A. SPECIFIC AIMS

Depression remains among the top ten chronic illnesses, costing $83 billion annually (Greenberg, et al., 2003). Numerous efficacious psychotherapies exist (e.g., Cognitive Behavioral Therapy; Butler et al., 2006), but are relatively unavailable in community mental health settings. Implementation of these complex psycho- therapies is resource-intensive (Clark, 2011) and sustainment is rare (Stirman, et al., 2012). Measurement- based care (MBC; i.e., routine measurement of client symptoms on which care decisions can be made) is a highly accessible evidence-based framework (Lambert et al., 2003; Scott & Lewis, *in press*) that enhances usual care psychotherapy by increasing the number of treatment responders and decreasing rates of deteriora- tion (Bickman et al., 2011; Whipple, et al., 2003). *Simply providing clinicians (i.e., mental health counselors) with symptom scores improves outcomes.* We contend that MBC can be the minimal intervention needed for change (Glasgow et al., 2013). Unfortunately, fewer than 20% of community clinicians use MBC (deBeurs et al., 2010) due to perceived barriers such as time and feasibility (Garland, Kruse, & Aarons, 2003). Tailored im- plementation (in which strategies are designed to target determinants of practice revealed through careful as- sessment; Wensign, Bosch, & Grol, 2010) is touted as the optimal approach (Grol & Grimshaw, 2003). Moreo- ver, it is possible that tailoring MBC protocols to the site may optimize sustainment (Chambers, Glasgow, & Stange, 2013). However, no studies, to our knowledge, have directly compared standardized and tailored ap- proaches, revealing a critical gap in the implementation literature and the potential for high impact results.

We propose a randomized trial of standardized versus tailored MBC implementation in Centerstone, one of the nation's largest not-for-profit community mental health centers. This proposal builds on a 2-year ac- ademic-community partnership in which the *long-term goal* is to introduce MBC across 100+ sites. This hybrid type 2 design will assess both implementation (clinician-level; MBC fidelity) and intervention (client-level; de- pression severity) outcomes. We have the unique opportunity to evaluate MBC implementation, as Center- stone will have recently introduced a new electronic health record (EHR) system. The implementation protocol is informed by our 2-site pilot study in which MBC achieved 67% penetration. The Patient Health Questionnaire (PHQ-9; Kroenke, 2001) will be embedded in the EHR using tablet computer client data capture. Both condi- tions will use a blended implementation protocol of the best available evidence-based strategies to ensure equal access to resources, including (a) a needs assessment, (b) formation of an implementation team, (c) MBC use guidelines, (d) training, and (e) triweekly group consultation. Mendel et al.'s (2008) *Framework for Dissemination* will guide evaluation (needs assessment, implementation, and outcome evaluation). This framework will also be used to tailor training and consultation content to target barriers identified in the needs assessment (contextual factors, e.g., attitudes); the standardized condition content is set *a priori*. In the tailored condition, the implementation team will establish the MBC use guideline (e.g., monthly administration), where- as the standardized condition guideline will require routine administration prior to each session with a de- pressed client (Lambert et al., 2003). This design will test the Dynamic Sustainability Framework (Chambers, et al., 2013), as sites in the tailored condition will adapt MBC guidelines to fit their context. MBC fidelity (range 0-3; client completed=0/1; clinician reviewed=0/1, scores discussed=0/1) and reasons for deviations (e.g., lack of time) will be monitored via EHR enhancements; clients will also report on clinician discussion of scores.

Phase I: Pre-Implementation (Months 0-8). The PHQ-9 and fidelity measures will be embedded in the EHR and the PHQ-9 linked to tablet computers for client completion to promote feasibility. *Phase 2: Random- ized Implementation Trial: Dynamic Waitlist Control* (Months 8-38; Sites: *N*=12; Clinicians: *N*=150; Clients: *N*=500; mixed within- & between-subjects design). MBC implementation will occur across 4 cohorts (2-4 sites) at early and later stages (each with 5-months active implementation, 10-months sustainment) to reduce con- founds (timing) and increase feasibility (phased training). Both conditions will enact the 5 strategies within the active implementation period. We will use rapid ethnography (month 1) to synthesize the needs assessment data and develop the tailored content. *Phase 3: Characterization of MBC Fidelity* (Months 38-48). MBC fidelity will be coded, clinician and client fidelity reports will be triangulated, and sustainment will be evaluated.

Specific Aims. The hybrid design yields *one co-primary aim* (outcomes at the clinician- and client- levels) and *two secondary exploratory aims* in the context of a pragmatic trial (Thorpe et al., 2009).

Aim 1: To compare the effect of standardized versus tailored MBC implementation on clinician-level (**1a**) and client-level (**1b**) outcomes. We hypothesize that tailored implementation will outperform standardized in terms of (**H1a**) MBC fidelity, and (**H1b)** reducing client depression severity.

Aim 2: To identify contextual mediators of MBC fidelity. We hypothesize (**H2**) that contextual mediators (struc- ture, norms, etc.) will be leveraged in the tailored condition, but serve as barriers in the standardized condition. **Aim 3:** To explore the impact of MBC fidelity on client outcomes (Chambers et al. 2013). We hypothesize (**H3**) that adapted MBC protocols (tailored condition) will outperform weekly administration of PHQ-9s (standardized condition) with respect to clinically significant change in depression severity from intake to week 12.

B1. SIGNIFICANCE

The long-term goal of this research project is to provide generalizable and practical recommendations about implementation approaches that promote Measurement-Based Care (MBC) use and effectiveness in community mental health centers, a goal developed in partnership with stakeholders at Centerstone. Previous attempts to integrate MBC into real world settings have focused on the development of standalone feedback systems (Koerner, Dailey, Lipp, Connor, & Sharma, 2012; Sapyta, Riemer, & Bickman, 2005). However, to our knowledge, no studies have investigated the strategies necessary to integrate MBC into community mental plementation support or (b) taking into account stakeholder perceptions and needs when building the imple- mentation approach. This proposal reflects the ideas generated by a 2-year academic-community partnership between the proposal PI (Lewis), Centerstone Research Institute Director (Co-I, Ayer) and regional clinic direc- tors whom constitute our advisory board (Drs. Harrison, Hardy, Pardue, Moran, Marshall; *Letters of Support*).

The proposed implementation of MBC by community mental health clinicians who treat depression is *significant* because despite decades of research revealing numerous efficacious treatments for depression, this disease remains among the top ten chronic diseases in the nation (Greenberg et al., 2003). Moreover, MBC is an evidence-based framework that has established **effectiveness**, broad **reach**, and multifaceted **utili- ty** for enhancing usual care. MBC presents a simple framework in which care is based on the results of symp- tom measurement. A meta-analysis indicated that MBC is particularly **effective** in improving outcomes when depressed clients are not demonstrating progress (Shimokawa, Lambert, & Smart, 2010) and by reducing cli- ent deterioration (Lambert, et al., 2003) with medium effect size improvements over usual care (Bickman et al 2011; Whipple, et al., 2003). MBC has greater **reach** potential than complex Evidence-Based Practices (EBP) that include multiple theory-specific components targeted at single disorders; MBC is a simple standalone practice framework that increases the effectiveness of diverse usual care offerings for clients with multiple problems. MBC may be the "*minimum intervention needed for change"* (MINC; Glasgow et al., 2013). The reach of MBC is particularly strong because its relevance is transtheoretical (relevant for use by clinicians re- gardless of background) *and* transdiagnostic (effective in enhancing usual care for numerous disorders) (Scott & Lewis, *in press*). MBC's **utility** is multifaceted and aligns with the Affordable Care Act by focusing on moni- toring outcomes. MBC presents a systematic approach for selecting and adapting interventions (Trivedi & Daly, 2007); it flags clients who are not improving; and, it highlights treatment targets (Lambert et al., 2005). NIMH's nationwide public health clinical trial, the STAR*D (Sequenced Treatment Alternatives to Relieve Depression), demonstrated MBC's utility for guiding both medication and psychotherapeutic interventions (Trivedi et al., 2006). MBC also has established utility for promoting care coordination across disciplines (Unutzer et al., 2002). MBC provides the basis for evaluating subsequent EBP implementation efforts through a foundation of progress monitoring, which leverages the soon to be ubiquitous electronic health record technologies.

By design, MBC has great potential for implementation success, yet barriers such as attitudes (percep-

tions that standardized measures have limited utility) and feasibility (perceptions that measures take too much time) exist (Garland et al., 2003), and the gap between documented MBC effectiveness and use in practice remains. Research to date has largely focused on evaluating standardized approaches to implementation, de- spite a recent Cochrane meta-analysis highlighting the potential impact of tailoring implementations (Baker et al., 2009). There is a crucial need for process-focused implementation research. Hence our proposed compari- son of implementation conditions (i.e., standardized versus tailored) is *both clinically and scientifically signifi- cant* because it will (a) reveal whether standardized or tailored approaches to implementation optimize MBC fidelity, (b) enhance our understanding of both theory and processes for standardized versus tailored imple- mentation; and, (c) illuminate predictors, moderators, and mediators of successful implementation. Our pro- posed implementation-effectiveness hybrid design will yield important insights regarding MBC clinician level implementation outcomes. It will simultaneously shed light on the effect of MBC on adult mental healthcare for depression in community settings when adapted by stakeholders to fit their context. Our research will answer the *how* of implementation by evaluating the effect of contextual factors on the process, an effort that directly aligns with NIMH's Strategic Plan 4.1 to "Improve understanding of the factors that affect…the means by which newly discovered effective mental health interventions are disseminated and implemented."

B2. INNOVATION. *This proposal is innovative in at least three ways.*

1) Minimal Intervention Needed for Change (MINC; Glasgow et al., 2013)**.** Our focus on testing strat- egies to implement MBC in community mental health is innovative because this simple MBC framework may be the minimal intervention needed for significantly reducing the burden of depression on society. For the treatment of depression, we opted to focus on MBC rather than a complex, theoretically-driven EBP like Cogni- tive Behavioral Therapy not only because of the MBC implementation gap, but also because the simplicity and accessibility of the MBC framework will reduce the number of implementation barriers. Moreover, MBC has

been isolated as a core component of many of EBPs. Therefore, identifying effective implementation strategies for MBC would build the case for a phased or staged approach to full package EBP implementation to deter- mine whether later EBP implementations enhance outcomes beyond improvements observed with MBC.

2) Leveraging Low Cost Technology. We will use tablet computers linked to an online MBC platform that is embedded within the electronic health record system. The use of technology will decrease the time burden of MBC and will enhance the utility it brings to clinicians, clients, the organization, and research (Powell et al., 2005). The tablets' high-tech features have the potential to promote client engagement in treatment and may help to emphasize the importance of symptom monitoring. Linking the tablet data collection with the elec- tronic health record will also allow us to build useful, innovative features such as symptom trajectory graphs, alerts when suicidality is endorsed, and ideas/suggestions for treatment targets. With electronic health record prevalence increasing and tablet computer costs decreasing, this approach presents a generalizable and cost-effective method for engaging in systematic outcome monitoring that maximizes therapeutic benefit.

3) Tailored Implementation. The majority of existing implementation research has focused either on descriptive studies that explore barriers and facilitators (determinants of practice) *or* on comparisons of *a priori* selected implementation strategies that generally neglect contextual tailoring of the interventions. A qualitative analysis of 22 implementation studies revealed that few focused on matching strategies to deteminants of practice (Bosch, van der Weijden, Wensing, & Grol, 2007). A critical research agenda has emerged seeking to identify, "how and why implementation processes are effective" (Proctor, Powell, Baumann, et al., 2012) by experimentally evaluating implementations that are tailored to the context. Table 1 summarizes the conceptual differences between standardized and tailored conditions in this proposal.

Table 1. Implementation Conditions

Standardized	Tailored
M**anualized** implementation content	Content adapted by implementation team to address barriers
Developed *a priori*	Responsive to local needs
Standardized MBC guideline	MBC administration set by site

Tailored Implementation and Quality Improvement approaches overlap with respect to their ultimate goal of improving client care through changing provider behavior using context-specific strategies. However, *Tailored Implementation and Quality Improvement differ in three key ways*. One, Quality Improvement focuses primarily on change as it occurs outside of the intervention whereas Tailored Implementation allows for chang- es to the intervention to fit the context (Chambers, Glasgow, & Stange, 2013). Recent findings support the need to adapt evidence-based practices during the implementation process (Aarons, Miller, Green et al., 2014; Stirman, et al., 2013), but no studies have directly compared this approach to standardized EBP implementa- tion. Two, Quality Improvement engages the Plan-Do-Study-Act as a means for identifying necessary change strategies driven by data in a cyclical fashion, whereas Tailored Implementation begins with a needs assess- ment to identify context-specific determinants of practice and then adapts implementation content to match de- terminants of practice. Three, implementation is focused on the goal of integrating an EBP, in this case MBC, into real world settings (Eccles, et al., 2009) whereas Quality Improvement is a general organizational man- agement approach to improving care not necessarily focused on EBP integration (Baker, 2006). This proposal reflects a movement in the field (e.g., Dynamic Adaptation Process; Aarons, et al., 2012) to consider planned adaptations of the EBP and systems/organizations to promote EBP integration and sustainment.

C. APPROACH

Overview. Given the underwhelming use of MBC in community mental health settings coupled with the demand for performance outcome assessment (Affordable Care Act), this randomized implementation trial aims to compare the effectiveness of a standardized versus tailored approach to implementation of MBC with co-primary outcomes at the clinician (MBC fidelity) and client (depression severity) levels. We will randomize 12 sites of a large community mental health center (Centerstone) to early or later stage standardized or tai- lored implementation enrolling 150 clinicians and 500 depressed clients in a pragmatic trial (Thorpe et al., 2009). The main clinician level outcome is MBC fidelity, defined as (a) client completion of the PHQ-9, (b) clini- cian review of scores in the electronic health record, and (c) discussion of scores in session. Phase 1 (months 0-8) will interface the most widely used and validated depressive symptom severity measure (Patient Health Questionnaire-9 item; PHQ-9; Kroenke, 2001) with the electronic health record; this measure is the main client level outcome. Phase 2 (months 8-38) constitutes the active implementation (5 months) and sustainment (10 months) phase. In both conditions, clients will have the option to complete the PHQ-9 on tablets in the waiting room prior to session, which will feed scores to clinicians via the electronic health record. Sites randomized to the standardized condition will begin with a baseline mixed methods needs assessment (for the purposes of putative mediator data collection) and receive the guideline that MBC is to be used in each session with a depressed client. The standardized condition will include manualized training and triweekly group consultation with experts to promote MBC fidelity and optimize its clinical utility. An implementation team (including a site

administrator, opinion leader, MBC champion, and research personnel) will convene prior to each triweekly group consultation to review progress and troubleshoot problems. Sites randomized to the tailored condition will also begin with a needs assessment to identify contextual factors that may serve as barriers to the imple- mentation (guided by the *Framework for Dissemination*; Mendel et al., 2008; see *C7*). Training and triweekly group consultation will be tailored to address these barriers (e.g., clinician attitudes toward MBC). The imple- mentation team (same composition as in standardized) will define a site-specific guideline for MBC use (e.g., monthly) and convene prior to each triweekly group consultation to troubleshoot MBC fidelity barriers. At the start of the active implementation across both conditions, depressed clients of participating clinicians will be enrolled to compare the effect of standardized versus tailored MBC implementation on client outcomes. Phase 3 (months 38-48) will characterize MBC fidelity using electronic health record data capture. The evaluation ap- proach is guided by the *Framework for Dissemination* (Mendel et al., 2008) and includes a baseline needs as- sessment, implementation/process evaluation (5 months into implementation), and outcome/impact evaluation (15 months into implementation). This design will allow for a direct test of the assumption that voltage drop in treatment outcomes occurs in the context of adapting the intervention to fit the context (Chambers et al., 2014), while simultaneously exploring the effect of standardized and tailored approaches to MBC implementation.

C1. Research Team Expertise, Roles, and Plan for Collaborating

The PI is strategically guided by two tiers of influence with the *first tier* (Kroenke & Ayer) including key leader- ship to help manage practical aspects of a clinical trial and the *second tier* (Mendel, Simon, Marti, & Rutkowski) including essential content and methodological expertise. Kroenke has notable experience with NIH-funded R01-level effectiveness trials that include depressed patients. Kroenke will mentor PI, Lewis, in the manage- ment of a scientific trial. Ayer will provide mentorship in community trials given his experience as site PI for federally funded trials at Centerstone (STAR*D & CATIE); Ayer will oversee participant enrollment and data collection. Lewis will meet with Kroenke and Ayer weekly during the start up phase and twice monthly thereaf- ter. The second tier brings expertise in implementation science and community-based participatory research (Mendel) and measurement-based care and community-based research (Simon); both experts will convene with Lewis at least monthly. Marti and Rutkowski bring quantitative and mixed methods expertise, respectively, with meeting frequency approximately monthly, but more frequent when expertise is needed (e.g., Rutkowski weekly during active implementation). Quarterly research team meetings will be held with all members.

C2. Centerstone Readiness and Representativeness

As a large behavioral health center with 100+ sites across IN and TN, Centerstone employs approximately 400 clinicians and annually provides services to over 70,000 individuals and families. Centerstone will soon intro- duce a new electronic health record system through a contract with NetSmart, a leading provider of technology solutions for health and human services, with advanced capabilities through their electronic clinical expert technology (Morrison *Letter of Support*). Given these forthcoming changes and their on-site research institute (Director & Co-I, Ayer), we have an unprecedented opportunity to evaluate an MBC implementation. Center- stone clinicians and clients are highly representative of the broader popula-

tion; therefore we anticipate that the results of this project will generalize to other community mental health centers. Table 2 depicts demographics for Centerstone clinicians. Consistent with typical community mental health cen- ter clinicians in the US, the majority of Centerstone clinicians are Caucasian females with Masters level training. Centerstone clientele represent the broader population of adults seeking mental health services in community set-

tings. Each year, roughly 36,000 Centerstone clients meet criteria for a prima- ry nonpsychotic depressive disorder.

Table 2. Clinician Demographics	
Gender: Female	83.4%
Age	43 yrs
Education: Masters	96.0%
Time at Centerstone	6.04 yrs
Licensed: Yes	11%
Weekly Caseload	45
Productivity Requirement	1200 hrs/yr
Met Productivity: yr 11/12	62.0%
Supervisor : Clinician	1:3

C3. Overview of Measurement-Based Care

MBC is the systematic monitoring of client outcomes, using standardized measures, to inform treatment. Re- cent efforts to implement MBC in community mental health settings have primarily focused on the use of measurement feedback systems and not on the implementation process (e.g., Bickman, 2008). These systems are not readily available due to high costs, nor are they easily integrated within the electronic health record to interface with existing documentation requirements. To address these limitations, our team will introduce the MBC as an evidence-based intervention framework (Scott & Lewis, *in press*) and capitalize on the ways MBC has been used effectively in medicine (Löwe et al., 2004) and in the UK's Improving Access to Psychological Therapies program (Clark et al., 2009). Centerstone clinicians (*N*=165) revealed that fewer than 24% use MBC with depressed clients (Lewis, Scott, Marti, & Ayer, *under review*), which is likely an *overestimate* given the

self-report nature of the data (Martino et al., 2009). To improve this rate of MBC use, we will integrate MBC capacities within the electronic health record as well as support and evaluate the implementation process.

C4. PHQ-9 Relevance, Specificity, Sensitivity

We will use the Patient Health Questionnaire depression scale (PHQ-9; Kroenke, 2001) as the primary depres- sion outcome measure in this proposal and as the core component of MBC. The PHQ-9 consists of 9 items that map directly onto the symptoms of a major depressive episode (DSM-IV TR; American Psychiatric Associ- ation, 2000), as well as 1 item pertaining to impairment. The PHQ-9 is one of the best-validated depression measures used in >1000 research studies (Kroenke, Spitzer, Williams, & Lowe, 2010). The PHQ-9 has de- pressive severity cutoff scores, is sensitive to change (Löwe, Kroenke, Herzog, & Gräfe, 2004), and is useful for weekly administration as an indicator of treatment effectiveness (Kroenke & Spitzer, 2002); a five-point change reflects clinically significant reduction in symptom severity (Kroenke & Spitzer, 2002). Three diagnostic meta-analyses and a recent review have confirmed the good sensitivity and specificity of the PHQ-9 in making a major depressive disorder diagnosis (Kroenke, Spitzer, Williams, & Lowe, 2010). Clinicians in our pilot study appreciated the brevity of the measure; clients stated that they thought the PHQ-9 (a) was relevant, (b) would facilitate suicidality endorsement, and (c) would help them to understand their symptoms.

C5. Leveraging Technology: Interfacing Tablet Data Collection with the Electronic Health Record

NetSmart (Morrison *Letter of Support*) has agreed to support the integration of the PHQ-9 into the electronic health record system and to work with our team to develop advanced features of the MBC interface. Total score graphical displays showing session-by-session progress will be available to clinicians within the electron- ic health record and to clients on their personal health record via the tablet. Clinicians and clients will be able to view individual item-level information, with suicidality highlighted for careful review. Clinically significant change (5-point reduction), and lack thereof, will be flagged from session-to-session. The PHQ-9 will be available to clients on tablet kiosks in the waiting area for completion prior to session. In our pilot, clinicians indicated the importance of tablets as they: (1) felt clinician administration of the PHQ-9 was unnecessarily time-consuming, and (2) wanted to encourage clients to take ownership of symptom monitoring given the potential therapeutic benefits (Eisen, Dickey, & Sederer, 2000). Clients in our focus group unanimously requested private comple- tion of the PHQ-9, indicating that this would promote comfort in sharing suicidality. Tablets are a cost-effective option that has been successfully used in similar protocols (Crits-Christoph et al., 2012). The technological and clinical innovations developed for this proposal present a generalizable protocol (documented in a manual) for widespread implementation given the proliferation of electronic health records. These technological enhance- ments will be made in both conditions during Phase I (months 0-8; see *C11. Overview of Study Design*).

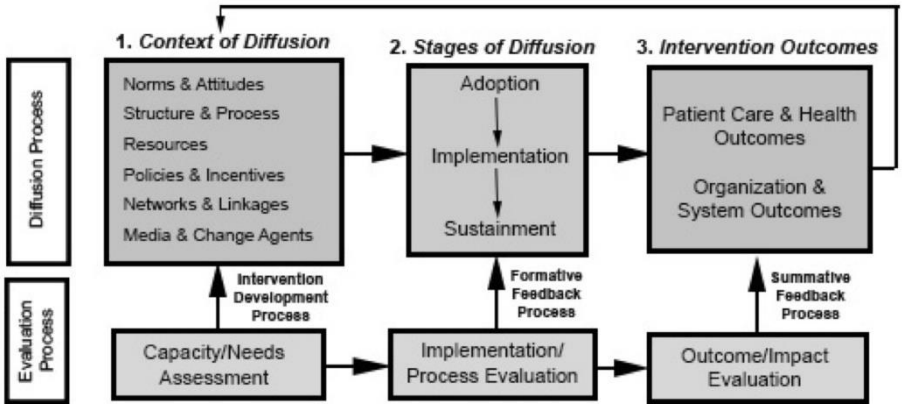
C6. MBC Fidelity

In this proposal, fidelity to MBC is a three-level categorical variable defined by (a) client completion of the PHQ-9 (No=0, Yes=1), (b) clinician review of scores in the electronic health record (No=0, Yes=1), and (c) dis- cussion of scores in session (No=0, Yes=1). The former two (PHQ-9 completion and clinician review of scores) will be automatically captured through the electronic health record. Clinicians will also check a box in the elec- tronic health record progress note to indicate if they discussed scores in session, as this practice optimizes the effectiveness of MBC (Eisen, Dickey, & Sederer, 2000). Given the known limitations to clinician self-report, this latter fidelity criterion will also be assessed with client self-report via an automated telephone survey immedi- ately after their session. In their first month of implementation, all clinicians (regardless of condition) will be asked to indicate factors they perceived to have limited MBC use. Through a drop-down menu embedded in the electronic health record progress

note, clinicians will select contextual factors based on the literature (Dowrick et al., 2009; Garland, Kruse, & Aarons, 2003; Valenstein et al., 2009) and clini- cian-identified factors (from our pilot data); See Appendix for complete list of options (e.g. lack of time, client re- fused, clinician forgot).

C7. The Evaluation Process Figure 1 depicts the *Framework for Dissemination*, which outlines the diffusion and evaluation processes for this study (Mendel, Meredith, Shoenbaum, Sher-

Figure 1. Framework for Dissemination



bourne, & Wells, 2008). Contextual factors (Box 1) theorized to influence the stages of diffusion (Box 2) are identified and both individual and organizational outcomes are considered (Box 3). This framework is based upon the best available research and includes a 3-phase evaluation process (see bottom row) with a communi- ty partnership emphasis directly suited to guide this proposal. This model will allow us to evaluate the stand- ardized implementation protocol and to identify contextual factors that may limit or facilitate its effectiveness. This model will also be used to guide the tailored approach to implementation (Mendel; *Letter of Support*).

C8. Complementary Testable Model. Chambers, Glasgow, and Stange (2013) recently put forth the *Dynam- ic Sustainability Framework* to promote testing of falsifiable hypotheses that program drift from "fidelity" of evi- dence-based practices leads to a voltage drop in implementation outcomes as compared to effect sizes ob- served in efficacy trials. Chambers et al. (2013) contend that an alternative hypothesis is important to consider: intentional adaptations to EBP implementation that are informed by community stakeholders and account for relevant multi-level contextual factors may optimize sustainment and intended outcomes. This proposal intends to test this model. Specifically, the standardized condition requires (via a guideline) that MBC be implemented weekly prior to each psychotherapy session according to its documented efficacy (e.g., Bickman et al., 2008; Whipple et al., 2003). Conversely, the tailored condition will allow the implementation team at each site to adapt this guideline, taking into account their specific context (e.g., monthly MBC implementation).

C9. Pilot Studies

Two Centerstone sites participated in our pilot study to assess the feasibility of the implementation and evalua- tion process and to inform the implementation protocols for this proposal (*C10. Multifaceted Protocol*).

Baseline Needs Assessment. The mixed methods needs assessment included baseline in-person clinician (N=10, 1.5 hours) and client (N=6, 1 hour) focus groups and clinician (N=24) self-report survey assessments to evaluate the contextual factors of diffusion (Box 1, Figure 1). This needs assessment procedure proved successful for data collection and resulted in 100% clinician participation. At baseline, the Attitudes to- wards Standardized Assessment scale (ASA, scale ratings 1-5; Jensen-Doss & Hawley, 2010) indicated that clinicians at both sites had generally neutral attitudes about MBC practicality (M=3.03, SD=0.54 and M=3.14, SD=0.42, respectively; Cohen's d=0.23), its benefit over clinical judgment (M=2.88, SD=0.46 and M=3.40, SD=0.93, respectively; Cohen's d=0.71), and its psychometric quality (M=3.37, SD=0.56 and M=3.89, SD=0.53, respectively; Cohen's d=0.95), with Site A demonstrating moderately lower scores across the sub- scales. Sites also differed on their intention to use MBC; Site B had more positive views of social influence to use MBC (t=2.48, p=.042) and MBC self-efficacy (t=3.49, p=.010).

Qualitative analyses of clinician focus groups (2 sites, N=10) also revealed site differences in implementation barriers. Notably, significant site differences were observed in the ratio of negative to positive attitudes about MBC (Site A: 44 negative to 17 positive, versus, Site B: 35 negative to 33 positive). Clinicians at Site A frequently cited that MBC was artificial and was overly evaluative of the clinician's abilities. At Site B, clinicians endorsed concerns about how MBC would impact clinical productivity, the feasibility of MBC implementation, and the utility of MBC in achieving therapy goals. Simultaneously, clinicians at Site B indicated that MBC would be useful for evaluation and diagnosis and could be used to identify lack of progress. Clinic director participants indicated that leveraging technology for client completion would be essential.

Implementation. We then piloted a standardized implementation protocol consisting of (a) embedding the PHQ-9 into the electronic health record (requiring the clinician to verbally assess clients as tablets were not available), (b) a site-specific guideline for PHQ-9 use, and (c) a brief training. The 4-hour training content was based on the work of Persons, Hong, and Koerner (2012); topics included: MBC as a foundational framework; MBC clinical utility; the research evidence for MBC and the PHQ-9; the MBC protocol; research and IT supports to enact the protocol; introduction to the electronic health record interface; and steps for working with lack of progress. These strategies reflect a minimum set of discrete evidence-based implementation strategies that could be blended to facilitate implementation. Pre-training Intention to Use MBC scores were highly correlated with the frequency of subsequent PHQ-9 administration (r=.67, p=.036). Across sites, 67% MBC penetration was achieved (number of clinicians implementing MBC/number of participating clinicians). Site A achieved 44% penetration while Site B achieved 80% penetration. One limiting factor at Site A was technology problems as the new electronic health record had not yet been introduced and the PHQ-9 did not consistently show up for clinicians. Despite these relatively high penetration scores at the clinician level, this minimal standardized implementation protocol and site-specified MBC guideline resulted in 13.4% (Site A) and 38.6% (Site B) use of the PHQ-9 (by dividing number of administrations by total possible number of administrations) over the course of one year follow up. Unfortunately, we were unable to assess the differential effect of MBC implementation on client outcomes to determine whether adapted guidelines limited MBC's utility. These findings support the

proposal in three ways: (a) they emphasize the utility of a mixed methods needs assessment in identifying *site differences* in barriers, (b) they highlight the importance of tailoring strategies to barriers as this minimal standardized protocol led to superior outcomes in Site B where fewer barriers were present, and, (c) they under- score the potential importance of incorporating technologically advanced solutions for client PHQ-9 completion.

C10. Multifaceted Standardized and Tailored Implementation Conditions

Overview of the Blended Implementation Protocol. Both conditions (standardized and tailored) will employ the same blended protocol of implementation strategies to remove time and resource confounds (see Table 3). The guiding model (*Framework for Dissemination;* Figure 1; Mendel et al., 2008), the best available literature on related efforts to promote MBC implementation (e.g., Evans & Hser, 2004; Harding et al., 2011; Lambert et al., 2005; Morris & Trivedi, 2011; Persons, Hong, & Koerner, 2012; Teruya, Hardy, Hser, & Evans, 2006), personal communication regarding program evaluation of a loosely tailored MBC implementation effort at Group Health clinics (Steinfeld, February 11, 2014), the MBC intervention framework, the partnership goals, and the pilot study defined the blended protocol of implementation strategies (Powell, McMillen, Proctor, et al., 2012). It was determined that embedding the PHQ-9 into the electronic health record was not sufficient but that using tablet computers would be essential to promote feasibility of implementation. The proposed local needs assessment is necessary to assess site-specific contextual factors and to identify opinion leaders and champions. In our pilot, we did not involve clinicians on the implementation team, but literature suggests this may be critical to achieving sustainment (Teruya, Hardy, Hser, & Evans, 2006) and it is consistent with our partnership goals. As such, each site will form an implementation team consisting of the PI, Co-I (Ayer), the site administrator, a clinician identified as an opinion leader (via self-report; Childers, 1986), and a self-nominated MBC champion who will meet for at least 30 minutes prior to each triweekly consultation session. Training and consultation with experts are essential strategies for promoting clinician behavior change and fidelity to the intervention, particularly in the case of evidence-based psychosocial interventions (Herschell et al., 2010). A guideline will be set to specify the frequency of expected PHQ-9 administration with depressed clients. The order of strategies will proceed as follows within each site's 5-month active implementation period: (a) embed PHQ-9 in electronic health record; (b) conduct needs assessment; (c) form implementation team; (d) set guideline; (e) offer initial training; (d) conduct triweekly group consultation meetings (see *C11. Overview of Study Design*). In the 10 months post active implementation, the implementation team will be encouraged to continue to meet and consult with clinicians to promote sustainment. Table 3 depicts the protocol and unique focus of the implementation strategies across conditions. A similar blended protocol of implementation strategies led to successful MBC implementation using the PHQ-9 with 90% completion with over 30,000 clients each quarter at Group Health (personal communication, Steinfeld, February 11, 2014).

Table 3. Standardized versus Tailored Protocol and Focus

Contextual Factor	Strategies	Standardized Focus	Tailored Focus
Resources	PHQ-9 in EHR w/ Tablets	Client Completion on Tablets	Client Completion on Tablets
Networks & Linkages	Form Implementation Team	Monitor MBC Fidelity	To Identify Barriers
Policies and Incentives	Guideline	Each Session w/ Client	Determined by Site
Norms & Attitudes	Training	Standardized Protocol	Targets Barriers
Structure & Process	Progress Note Modifications	For Clinician Score Review	For Clinician Score Review
Media & Change Agents	Consultation with Experts	MBC Fidelity	Targets Barriers

Standardized Condition. The standardized condition includes all aforementioned strategies in the or- der listed above. The needs assessment will be conducted similar to our pilot study in that it is for data collec- tion purposes only (i.e., no tailoring to identified barriers). The implementation team meetings will focus on monitoring MBC fidelity per the guideline. Depressed clients of clinicians in the standardized condition will be asked to complete the PHQ-9 prior to each session on a tablet in the waiting room (guideline). PHQ-9 data will then be fed to the electronic health record for clinician review. Training will be offered to all enrolled clinicians using standardized material (described in *C9. Pilot Studies*). Consultation will focus on incorporating clinician review and discussion of PHQ-9 scores in session and providing tips on targeting lack of progress.

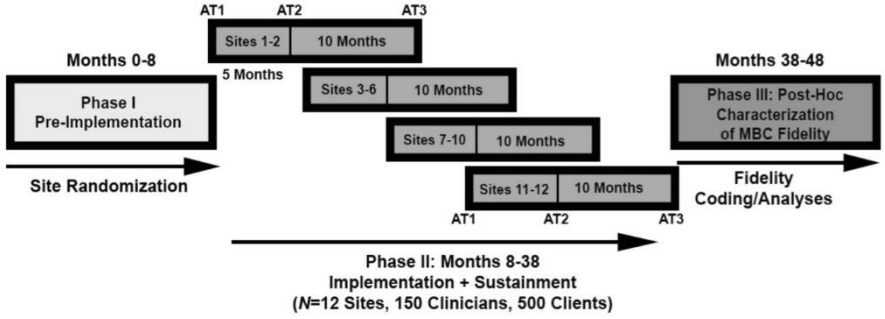
Tailored Implementation Condition. Tailored Implementation refers to the *responsive application of implementation strategies and content matched to determinants of practice (i.e., barriers) identified via a needs assessment*. The same strategies outlined in the standardized condition will be employed in the tailored condition, but with content tailored to the site. The needs assessment will reveal contextual factors that may serve as barriers to the implementation process (focus groups will be analyzed using rapid ethnography methods; *C13b. Qualitative and Mixed Methods Data Analysis Plan*). An implementation team will convene to define the site-specific guidelines for PHQ-9 completion. For instance, it may be that Site X decides that monthly PHQ-9 administration is optimal with respect to feasibility and clinical utility. Conversely, Site Y may prefer to have cli-

ents complete the PHQ-9 every other session. Depressed clients of clinicians in the tailored condition will com- plete the PHQ-9 in the waiting room on a tablet computer prior to their appointment with the enrolled clinician based on the site-specific administration guideline. PHQ-9 data will then be fed to the electronic health record for clinician review. Training will be offered to all enrolled clinicians using tailored materials that will target the identified barriers from the needs assessment. For instance, if clinicians at a particular site perceive the PHQ-9 to be irrelevant to clients, training content will incorporate client perspectives on its utility. If clinicians indicate that lack of time is a barrier, then training will incorporate experimentation to streamline review and discussion of scores. The implementation team will focus on identifying remaining barriers for discussion in the triweekly group consultation session. Similar to the standardized condition, consultation will also focus on incorporating clinician review and discussion of PHQ-9 scores in session and providing tips on targeting lack of progress.

C11. Overview of Study Design, Timeline, Sample, and Data Collection

The two years of planning and pilot studies in partnership with Centerstone have informed the implementation pro- tocols as well as its overall research design and data collection procedures. We propose an effectiveness- implementation hybrid design type 2 to allow for simultaneous investigation of clinician- and client-level outcomes. This design will be a dynamic waitlist randomized pragmatic trial comparing the effect of a standardized versus a tailored approach to MBC implementation (Figure 2 & Table 4).

Figure 2. Design Overview



Phase 1: Start-up/Pre-Implementation. Months 0-8 will be characterized by preparatory work for the randomized trial. Little needs to be done to create the research infrastructure in the participating clinics given the existing role of Centerstone Research Institute directed by the proposal Co-I (Ayer). We will prepare the tablet computers for client data collection. We will work with Netsmart (Morrison *Letter of Support*) to link the electronic health record to the PHQ-9 and create the optimal interface for clinicians within the progress note. We will enroll the identified sites (*N*=12), match sites based on size and urban/rural status, and randomize to either *early or later* stage implementation and to condition (standardized or tailored) (Brown et al., 2006). There will be four cohorts each with 5 months of active implementation and 10 months of sustainment monitoring. We will modify the progress note for clinicians to document fidelity (PHQ-9 discussed in session) and reasons for deviation (*C6. MBC Fidelity*). We will pilot the progress note modifications with our advisory board of clinic di- rectors to maximize the information gleaned and to minimize the burden. Because of our use of technology, we will create IT Frequently Asked Questions and instructions, which will be embedded within Centerstone's inter- nal news. We will also interface study research assistants with clinic staff by attending regular staff meetings at each site. Finally, we will refine measures using established protocols (e.g., Norms; Francis et al., 2004).

Phase 2: Randomized Trial: Implementation & Sustainment. Implementation will take place across 12 sites in months 8-38 using the dynamic waitlist control design (Brown et al., 2006; *C15. Justification and Feasibility*). Specifically, matched sites (based on size and urban/rural status) will be randomized to either *early or later* stage implementation in 4 cohorts (2-4 sites per cohort spaced 5 months apart), with half the sites ran- domized to the standardized and half to the tailored condition; see Figure 2 for a concise depiction of the im- plementation timing. The timing of this protocol is based on the published work of Miller et al. (2012) as well as the successful naturalistic MBC implementation at Group Health (personal communication, Steinfeld, February 11, 2014). Beginning at month 8, the earliest cohort (2 sites) will engage in the baseline mixed methods needs assessment (Assessment Time 1; AT1). Using purposeful sampling (Palinkas et al., 2013), a subset of clini- cians (*N*=5-8 at each site) representing extreme variation (nominated by clinic directors based on their support for or against MBC implementation) will participate in a 1.5-hour focus group. This sampling approach is critical to gain a wide range of clinician views. Rapid ethnography will then be used to uncover site-specific insights that will guide the content of training and consultation in the tailored condition only (with the aid of mixed meth- od expert Rutkowski; *C13b. Data Analysis Plan*). During the needs assessment, all enrolled clinicians will complete the battery of baseline measures (see Table 5, Section II), from which the opinion leader (Childers, 1998) and self-nominated MBC champion will be identified and invited to join the implementation team. Across conditions, this team will convene triweekly during the 5-month active implementation period to ensure imple- mentation strategy fidelity (Proctor et al., 2013) and review MBC fidelity. Following the needs assessment, cli-

nicians will participate in a 4-hour MBC training workshop (see *C9. Pilot Studies* for content) and will begin tri- weekly consultation. To characterize the differences in implementation team meetings and consultation between conditions, sessions will be audiorecorded and contextual factors logged by graduate research specialist on the MBC Barriers Log (informed by the *Framework for Dissemination*; Mendel et al., 2008; see *Appendix* for form template). Simultaneously a site team member will log meetings (using the same form) and data triangu- lated to calibrate site team members and prep for the exit of research personnel. Implementation/Process Evaluations (Mendel et al., 2008; AT2) at the clinician level will occur 5 months after the needs assessment at which point the research personnel will be removed. The site implementation teams will be encouraged to con- tinue meeting to promote MBC sustainment and the responsibility to log and address MBC barriers will transfer completely to the site team members. Outcome/Impact Evaluation (Mendel et al., 2008; AT3) at the clinician and client level will occur 10 months after the Implementation/Process Evaluation. Focus groups will be held with the implementation team at AT3 to review their experience and the site's progress since the research per- sonnel exited the team. All aforementioned steps will be repeated across the remaining three cohorts.

Phase 3: Post Hoc Characterization of MBC Fidelity, Data Analysis, and Manuscript Preparation. Consistent with the Dynamic Sustainability Framework (Chambers, Glasgow, & Stange, 2013), the approach to MBC implementation has the potential to be adapted by sites in the tailored condition. That is, early in the ac- tive implementation process (within the first month), the implementation team will generate a guideline for MBC implementation that is specific to their site. Characterizing fidelity for this condition will need to reflect the guideline established for each site. For instance, if a site set a guideline to administer the PHQ-9 monthly for each client then actual administration will need to be confirmed monthly. Data capture from the electronic health record will also include whether or not the clinician re- viewed the PHQ-9 scores prior to or in session. Finally, with re- spect to coding of MBC review in session the clinician self-report (via the electronic health record) and client report (via automated phone survey) will be triangulated. Concurrently, focus group data will be formally coded (see *C13b. Qualitative and Mixed Methods Data Analysis*) for manuscript preparation.

Table 4. Study Activities

ACTIVITIES	YEAR 1	YEAR 2	YEAR 3	YEAR 4
Study Phase	Phase 1	Phase 2		Phase 3
EHR Modifications				
Clinician Enrollment				
Randomization				
Clinician Assessment				
Active Implementation	Co1	Co2	Co3	Co4
Sustainment Monitoring		10-months for each cohort		
Client Enrollment & Assessment				
Rapid Ethnography				
Qualitative Coding				
Data Analyses				
Characterize MBC Fidelity				
Manuscript Preparation				

Note. Co = Cohort (2-4 sites with 1-2 randomized to each condition).

C12. Participants: Recruitment, Retention, and Data Collection Procedures

C12a. Clinicians

Recruitment. Participants will be recruited across 12 sites (Clinicians: *N*=187; target: *N*=150) (*Letter of Support;* CEO Guth). The number of sites and clinicians has been determined by a simulation-style power analysis to detect a small effect size predicted by previous research (*C13. Data Analysis Plan*). The main sites have been identified, but not enrolled (*Letters of Support* from regional clinic directors). As there are at least 16 sites from which to select (easily accessible from primary site) and at least 250 eligible clinicians across these sites, we are confident that we can obtain the targeted number of both sites and clinicians. Said differently, even if a site administrator enrolls a site, not all clinicians will need to participate, an important factor to avoid any perception of coercion. Given site diversity, the large number of eligible sites will maximize the likelihood that results will generalize to the broader population of community mental health centers. Sites range in size from 12 to 52 clinicians. Within each enrolled site, clinicians will have the option to participate if they (a) are at least 80% full-time equivalent (b) provide individual psychotherapy to (c) adults with depression (d) in English. These inclusion criteria reflect over 95% of clinicians at the eligible sites. Based on our pilot study, we have experienced that even those who are not supportive of MBC have agreed to participate, therefore making it unlikely that self-selection to participate would limit the generalizability of our sample. During Phase 1 (months 5-8; Table 4), clinician enrollment will begin across all sites and site randomization will occur as site level ran- domization improves project feasibility and reduces contamination confounds. This decision to randomize by site was also influenced by literature indicating the impact of organizational culture and climate on the imple- mentation process (Aarons et al., 2012; Damschroder et al., 2009), which will be assessed at baseline (AT1).

Data Collection. See *Table 5: Study Measures, Section II* for concise descriptions of the clinician battery. Each contextual factor of diffusion (Mendel et al., 2008) will be assessed via self-report (and qualitatively

via focus groups). MBC fidelity is the main clinician level implementation outcome. All clinician measures will be administered across three time points for each cohort with respect to their time since starting implementation: 1) Phase 1: Baseline Needs Assessment (AT1), prior to MBC implementation; 2) Phase 2: Implementation/Process Evaluation (AT2, 5 months in), following the active implementation phase; and, 3) Phase 3: Outcome/Impact Evaluation (AT3, 15 months in) 10 months after the research personnel have exited. Barriers to implementation will be collected for the first month of implementation via the electronic health record.

Retention. The total time required for clinician study participation is 15 months; however, the first two assessments are obtained within the first 5 months. The average length of employment for a clinician at Centerstone is 6 years with an average of 11.72% attrition last year. We anticipate stable clinician participation for the granting period. Fortunately, literature suggests that participatory approaches to organizational change in practice patterns result in lower clinician attrition (Minkler & Salvatore, 2012). Even so, we will recruit 1.25 times more clinicians (*N*=187) to accommodate attrition and achieve the target (*N*=150). Because of the dy- namic waitlist design, we will revisit enrollment in Phase 2, 3 months prior to each site's planned implementa- tion. Finally, the design can handle attrition given the within- and between-subjects analyses and multiple as- sessment points (3 ATs), as can the analyses (multilevel modeling with multiple imputation, described below).

Table 5. Study Measures

Domain	Measures & Indicators	Interval
I. Client Measures: Effectiveness Outcomes		
Depression Severity	*Patient Health Questionnaire-9* (PHQ-9; Kroenke, Spitzer, & Williams, 2001). The PHQ-9 is a 9 item self-report that assesses depression severity and has demonstrated good internal consistency (*α*=.85-.89) and sensitivity to change (Löwe, Kroenke, Herzog, & Gräfe, 2004).	All Sessions
II. Clinician Measures: Contextual Factors of the Diffusion Process (Putative Predictors, Moderators, & Mediators)		
Demographics	Developed by Lewis & Simons (2011) to assess clinician demographic information and training background.	BL
Norms	A measure of subjective norms will be developed (3 items; Francis et al., 2004) in proposal Phase I and used to assess normative behavior per the theory of planned behavior measurement development manual.	BL, AT2, AT3
Attitudes	*Attitudes Towards Standardized Assessment* (ASA; Jensen-Doss & Hawley, 2010) is a 22-item self-report that assesses attitudes toward use of standardized assessments (e.g., PHQ-9). The ASA has good internal consistency (*α*=.72-.75) for each subscale (Benefit Over Clinical Judgment, Psychometric Quality, Practicality) and good structural validity.	BL, AT2, AT3
Culture/Climate	*Organizational Culture Scale* (Glaser, Zamanou, & Hacker, 1987) is a 31-item self-report that assesses organizational culture using a 5-point Likert scale for 6 factors: teamwork, morale, information flow, involvement, supervision, and meetings. The OCS has demonstrated strong inter-item reliability (*α*=.98) among the subscales.	BL, AT2, AT3
Structure/ Process Policies/ Incentives	*Infrastructure Survey* (Keough, Comtois, Lewis, & Landes, 2013) is a 30-item self-report that assesses the impact of infrastructure (e.g., documentation, performance evaluation, productivity requirements) of clinical settings on the implementation and sustainment of empirically supported treatments. Psychometrics will be available Fall 2014.	BL, AT2, AT3
Resources	*Organizational Resources Scale* (ORS; Salanova, Agut, & Peiró, 2005). is an 11-item self report that assesses organizational resources across subscales of Training, Autonomy, and Technology and has good internal consistency (*α*=.84-.91).	BL, AT2, AT3
Networks & Linkages	We will map the network within each clinic and calculate: the number of links connecting network members (density), and the number of direct connections to and from the opinion leader (centrality).	BL, AT2, AT3
Media & Change Agents	*Opinion Leadership Scale* (OLS; Childers, 1986). The OLS is a 6-item opinion leader self-identification scale that will be employed to identify clinician opinion leaders who may serve as change agents. The OLS has demonstrated good internal consistency (*α*=.83).	BL, AT2, AT3
III. Clinician Measures: Implementation Outcomes		
MBC Fidelity	**1.** If clients complete the PHQ-9, it will be captured in the EHR (0=No, 1=Yes). **2.** The EHR will reveal whether clinicians reviewed scores (0=No, 1=Yes). **3.** Clinicians will self-report if they discussed scores in session (0=No, 1=Yes). Clients will respond via text to indicate whether clinician initiated score discussion in session. Reasons for MBC fidelity deviation will be captured via clinician report on progress notes.	BL, AT2, AT3

Note BL(AT1) = Baseline(Assessment Time 1), AT2 = Assessment Time 2, AT3 = Assessment Time 3.

C12b. Depressed Adult Clients

Recruitment. Adult clients (*N*=625; target *N*=500) seeking treatment for depression at Centerstone will be eligible for enrollment in the research study. As this is a pragmatic trial (Thorpe et al., 2009) client participa- tion criteria include: (a) age 18 and above; (b) depression is one of the primary treatment foci based on diag- nosis made by clinicians using usual care interview methods to reflect major depressive disorder, dysthymic disorder, depressive disorder NOS, adjustment disorder with depressed mood; (c) significant depressive symp- tom severity (PHQ-9 total score > 9); (d) receipt of individual psychotherapy; (e) fluency in English; and, (f) new client beginning treatment (g) with an enrolled study clinician during the proposed funding period. Exclusion criterion is minimal: an inability to sign the consent due to lack of competence or inability to read. Intake clini- cians will be trained to identify eligible clients and assess if they would be interested in hearing more infor- mation about a research study. If the client agrees, the clinician will share the client's contact information with the project coordinator. Because Centerstone has a strong research commitment, clinicians and clients are accustomed to a research environment

where the option to participate in studies is more routine than in many community mental health centers. Both Centerstone clinicians and clients have participated in a number of re- search studies and recruitment is expected to be very straightforward. However, to supplement this approach, Co-I (Ayer, Director of Centerstone Research Institute) will run weekly queries of the Centerstone database (in

accordance with Health and Human Services guidance) to identify eligible clients (see *Human Subjects* for previously used HIPAA compliant procedures) who will be contacted by our project coordinator to assess inter- est in study participation. Once a client has been enrolled, the study team will flag the client in the electronic health record to initiate study procedures for the clinician. Given the number of clients seeking treatment for depression at Centerstone (> 30,000/yr), we anticipate that our client recruitment goal will be feasible.

Data Collection. The goal of client data collection is to determine if routine measurement (in the standardized condition) improves depressive symptom severity and whether adaptations to the MBC assessment schedule (tailored condition) have differential effects on depression outcomes. Clients will complete the PHQ-9 on a tablet kiosk in the waiting room according to site-generated guidelines; this information will be automati- cally fed into the electronic health record for clinicians to review in session. Given the potential for variable PHQ-9 completion in the tailored condition (based on the site-generated guideline), we will also have clients enrolled in both conditions complete the PHQ-9 at baseline (immediately post consent) and at week 12 of treatment (via automated phone survey). The 12-week window reflects a commonly used time period in ran- domized clinical trials during which depressive symptoms are expected to remit. We will also supplement data collection with client 5-axis diagnoses and employment status captured in intake and progress review reports.

Retention. At recruitment, clients will complete a consent form and provide options for multiple contact methods (e.g. multiple phone numbers, address). Centerstone has consistently achieved greater than 75% cli- ent retention in federally-funded randomized trials (CATIE, Keefe et al., 2007; STAR*D, Insel, 2006). We will replicate previous efforts to maximize retention in the proposed study. In order to have sufficient power to de- tect statistical significance and account for client attrition, we intend to recruit 1.25 more client participants (*N*=625) to assure that we achieve our enrollment goal (*N*=500).

C13. Data Analysis Plan: C13a. Quantitative Data Analysis Plan

Data screening. Via frequency distributions and scatterplots, variables will be examined for unusual distributions, out-of-range, and extreme values. We will confirm randomization using chi-square tests, t-tests, and the Kruskal-Wallis nonparametric test. We will test assumptions and underlying statistical models during model fitting. For generalized linear models and multilevel models, we will examine the homogeneity of error, normality of residuals, linearity of relationships between independent and dependent variables, and outliers. For multilevel models, we will assess multivariate normality of random effects.

Missing data. All analyses will adhere to the intention-to-treat approach, which includes all participants assigned to their condition regardless of study completion (Wells, 1999). Multiple imputation (MI), an optimal technique for missing data (Graham, 2009), will include all participants and available data. For all MI analyses, 20 data sets containing plausible values for missing data will be constructed using the Amelia II package for R, which incorporates both cross-sectional and longitudinal information in data imputation (Honaker, King, Black- well, 2012). Each data set will be analyzed separately and model parameters combined for inferential tests (Rubin, 1987). The missing at random assumption will be assessed using a sensitivity analysis in which a se- ries of pattern-mixture models that adjust parameter estimates for missing data patterns (Hedeker & Gibbons, 1997), will be compared with basic models to identify any potentially non-ignorable missing data patterns.

Aim 1: Hypotheses: *Tailored implementation will outperform standardized in terms of (**H1a**) fidelity and (**H1b**) reducing client depression symptom severity.* Multilevel generalized linear models will be used to assess hypotheses for standardized versus tailored MBC implementation for both models of clinician and client out- comes. The multilevel generalized linear model framework includes continuous outcomes and extends the lin- ear model to accommodate nonlinear outcomes by including a distributional assumption and link function (e.g., a binomial distribution with a logistic link function will be used to implement logistic models). Specifically, we will examine the effect of the implementation condition on MBC fidelity (ordered categorical outcome; range 0-3 reflecting client completion, clinician review, discussion in session) measured across time. Multilevel models account for the non-independence of repeated measurements within participants and non-independence due to sites (Raudenbush & Bryk, 2002). Models for clinician and client outcomes will be constructed in an identical manner by following a model building-sequence recommended by Singer and Willett (2003) in which (a) empir- ical growth plots will be examined, (b) an unconditional means model will be fit, (c) an unconditional linear growth model will be fit, (d) unconditional non-linear growth models (a quadratic model) will be fit, (e) uncondi- tional linear and non-linear growth models will be compared using the Akaike Information Criterion to identify the best model of change across time, and (f) level-2 and level-3 predictors will be added.

Aim 2: Hypotheses: *Contextual mediators will be leveraged in the tailored condition, but serve as bar- riers in the standardized condition.* We will examine mediation models in which contextual factors (based on clinician-completed surveys, Table 5; and, clinician selection of drop-down menu reasons for MBC deviations captured in the electronic health record) mediate the impact of the implementation condition on both clinician-

and client-level outcomes. We will assess differences in MBC fidelity between implementation conditions by examining clinician, client, and organizational factors using multilevel generalized linear models that will pro- vide a general framework for assessing group differences for a variety of outcome distributions (normal, bino- mial, Poisson, etc.) that we anticipate will be necessary to characterize the factors impacting MBC fidelity. Me- diation models will be two-level models (i.e., clinicians nested within sites) or three-level models (clients nested within clinician nested within sites) in which outcomes are measured at the individual level, condition is as- signed at the site level, and mediators are at the clinician or site level. For assessing mediation in a multilevel context, models will be constructed following recommendations from Preacher, Zyphur, and Zhang (2010). To assess mediation, we will test whether (a) implementation condition predicts the change in the mediator (path *a*), (b) the mediator predicts growth change in MBC use (path *b*), (c) condition predicts change in the outcome (path *c*), and (d) whether the implementation condition's effect on MBC use becomes significantly weaker when controlling for the mediator (path *c'*) (Baron & Kenny, 1986; MacKinnon, 2008). We will also apply rec- ommendations from Kraemer, Wilson, Fairburn, and Agras (2002) to demonstrate that change in the mediator precedes change in MBC use. The indirect effect (i.e., the product of paths *a* and *b*) will be tested using bi- ased-corrected bootstrapped confidence intervals (Preacher & Hayes, 2008).

Aim 3 Hypotheses: *Adapted MBC protocols (i.e., tailored condition) will outperform routine weekly administration of PHQ-9s (i.e., standardized condition) with respect to clinically significant change in depression severity from intake to week 12.* We will assess the impact of MBC fidelity (standardized versus tailored) on clinically significant change observed in each client between intake and session 12 using generalized linear mixed models. Models will represent the three-level structure (i.e., clients are nested within therapists and therapists are nested within sites) with a binary outcome, representing whether a client exhibited clinically significant change using the reliable change criterion (Jacobson & Truax, 1991), modeled with a binomial distribution with a logistic link function.

Power calculations. A power analysis for the multilevel models for Aim 1 was assessed with Monte Carlo studies in which power is the proportion of significant effects (2-tailed α, $p < .05$) for parameters of interest observed over repeated analyses of simulated data (Muthén & Muthén, 2002; Thoemmes, Reiser, & MacKinnon, 2010) using MPlus (version 7). For each model, 10,000 data sets were simulated and analyzed. Data in the Monte Carlo studies were simulated with the goal of identifying the smallest detectable effect size with power > 80. Dropout was simulated to reflect an increase of 5% missing data per wave. Repeated measurements were nested within participants (ICC = .50) and participants were nested in sites (ICC = .05). Average effect sizes for Aim 1 analyses were computed using an approximation of Cohen's *d* for growth models (Feingold, 2009). Using this metric, we are sufficiently powered to detect effect sizes as small as $d = .46$ for the clinician models ($N = 150$) and effect sizes as small as $d = .30$ for the client models ($N = 500$). For Aim 2, we conducted power analyses for the hypothesized mediation effects with the same assumptions described above but with the use of effective samples size estimates (an ICC corrected sample size) based on a design effect adjustment (Bickel, 2007) in order to use standard effect size metrics. The κ^2 effect size for mediation (.01, .09, and .25 represent small, medium, and large κ^2 respectively) was computed (Preacher & Kelly, 2011). We are sufficiently powered to detect effect sizes as small as $\kappa^2 = .16$ for the clinician models and effect sizes as small as $\kappa^2 = .10$ for the client models. For Aim 3 analyses, we are sufficiently powered to detect effect sizes as small as $r = .27$ for clinicians and as small as $r = .21$ for clients. The planned sample sizes are consistently sufficient for detecting medium effect sizes for clinician outcomes and small effect sizes for client outcomes, with the power to treat site as a random effect based 6 sites per condition (Atkins & Baldwin, 2013).

C13b. Qualitative and Mixed Method Data Analysis Plan

Overview. Mixed methods will be used to integrate findings from Aim 2 using a quantitative + qualitative structure (wherein both types of data are collected simultaneously) to achieve the function of data expansion for the purposes of evaluation and elaboration (Palinkas et al., 2011). We will use a connecting process (whereby the datasets build upon one another) and work closely with our mixed methods expert (Rutkowski). Rapid ethnography (Millen, 2000) will be used to synthesize the needs assessment data only in the tailored condition to characterize participant experiences. Focus groups will be analyzed separately to characterize participant responses within each site, across conditions. Graduate student researcher (Scott), who was trained in qualitative inquiry methods during the pilot studies, will work with the postdoctoral fellow to train re- search assistants to identify and code analyzable units of meaning in the focus group transcripts. An iterative approach to coding will resolve disagreements through research team discussion. Inductive analyses based on emergent themes rooted in grounded theory will be conducted (using QSR N-Vivo software). Codes will also be assigned based on contextual factors using Mendel et al.'s (2008) *Framework of Dissemination*. The final list of consensus codes will include themes established *a priori* and through emergent themes analysis.

Using the U.S. NIH guidelines for mixed methods best practices (Creswell, et al., 2011), we will connect the quantitative and qualitative datasets in QSR N-Vivo to allow for case-specific pattern identification and hy- pothesis testing. For example, we will enter clinician-specific MBC fidelity data (categorized as "none", "low", "moderate", "high") and query each qualitative theme for matched clinician focus group quotes in order to investigate the influence of contextual factors on level of MBC fidelity. Based on pilot study qualitative findings, we anticipate that focus groups will yield both positive and negative valenced statements for each of the a pri- ori and emergent themes. We will investigate the extent to which differences exist in the valence of contextual themes between conditions. This approach will allow us to distinguish factors that might explain the differences in the quantitative findings, and notably MBC fidelity.

C14. Potential Problems & Alternative Strategies.

Our hypothesis is that tailored implementation will outperform the standardized approach. However, it is possi- ble that this hypothesis will not be supported. Findings of this nature would not be undesirable, but rather would illustrate that while emerging research suggests the need to contextualize implementation interventions (Fixsen, 2005; Wallerstein & Duran, 2010), this customization compromises ultimate outcomes—a critical reali- zation for the field of implementation science. Furthermore, if we are unable to detect mediators of implementa- tion and effectiveness outcomes included in this proposal, it may suggest the need to re-evaluate the *Frame- work of Dissemination*. Specifically, putative mediators of the dissemination and implementation process not included in this model might require empirical investigation. Our qualitative analyses will allow for careful exam- ination of unanticipated mediators. At the level of the clinician, we anticipate substantial variability in compe- tency and general approach to psychotherapy. However, we are not concerned about the effects of this varia- bility on study outcomes because (1) randomization should result in equivalent variability across conditions and

(2) MBC is conceptualized as transtheoretically relevant, regardless of the therapist's orientation or training.

C15. Justification & Feasibility.

We selected an effectiveness-implementation hybrid to investigate one co-primary aim that focuses on

(1) implementation outcomes at the clinician level and (2) effectiveness with respect to client outcomes. To test the Dynamic Sustainability Framework (Chambers et al., 2013), we will need to compare the clinical effective- ness of the adapted use of MBC (tailored) as compared to the empirically supported MBC approach (standard- ized). Simultaneously, because no studies have attempted to scale up MBC in community mental health, we need to evaluate the implementation (clinician-level: fidelity) outcomes. The effectiveness-implementation hy- brid design type 2 was identified as the optimal and innovative design solution for this proposal.

Within the effectiveness-implementation hybrid design, we will randomize sites to condition using a dy- namic waitlist controlled approach. Half of the sites will receive a standardized approach to implementation and the other half will receive a tailored approach. This design reduces the effect of management- or clinician-level readiness or client factors that might otherwise confound the training effects allowing for unbiased data (Brown, et al., 2006). This design also affords the opportunity to conduct blocking on smaller time units and statistically provides large gains in efficiency (range from 33 to 100% gains). Moreover, training efficiency is achieved as not all sites must be trained at once, therefore allowing the same trainer(s) to train all sites to reduce any pos- sible effect at the level of trainer expertise (Herschell, Kolko, Baumann, & Davis, 2010).

We have already piloted many of the implementation strategies and the evaluation

approach (*C8: Pilot Studies*). Moreover, Centerstone has successfully completed >150 studies since 2003; two of these studies were NIMH-sponsored (CATIE, Keefe et al., 2007; STAR*D, Insel, 2006), whereas others involved wide-scale implementation of EBPs for SAMHSA-sponsored program evaluations. Co-I (Ayer) has coordinated many of these multi-site clinical trials at Centerstone. This proposal's design considerations and the established strong collaborative relationship of our investigative team, we have no concerns regarding this proposal's feasibility.

C 16. Implications and Future Directions

Few experimental implementation studies have been conducted. Findings from this proposal have the potential to: (1) yield a robust theoretical and practical model delineating contextual factors and evaluative processes for implementation in an academic-community partnership; (2) demarcate the benefit of using standardized versus tailored protocols for implementation; (3) establish a blended protocol for MBC implementation with capacity for generalization to community mental health centers nationwide; and, (4) highlight contextual factors responsible for sustained MBC implementation. With depression maintaining its place among the nation's top chronic ill- nesses, costing billions of dollars annually, positive findings from this proposal will present a feasible and effec- tive approach to alleviating great societal burden through a minimal intervention needed for change. This study will lay the groundwork for subsequent research (by establishing progress monitoring) to enhance usual care for multi-problem clinical presentations, should MBC effects plateau and additional interventions be necessary.