Recovery-Oriented Collaborative Care Study (ROCC, R01 MH79994) involved sites from Michigan and Colorado randomized to **REP+EF/IF** vs. **REP** alone to implement LG for bipolar disorder. Primary outcomes included LG implementation and patient-level mental health-related quality of life (SF-12). REP consisted of dissemination of the LG package and training for site providers. **REP+EF/IF** added external facilitation (6 months of technical assistance by study staff) as well as internal facilitation, which consisted of consultation with clinic leadership over a 6-month period to address organizational barriers to implementing LG. Each site identified a behavioral health provider to offer LG to patients, and sites randomized to **REP+EF/IF** also identified an IF, who was typically an MSW-level clinical manager supervising the LG provider and with direct line of authority to the clinic director. Site providers completed organizational assessments and study staff conducted patient baseline, 6-, and 12-month computerized assessments that included quality of life (SF-12, symptoms), and functioning (WHO-DAS). The LG fidelity assessment was used to assess degree to which core components of LG were implemented using provider logs and chart review.

Five sites were randomized to receive **REP+EF/IF** and four randomized to **REP** alone. A total of 384 patients were enrolled (mean age=42, 66% female, 31% African-American). Patients from **REP+EF/IF** sites compared to those from standard REP sites had improved 12-month mental health-related quality of life scores (37.2 vs. 35.6, beta=1.22, p=.04) and decreased PHQ-9 scores (10.2 vs. 13.4, beta=-2.3, p=.04). Mean number of LG sessions was also greater for **REP+EF/IF** versus REP only patients. **REP+EF/IF** and **REP** sites did not differ on organizational characteristics.

Fidelity/cost measures for REP, EF, and IF were also operationalized based on careful observation, review of study staff and provider logs, and clarification of EF/IF roles via expert panel input. These tools were used in the R01 to monitor potential contamination across EF/IF roles as well as competence. IF costs were estimated using monthly provider logs. Total costs for IF for each site was $5,500 over the 12-month period, and involved specific activities listed in Table 1. Nonetheless, the value of IF in addition to EF has not been assessed in a fully powered clustered randomized controlled trial.

V. Methodology

Overview: This is an adaptive implementation study involving cluster randomization at the site level of previously established implementation strategies designed to implement promising ways to improve health care operations. Providers will implement an EBP (Life Goals) as part of routine clinical care and no patients will be randomized. Outcomes data include site-level use of the EBP as well as assessments already available as part of routine clinical care (e.g., symptoms, quality of life).

A total of 80 community-based clinics (sites) from Michigan (MI), Colorado (CO), or Arkansas (AR) that provide care for persons with mood disorders (depression or bipolar disorders) for a total of 1,600 patients with mood disorders (N=20 per site). The primary aim of this study will determine whether non-responsive sites (i.e., limited LG uptake) randomized to receive REP and additional Internal and External Facilitation **(REP+EF/IF)** implementation strategies to help adopt an EBP (Life Goals-LG) versus sites randomized to receive REP and additional External Facilitation only **(REP+EF).**

A. Site study population: Site inclusion criteria include the following:

1. Community-based mental health or primary care clinic located in MI, AR, or CO with at least 100 unique patients diagnosed with or treated for mood disorders in a given year (to ensure adequate patient N).
2. Availability of a bachelor's or master's level health care provider with a mental health background and experience with implementing group sessions (core modality of LG) who can be trained to provide LG to up to 20 adult patients with mood disorders in the clinic in a one-year period.
3. Availability of an employee at the site with direct reporting authority to the leadership of the site and network who could serve as potential internal facilitator.

B. Site selection, representation: A total of 80 community-based mental health and primary care clinics (e.g., Federally-Qualified Health Centers) out of a total of 128 eligible sites from three states (Michigan, Colorado, Arkansas) will be randomly selected to participate in the study. Since the EBP to be implemented (Life Goals) has been shown to be effective in improving outcomes across different settings (primary care, community mental health), a diverse array of sites was recruited to maximize the potential generalizability of this proposed adaptive implementation study. These sites are also community-based safety net clinics serving a disproportionate number of low income and minority patients.

For the purposes of this study, a site is a stand-alone clinic providing outpatient health services. The sites' parent practice organizations were approached at the following state-level primary care and mental health association meetings: the Michigan Association of Community Mental Health Boards (November 2011), the Michigan Primary Care Association (February 2012), Community Health Centers of Arkansas, and Mental Health Council of Arkansas (January 2012), and the Colorado Regional primary care and mental health boards (January 2012). At these meetings study investigators provided an overview of Life Goals and the proposed study. A total of 128 out of 192 mental health or primary care sites representing several practice networks agreed to participate, including 40 from MI, 62 from CO, and 26 from AR. Primary reasons that sites gave for not wanting to participate included not having an individual that could serve the function of Internal Facilitator, no on-site mental health provider to implement LG, or too busy to participate.

C. Study Design flow. Primary care or mental health outpatient clinics agreeing to participate will be randomly selected (N=80 total) and initially offered REP for six months in order to implement LG. Based on previous research and preliminary data, it is expected that after six months of REP at least two-thirds of sites will be non-responsive to REP. The primary focus of the randomized comparisons in this study are sites that are initially non-responsive to REP (k=40), defined based on our preliminary studies as <10 patients receiving LG within six months of initiating REP and that patients received <75% group sessions. (Although not part of the primary randomized comparisons, sites that are responsive at 6 Months will continue to be followed and outcomes will be assessed). The non-responsive sites will be randomized 1:1 to receive additional External Facilitation **(REP+EF)** or External plus Internal Facilitation **(REP+EF/IF)**. After another six months (at Month 12), sites that are still non-responsive (based on the same criteria) will be randomized 1:1 to either continue **REP+EF** or augmentation with IF (**REP+EF/IF)**. All sites are followed for a total of 24 months. Patient-level outcomes will be assessed by study staff using assessments considered part of routine clinical care (e.g., symptoms and quality of life) starting at the initiation of REP and then at 6, 12, 18, and 24 months later among a pre-selected cohort of n=20 patients per site who are identified by site providers for LG (total patients participating in the projectl N=k*n=800). Patients receiving Life Goals as part of their routine clinical care may opt in our out in participating in the outcomes assessment component. As with our prior implementation work (R01 MH79994), independent evaluators (study staff who are not aware of the assignment to **REP+EF** or **REP+EF/IF**) will conduct study outcomes assessments to ensure consistency of

data collected across sites and to prohibit provider/site or investigator assessment bias. Pre-identification of LG recipients also maximizes consistency of the patient population across sites (see patient criteria below).

D. Site Organizational Randomization: The unit of randomization is the site and will be stratified using a minimization allocation method. This procedure will ensure that groups are balanced for site variables that may correlate highly with outcomes. The Month 6 randomization for REP non-responsive sites, will be stratified by state, type of practice (primary care or mental health site), and site-aggregated mean mental health related quality of life measured at Month 6. The Month 12 randomization for non-responders to **REP+EF** will be stratified by site-aggregated quality of life measured at Month 12. Based on interviews with site leaders and the literature, participating sites differ more by state and practice type than by type of network, and state and practice are correlated with mental health related quality of life and number of LG encounters.

E. Implementation Components (Table 1)
REP: All sites will receive REP (Table 1) in the first three months and will be monitored monthly up to the sixth month in the use of LG. REP includes dissemination of the LG package, training, and LG uptake monitoring for up to six months. REP includes an off-site trainer, which is neither an External nor Internal Facilitator. The following REP components were previously operationalized by study investigators (R01 MH79994):

Step 1: Dissemination of LG package, in-service, and patient selection: Each site will designate at least one provider with a mental health background (master's in social work, nursing degree, or bachelor's with two years' experience in mental health psychosocial treatment) to implement LG ("LG provider"). Regional two-hour in-services will be provided by study investigators who will give an overview of LG including the evidence, and details on how to implement LG in their setting. During the in-service, the LG package will be disseminated and the REP trainer will coach the LG providers in pre-identifying a cohort of patients.

Table 1: Summary of REP, REP+EF, and REP+EF/IF Implementation and Fidelity Measures

Implementation Component	REP	REP+EF	REP+EF/IF
REP (REP)	**All sites**	**Randomize to Non-Responding Sites**	**Randomize to Non-Responding Sites**
Step 1: **Disseminate package**: LG in-service and identify appropriate patients using medical record review	√	√	√
Step 2: **Train** site providers in LG	√	√	√
Step 3: Monitor LG uptake via monthly reporting sheets	√	√	√
REP+External Facilitator (REP+EF)			
Step 1: **Provider Contact**: EF sets measurable goals in LG uptake		√	√
Step 2: **Technical assistance**: EF makes structured calls to site's LG providers, giving specific guidance on implementing LG components		√	√
REP+External and Internal Facilitator (REP+EF/IF)			
Step 1: Initiation: EF identifies IF within the site; IF meets with EF, LG provider, and leadership, establish measurable goals in LG uptake			√
Step 2: Relationship-building: IF identifies site priorities per leadership input, identifies other LG program champions		√	√
Step 3: Benchmarking and Ongoing Rapport: EF continues coaching IF, IF measures LG progress, IF develops rapport with leadership			√

Step 4: Cultural adaptation: IF uses local site culture knowledge to facilitate LG, addressing potential barriers, aligning LG goals with site			√
Step 5: Ongoing marketing and sustainability: IF, EF and LG provider summarize progress with leadership, develop business/training plans			√

REP LG Package: The LG REP package includes all of the components needed to implement LG, including the LG provider manual, group session scripts and focus points covered in each session in a semi-directed fashion, the registry template for monitoring mood and LG progress, scripts for follow-up calls, patient workbooks, and an implementation manual describing logistics (e.g., identifying group session rooms, identifying patients for LG, medical record templates for LG sessions, billing codes).

Identifying appropriate LG target population: In REP, providers identify the appropriate target population for the EBP. We chose to focus on mood disorders (depression and bipolar disorder) because they are common, considered to be high priority populations for intervention based on input from community partners, and LG was shown to improve outcomes in this group. The REP trainer will work with LG providers to identify up to 40 patients who are appropriate for the LG program and who have appointments within a short time period of each other (within the first three months after the in-service) so that LG groups can be scheduled by the LG provider with minimal delay. Although LG providers will be expected to offer LG to 20 patients, identifying 40 ahead of time allows an ample number of participants to complete LG in the event that some patients either refuse or are ultimately not eligible due to illness or cognitive impairment (see criteria below). In prior LG implementation studies (R01 MH79994), medical record reviews were successfully used to pre-identify appropriate participants in both primary care and community mental health sites, and of those approached, ~10% were ultimately ineligible and ~25% refused to participate in LG. Patients who receive Life Goals at the clinic will be asked if they would be willing to participate in periodic outcomes assessments involving routine clinical assessments to measure the effect of Life Goals on long-term outcomes.

E.1. Patients considered appropriate for LG (i.e., eligible for the study) include:

1. Adults 21 years or older with a diagnosis and current documentation of antidepressant or mood stabilizer for a mood disorder (depression, bipolar disorder) based on medical record review;
2. Not currently enrolled in intensive mental health treatment (e.g., assertive community treatment, residential treatment) based on medical record review and confirmation by treating clinician;
3. No terminal illness or cognitive impairment that precludes participation in outpatient treatment based on medical record review and confirmation by treating clinician.

Table 2: Core Components of Life Goals Program

Component	Description
Group Sessions	Four sessions lasting 60-80 minutes focused on active discussions around personal goals, psychiatric symptoms, stigma, and health behaviors
Session 1: Personal goals	Personal goals and self-management; Understanding stigma; Symptoms & wellness
Session 2: Depressive symptoms (sx)	Overview, triggers to depressive episodes; Action plan for depression, self-assessment
Session 3: Anxiety/manic sx	Overview, triggers to episodes; Action plan: anxiety/mania, self-assessment
Session 4: Wellness plan	Building behavior change goals; Relapse prevention and monitoring, medications
Individualized sessions	Provider makes 6 weekly individual contacts(15-20 min), encouraging ongoing healthy behavior change tied to sx coping strategies, identifying strategies to overcome barriers to behavior change, and encouraging ongoing sx and behavior monitoring

Life Goals (LG) description and operationalization: The evidence for Life Goals was described earlier. There are three stages to the Life Goals program: initial contact, group sessions, and follow-up contacts/referral (Table 2). First, upon creating a list of patients appropriate for LG, providers will review medical records and confirm eligibility (see above). The LG provider will make an initial call to the patient, and introduce the LG program and schedule group sessions. After the LG provider identifies 6-10 patients, he or she will initiative the first group session, and will hold cohorts of group sessions until enrolling 20 participants. Participants can make up sessions over the phone or in person if they are unable to make group sessions. In the sessions, the LG provider will encourage active discussions that progressively have participants identify triggers to the symptom or episode, develop an action plan for identifying warning signs of symptoms, and an activity plan for adopting a specific health behavior to mitigate symptoms and promote wellness. Participants will be given a workbook with exercises on behavior change goals, symptom assessments, and coping strategies. The LG provider will then contact the patient six times after the end of the group sessions on a weekly basis to review symptoms, behavior change, and any concerns the patient might have. LG providers will also track patients' mood symptoms and health behaviors using a registry. Once participants complete the LG program, a one-page summary of their current mood symptoms and health behavior changes will be routed to their primary care or mental health provider for treatment planning. As in previous studies, LG providers will be trained to inform providers immediately if patients have elevated symptoms or suicidal ideation. This is incorporated into the clinic's routine clinical care. Study staff (outside outcomes assessors) will complete outcomes assessments on up to 20 patients who are receiving Life Goals at the clinic in order to measure the program's reach over time.

Step 2: REP LG training and provider competency: LG providers will undergo a one-day training program developed by study investigators that has been provided to over 100 clinicians nationally. The LG trainer will first provide an orientation to the evidence behind LG and core elements, then a step-by-step walk-through of LG components. The trainer will then demonstrate each LG group session and follow-up contact procedures, as well as review options for adapting LG to sites without compromising core components (Table 2). After each demonstration, LG providers will break into groups and practice each component. The trainer will then go over record keeping in the LG registry log and how to market groups to patients and other providers.

Step 3: REP LG tracking - monitor uptake of LG: The final phase of REP consists of a standard monitoring form sent by the trainer in which each LG provider reports on the number of patients approached and number receiving each LG session. Monitoring forms will be used to assess non-response across sites and corroborated based on patient self-report of LG use.

REP+EF: External Facilitators (EFs) are part of the study team and reside outside the clinic and provide technical expertise to providers in adapting EBPs to address organizational and financial barriers. There will be one centralized external facilitator on the study team who has previously provided technical expertise in implementing LG. The EF's core functions include monthly technical assistance calls and dissemination of additional materials on LG based on the site needs. The EF will initially contact the LG provider and set measurable objectives in implementing LG (e.g., number of patients completing at least one group session), and review progress based on these measures via monthly calls for six months. Based on the previous implementation trial (R01 MH 79994), the monthly calls will last approximately one hour and be used to discuss barriers to LG implementation and specific guidance on implementing LG components.

REP+EF/IF: In contrast to EFs, Internal Facilitators (IFs) (Table 1) reside within each site and have an internal working knowledge of the site. IFs are responsible for enhancing the uptake of LG, notably by incorporating input to support the adoption of the EBP from frontline providers and

aligning the EBP with organizational priorities via a direct reporting line with leadership. The IF will be identified at the time of randomization to EF/IF and will be a clinician with direct reporting authority to the clinical director (or be the clinic director himself or herself). The IF will work to build relationships with site personnel and leaders during the six-month period. Using their knowledge of the local site's culture and needs, the IF will identify the site's priorities, align the goals of implementing LG with these priorities, and identify other provider champions to assist in implementing LG. The EF will continue to coach the IF on how to monitor uptake to LG components, and continue to contact the IF and LG provider via monthly one-hour conference calls to review progress based on the established site goals as well as mitigate barriers to implementation.

Ensuring Fidelity to REP, EF, IF: Fidelity monitoring will be used to assess whether each site is receiving the core components of each implementation strategy (REP, EF, and IF), and to ensure that there is no contamination. Data from LG provider logs and REP technical assistance and EF/IF activities completed by study staff will be used to ascertain fidelity within each six-month period of implementation exposure using established checklists. All sites will get the same LG REP package, and LG training will be conducted by the same study investigators who will hold regional trainings in each state. As with ROCC (R01 MH79994), EFs will be trained by study investigators based on a two-day training program developed for national roll-out of both the REP and EF/IF programs. To avoid potential contamination across EFs and IFs, a separate training for IFs will be held in each state once randomization occurs in months 6 and 12. REP study staff, EFs, or IFs with suboptimal fidelity (described below) at 3 months into each study wave will undergo additional training by study investigators. Fidelity to REP is defined based on number of sites receiving an LG package, number of providers completing the one-day LG training program, and number of completed monthly LG logs. Fidelity to EF will be defined based on whether the EF developed specific measurable goals to LG uptake and number of completed out of the six monthly technical assistance calls to the LG providers at each site. Fidelity to IF is defined as establishment of measurable goals to LG uptake, number of meetings with leadership by IF and EF, documentation of LG barriers and strategies to mitigate barriers, and development of a strategic plan to implement LG. Sites not providing reporting sheets will be visited to assess implementation and further training will be offered.

Mitigating contamination between implementation components: The possibility that EFs might inadvertently provide IF components is minimized given that EFs are study staff external to the site, while IFs are site employees. Nonetheless, there is a chance that EFs in the EF only group might inadvertently provide internal facilitation (e.g., contact providers or leaders about LG implementation, which is a core component of IF). We will monitor for potential contamination by assessing whether the EF makes any contacts to site personnel other than LG provider at EF only sites and provide additional training to EFs if necessary.

F. Data Collection and Measures

Data for primary and secondary aims will be collected by study staff from patient surveys, organizational surveys, and provider logs. The assessment package previously developed and implemented by study investigators (R34 MH74509, R01 MH79994) was informed by the RE-AIM framework for evaluating implementation of EBPs. Key measures include patient-level outcomes, LG uptake and fidelity, organizational factors, and REP, EF, and IF activities (Table 3). Data sources include patient-level (surveys), site-level (provider surveys), and project staff logs.

Patient data: Lists of patients and contact information that were identified by the LG providers during the first 3 months of REP (pre-randomization) will be sent to study outcomes assessors who will conduct phone surveys at baseline (after the REP provider training is complete), and 6, 12, 18, and 24 months later. Patient baseline assessments will include assessments already used

in routine clinical care and will be conducted by project staff by phone after the LG provider identifies eligible patients but before the first LG sessions are implemented. Once project staff receive patient lists, they will contact patients, describe the purpose of the study, and ask if the patients would like to participate. Patients will be compensated $10 for completing each assessment. Patient-level data will be coded with a unique identifier. There will be a crosswalk file that it password protected that is only available to be access by study staff that will link unique study ID with a link to the person's identity.

Table 3: Primary and Secondary Assessments – Baseline and Follow-ups

Aims	Measure	Source
1a. Primary outcomes	Health-related quality of life-SF-12 mental health score	Patient survey
1b. Secondary outcomes	Functional impairment-WHO-DAS	Patient survey
	Psychiatric symptoms-PHQ-9, GAD-7, ISS	Patient survey
	LG fidelity and uptake (# sessions, contacts)	LG provider logs, patient surveys
Secondary aims	LG implementation costs (patient, site perspective)	Patient survey, chart review, logs
	REP costs	Study staff logs
	Facilitation costs	Staff, LG provider, Facilitator logs
Covariates	Patient demographic, clinical factors, behaviors use	Patient survey, chart review, logs
	Organizational factors (OTM, ORCA, EBPAS)	Site leader, provider surveys

Patient outcomes will be ascertained from a brief, previously established survey used in routine care settings that includes health-related quality of life (the primary outcome, SF-12), functional impairment (World Health Organization Disability Assessment Scale- WHO-DAS), and mental health symptoms (secondary outcomes), including the PHQ-9, GAD-7 for anxiety symptoms, and the Internal State Scale for manic symptoms. Additional questions on LG use will also be included to provide confirmatory information on LG fidelity and uptake (see description of LG fidelity measures below).

Patient demographic, clinical, and use data will be ascertained from the survey including race/ethnicity, age, marital status, education, employment status, social support, incarceration history, homelessness, adherence, and substance use. Utilization, including inpatient, outpatient, as well as data on medical and psychiatric comorbidities will be ascertained from the patient assessment.

Provider surveys: Provider surveys will be used to ascertain information on organizational factors. These organizational surveys will be used to inform activities designed to implement promising ways to improve clinical care and health care operations. The site clinical leader or administrator as well as the LG provider and the IF from sites randomized the **REP+EF/IF** will complete surveys on organizational factors that might impact implementation and outcomes, and inform the identification of more or less responsive sites for future adaptive implementation work. First, site leaders will be contacted prior to the initiation of the REP in-service to complete an organizational survey previously developed by study investigators (with a >90% completion rate) at the beginning of the study. This survey is used to determine organizational characteristics that might potentially explain variation in EBP uptake, including resources, staff turnover, and degree of integrated primary and mental health care.

Additional organizational factors based on surveys completed by the site clinical leaders, LG provider and IFs will be assessed prior to the initiation of REP, then again at 12 and 24 months later to assess changes in organizational features that are potentially impacted by REP and Facilitation.

LG fidelity: Because this study is designed to assess real-world implementation of routine clinical care, minimally invasive measures developed by study investigators will be used to assess use of LG services. LG providers will complete a computerized log of LG encounters, which will

ascertain the number of completed group sessions and provider follow-up contacts received by each patient. LG fidelity will also be assessed using a previously established measure that combines information from the LG provider logs with confirmatory information from patient surveys. The fidelity monitor calculates a total score based on number of group sessions (0-4) and follow-up contacts (0-6) completed by each patient. Average patient completion of group sessions of >=75% was associated with improved mental health-related quality of life.

Table 4: Recording Time Spent on REP, Facilitation, and LG

REP (all sites)
LG provider and site representative time spent at in-service, training
LG provider time spent with LG trainer on phone follow-ups, documentation
Project staff (investigators, personnel): Packaging LG, training, site contacts, note-taking
EF (REP+EF sites)
LG provider time spent with External Facilitators (phone contacts, email follow-ups)
LG provider actions taken to facilitate LG, documentation
Project staff (EF): Time spent with provider contacts, follow-up technical assistance, documentation of goals with each site
IF (REP+EF/IF sites)
Time IF spent with EF, LG providers in meetings and establishing goals, site priorities, develop rapport
Time IF spent working out LG barriers, strategizing and aligning LG goals with site goals
Time IF spends with EF and LG provider in summarizing implementation progress with leadership, business plan development
LG Implementation (all sites)
Group sessions: Number of outpatient clinic visits w/ LG patients actually completed
Follow-up contacts: Time spent on each contact
Other Face-Time: Any time spent seeing LG patients face-to-face or on phone outside of sessions/contacts
Phone Time: Any time spent on the phone only with LG patients. Include time spent leaving messages, playing "phone tag", etc.
Care Coordination: Any and all time spent on behalf of a LG patient when patient is not present (e.g., phone, consultation)
Charting Time: Any time spent charting for a LG patient (e.g., registry, progress notes, updating treatment plans, etc.)

Implementation Strategy (REP, EF/IF) Use and Costs (Table 4): Personnel time is likely to account for the vast majority of costs associated with REP and Facilitation. All activities involving REP, EF, and IF will be documented using previously established log forms (e.g., R01 MH 79994) and all costs will be multiplied by personnel wage rates including fringe. We will estimate time costs incurred by both site employees as well as project staff (REP trainer, Facilitators). We chose to focus on a cost analysis from the perspective of the sites because the added cost of paying for and providing Internal Facilitation will be the major concern of these stakeholders, who are the target audience for potentially spreading value-based implementation frameworks

REP Costs from the site's perspective: We will estimate the costs of the REP implementation from the site's perspective by collecting information on the total time LG providers spent on 1) in-services, 2) training, and 3) monitoring by surveying the providers involved in each step based on the LG registry log.
REP and External Facilitation costs: Total costs of REP and EF implementation will be estimated based on study staff logs by summing up the total time spent by the study staff in LG package dissemination, in-services, training, and follow-up site calls and documentation.
Internal Facilitation Costs: IF costs are primarily borne by the site and are detailed in Table 4. Each IF will complete a log of activities using similar procedures in ROCC. The total time spent in IF activities will be multiplied by personnel wage rates.
LG Costs from the site's perspective will also be estimated for each site. Study staff will ascertain information from the LG provider registry on number and time for each group session, follow-up contact, as well as for additional provider and patient encounters and clinical documentation

(Table 4).

VI. Analyses and Evaluation

Intent-to-treat. Every effort will be made to collect patient level outcomes across all 80 sites and patients (N=1600) to conduct the primary and exploratory analyses (see below). The 40 sites randomized at month 6 (total 800 patients) will be included in the intent-to-treat randomized sample. The Primary Aim analysis will compare strategies in non-responding sites (k=40) beginning with **REP+EF/IF** versus strategies beginning with **REP+EF** on longitudinal change in patient-level SF-12 mental health scores (MCS- primary outcome). This analysis is a comparison of cells A+B+C vs. D+E (Figure 2). For this analysis, the longitudinal outcome is SF-12 mental health scores measured at Months 6 (pre-randomization), 12, 18, and 24. The primary contrast is the between groups difference in change from Month 6 to Month 18. The follow-up contrast at Month 24 will also be examined in this and all subsequent analyses. Linear mixed models (LMM), also known as random effects models, fit with SAS PROC MIXED will be used to analyze the longitudinal data. LMMs use all available measurements, allowing subjects to have an unequal number of longitudinal observations and producing unbiased parameter estimates as long as unobserved values are missing at random. The analysis will fit a 3-level (repeated measures for each person clustered within site) LMM with fixed effects for the intercept, time, group, and a group-by-time interaction term, where group is an indicator of **REP+EF/IF** vs. **REP+EF**. The LMM will also include random effects for site and time, an unstructured within-person correlation structure for the residual errors, and it will adjust for the following pre-randomization measures collected through Month 6: state and type of practice (primary care- or mental health site). Model diagnostics will be used to determine the suitability of more parsimonious (e.g., autoregressive) correlation structures, and nonlinear (e.g., piecewise linear or quadratic) effects for time. LMMs similar to the above for the primary outcome will be conducted for the secondary outcomes: **REP+EF/IF** vs. **REP+EF** on change in number of LG encounters, functional impairment, and psychiatric symptoms.

The goal of the Secondary Aim 1 analysis is to determine whether continuing REP+EF versus augmenting with **REP+EF/IF** leads to changes in outcomes, among sites who are non-responsive at Month 12. This analysis is a comparison of cells B vs. C (Figure 2). Both primary and secondary longitudinal outcomes above will be examined using an LMM similar to that described above, except (a) including only the subset of sites that do not respond at Month 12 to **REP+EF**, (b) using monthly longitudinal outcomes from Month 12 to Month 24, and (c) the LMM will use dummy-indicators for time (i.e., time-saturated model since there are only 3 measurement times for each longitudinal outcome).

The Secondary Aim 2 analysis will involve an analysis of implementation costs. The implementation (REP, EF, IF) costs will be summed for each site as a measure of total costs and changes in costs will also be assessed over time (6, 12, 18, 24 months). An exploratory analysis of the incremental effectiveness of IF by comparing costs from sites given **REP+EF/IF** versus those with **REP+EF** will be conducted from the site's perspective. In regression models of costs, Generalized Linear Models with log link functions will be used to correct for heteroscedasticity and reduce the impact of outliers. Effectiveness will be measured by changes in health utilities using the SF-6 (a subset of SF-12 questions) as well as the Euro-QOL 5D. Cost-effectiveness will be calculated as the ratio of incremental average site-level cost and incremental average effectiveness (change in patient-level utilities) of IF. A standard nonparametric bootstrapping approach will be used to calculate confidence intervals and cost-effectiveness acceptability curves.