DESCRIPTION (provided by applicant): Primary care does not reliably meet the needs of patients with mental health, substance abuse, or health behavior (MHSHB) problems, 43-60% of whom are treated solely by a primary care provider (PCP) (Kessler and Stafford 2008). Furthermore, between 50% - 90% of primary care referrals made to out-of- office mental health practitioners fail to result in a follow up appointment (Kessler and Stafford 2008). Although some primary care sites have explored integrating mental health services into their patient care processes, they have neither systematically resolved core issues nor addressed the broad range of needs (mental health, substance abuse, and health behavior issues) presented in primary care settings. The objective of this study is to refine a toolkit previously trialed in to primary care practices using an innovative, evidence-supported model for integrating primary care and behavioral health services. This study will pilot the toolkit in two sites, with the first conducted by an expert facilitator and the second with an on-site facilitator supported remotely. The toolkit is based on "Lean Management," a method of structured, analytically based problem solving focused on work processes. The broad goal of this work is to improve delivery of psychological services to patients who present in primary care settings. Specific aims: Aim 1: Refine a preliminary toolkit based on Lean, by sequentially piloting it in two primary care sites and collecting user feedback on its value. We will use a concurrent, mixed methods approach to obtain provider and staff evaluations of the Toolkit. In the first pilot, an expert outside facilitator will use the toolkit to help a practice team plan the implementation of PCBH and follow activation of the plan. Practice members will provide feedback on the toolkit and on PCBH implementation. After further refinement of the toolkit, the outside expert facilitator will train staff member of a second primary care site as in-practice facilitator. The in-practice facilitator will use the toolkit with the practice to plan the implementation of PCBH. Practice members will again provide feedback on the Toolkit and on PCBH implementation. Aim 2: Evaluate the reach and effectiveness of the PCBH Toolkit. We will collect de-identified patient data using an electronic health record (EHR) in each pilot site to report study outcomes as measured by depression severity and, secondarily, access indicators such as treatment initiation and waiting time for scheduled appointments. We will compare measures among patients receiving PCBH services at baseline and 6 months post-implementation at each site. This work will provide a field-tested Toolkit to systematically support the integration of MHSHB within primary care. We anticipate a follow-on multi-site, multi-state study of underserved primary care populations using two large, national practice-based research networks.

Introduction to Resubmission: Implementation Toolkit to Integrate Behavioral Health Services

Thank you for your reviews of our application. We are pleased that all reviewers agreed that the study addresses a significant need in implementation science using a productive, innovative method of organizational change. We have revised the original application based on comments made by the reviewers about the study's significance, innovation, and approach. Revisions are extensive and touch the majority of the text. Key changes responding to comments are noted by [brackets] surrounding the sections or paragraphs. Based on new data available from preliminary studies and a rigorous review of the proposal using reviewer comments, these changes strengthen the proposal in several meaningful ways:

1. Significance: "The choice of outcome variables (that)… are not really health outcomes" (Reviewer 2), "link of workflow improvements to client outcomes not developed" (R1), lacked evidence on Lean method (R4), "lacked a clear description of Lean… big tasks seem to require more time" (R4)
   - The primary outcomes measure is now patient health (depression scores measured by Patient Health Questionnaire-9 (PHQ-9) pre- and post-intervention) rather than referral rate. The secondary analyses will include evaluation of the original process measures.
   - The relationship of workflow improvements (Toolkit) to client outcomes is supported by a conceptual model drawing on the work of Helfrich, 2007 and is further supported by a national report linking process change with health outcomes (IOM, 2012). The Lean method of implementing process change to improve health outcomes is specifically cited by the IOM report and other sources.
   - Language in the application clarifies that the Toolkit sets the stage for implementation by planning and adjusting to the culture of the workplace. The 8 hour framework is a planning exercise only. This approach is novel in the health care sector and this description now appears under Innovation.
2. Innovation: "Research methods are not innovative" (R1), "incorporating a behavioral health specialist (PCBH) is not new" (R2), how (do) clinical, operational, and financial components contribute to implementation (R4), "operationalize implementation" (R4), "no discussion of implementation process" (R3)
   - Key innovations offered by this study are the use of Lean to rapidly plan and begin implementation and a method to address clinical, operational, and financial barriers inherent in doing so. PCBH is a well-known service but not currently integrated into primary care settings systematically.
   - The relationship of Lean to the clinical, operational, and financial barriers are addressed in Table 2.
   - The Toolkit establishes timeframes for implementation planning (8 hours). The Lean method requires that the implementation plan itself is the work of a front-line team, and cannot be prescribed by this model. The implementation process is outlined. Based on past pilots, implementation can be expected to be complete in three months after the 8 hours of planning are concluded.
3. Approach: Clarify conceptual framework (R1), specify quantitative analysis (R1), guard against adverse selection (R2), focus on health outcomes (R4), clarify content, process and lessons of Lean (R3, R4)
   - The conceptual framework draws together practice content/flow and patient outcomes. Examples of workflow issues are highlighted in Table 2; results from a previous study appear in Table 3, identifying statistically significant results for all measures.
   - The quantitative analysis plan now specifies the method of aggregating and testing paired results, including clustering within providers.
   - As the primary outcome measure is now patient outcomes, not referral rates, the concern regarding adverse selection is no longer an issue.
   - The rationale for the study's reliance on Lean methods of implementation is clarified in the Innovation section. The Appendix more fully reproduces the instrument from which the Toolkit will be developed.
   - Examples of new insights that the researchers gained from preliminary studies is documented and presented in Tables 1, 2, and 3.
4. Other Key Changes:
   - The likelihood of low representation of minorities among the subjects is a limitation and addressed as such. This R03 application is to refine and pilot the Toolkit; future studies will assess the degree to which it can be widely applied.
   - The changing health care environment is an important challenge to quality improvement efforts. The Toolkit is intended to provide precisely the resources needed to respond to this new world. The Institute of Medicine national report, "Best Care at Lower Cost" (2012), confirms this perspective.

Specific aims

Most patients needing mental health, substance abuse, or health behavior (**MHSHB**) services are cared for in primary care settings. However, the additional health resources needed to serve them are historically found in specialty care offices. The lack of access to **MHSHB** services in primary care offices can be addressed by a new specialty of psychology, Primary Care Behavioral Health (PCBH). Implementation of PCBH involves a complex set of clinical, operational, and financial issues and has not advanced rapidly in primary care. The **PCBH Toolkit** will provide a novel solution to this problem.

Integrated PCBH involves placing a clinician skilled in primary care mental health and substance abuse services on-site with primary care providers as a member of a team providing continuous, comprehensive, first-contact care. The PCBH specialist offers brief, timely, evidence-based treatment for a broad range of MHSHB services and facilitates referrals to external specialists.

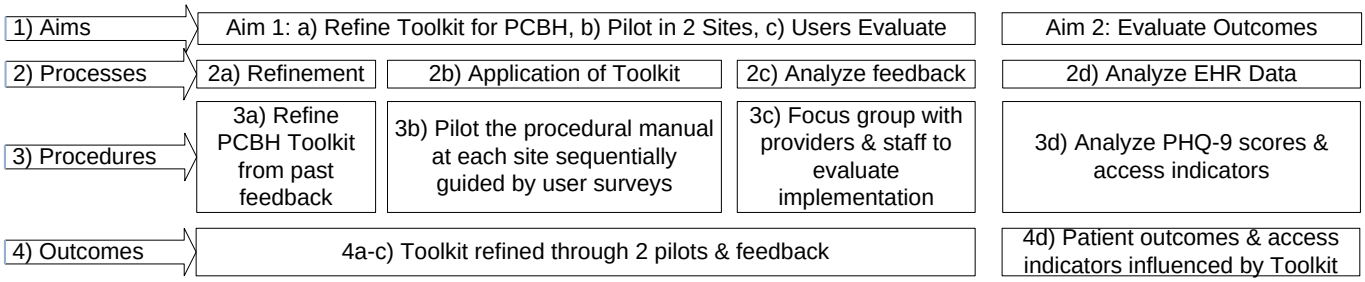
Integration of PCBH requires the redesign of clinical, operational, and financial processes to support such care. The challenges of redesigning practice processes have inhibited the work of integrating PCBH. **The PCBH Toolkit will provide a systematic process, "Lean," to plan integration of MHSHB into primary care. It will take the form of an electronic and hardcopy program of process steps, check lists, decision guides, and example diagrams to construct practice specific workflows.** This method addresses both the tactical components of integrated PCBH and the strategic needs of the organization's culture regarding innovation and change.

The broad goal of this study is to improve the health status of the U.S. population through better coordination and delivery of behavioral health within primary care. The PCBH Toolkit will facilitate these outcomes, measured by changes in depression care outcomes and secondary measures of access to care. This pilot will refine and field test an implementation toolkit by planning and supporting integration of PCBH in two primary care sites. It will accomplish two aims, described below and illustrated in Figure 1.

Aim 1: Refine a preliminary toolkit based on Lean, by sequentially piloting it in two primary care sites and collecting user feedback on its value. We will use a concurrent, mixed methods approach to obtain provider and staff evaluations of the Toolkit. In the first pilot, an expert outside facilitator will use the toolkit to help a practice team plan the implementation of PCBH and follow activation of the plan. Practice members will provide feedback on the toolkit and on PCBH implementation. After further refinement of the toolkit, the expert outside facilitator will train a staff member of a second primary care site as in-practice facilitator. The in-practice facilitator will use the toolkit with the practice to plan the implementation of PCBH. Practice members will again provide feedback on the Toolkit and on PCBH implementation.

Aim 2: Evaluate the reach and effectiveness of the PCBH Toolkit. [We will collect de-identified patient data using an electronic health record (EHR) in each pilot site to report study outcomes as measured by depression severity] and, secondarily, access indicators such as treatment initiation and waiting time for scheduled appointments. We will compare measures among patients receiving PCBH services at baseline and 6 months post-implementation at each site.

Figure 1: Aims, Processes, Procedures, and Outcomes



3. Research strategy

3.a Significance

Primary care behavioral health (PCBH): The current health care system does not meet the mental health, substance abuse, or health behavior (MHSHB) needs of most U.S. citizens. Summarizing the literature, Kessler and Stafford found that 43-60% of patients with psychological problems are treated solely in primary medicine, while only 17-20% are treated in a specialty mental health care system [1]. Despite the concentration of patients that present in primary care, a survey of 6,600 primary care physicians found that quality mental health services were the most difficult sub-specialty to access [2]. Access to behavioral health services in these settings is an important public health issue, as is shown by findings that 50% - 90% of primary care referrals made to out-of-office mental health practitioners fail to result in a follow up appointment [1].

The past 20 years have seen a non-systematic evolution of integration of mental health care into primary care. While frequency of integration has increased, systematization has not, particularly in non-military based systems. Multiple studies support psychiatrically-supervised nursing care management, but have neither generated broad uptake in non-research settings [3], nor addressed the issues of MHSHB so prevalent in primary care [4] [5].

Description of primary care behavior health integrated model: An innovative, evidence-supported model for addressing the clinical, operational, and financial challenges of integrating mental health into primary care exists [6] and is the basis for the proposed work. (Table 1).

Table 1: Primary Care Behavioral Health Intervention Components [7]

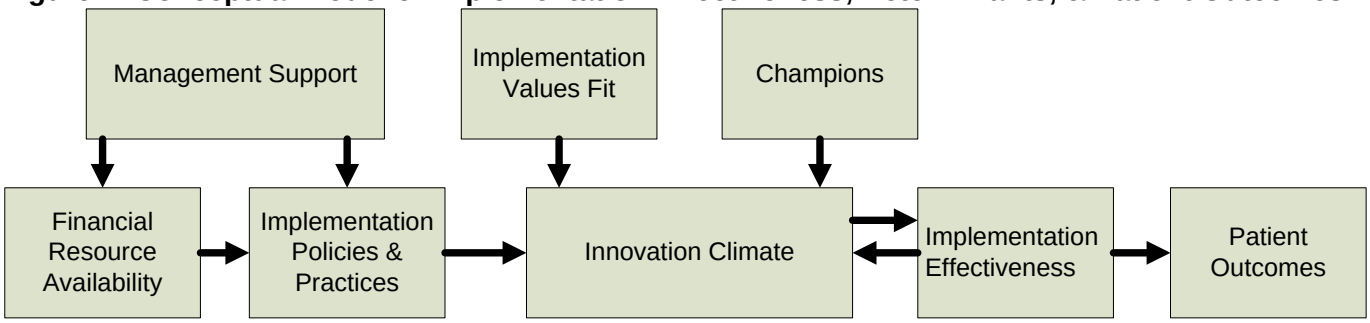
Clinical	• Full time on-site primary care behavioral health clinician (1 per 7500 patients [8]) • Clinician availability for personal, face-to-face introductions (“warm handoffs”) and consultation • Brief evidence-supported treatment interventions; other clinical care responsibilities • Intensive training of primary care behavioral health clinicians, using standardized protocols for a broad range of psychological and medical problems amenable to behavioral health treatment • Population (panel) based care using measurement-based, stepped treatment and other resources
Operational	• Screening for MHSHB issues and prescriber decision support seamlessly integrated into patient flow • Reengineering of practice processes, e.g. “warm handoffs”, automated scheduling, referrals, *etc.* • Training providers and staff in behavioral care procedures • Appointment frequency and interval consistent with primary care • Shared transparent EHR with two-way notes and access to information • Care management to coordinate referrals and information with specialty care as needed
Finance	• Brief interventions, which are lower cost services, provided over shorter episodes of care • Coordination of services and finances to optimize sustainability • Negotiation of appropriate reimbursement • Regular reports of performance, RVU and financial data

The model challenges a long-held assumption and practice that medical and mental health care delivery systems are separate realms. A goal of the American Academy of Family Physicians [9] is integration of behavioral health into the core principles of the Patient Centered Medical Home. Although the operational and clinical components needed to implement the model are well documented [10], the lack of a method to address key clinical, operating, and financial issues continues to challenge implementation [1].

The need for new methods of system redesign and implementation: Finding an effective way to redesign complex patient care processes is an identified need across many health care settings [11], including health systems [12], multi-provider clinics [13, 14], and primary care practices [15, 16]. These studies suggest that effective implementation should include an analytic problem-solving method that front line health care workers can use. Implementation should eliminate wasteful work processes and integrate new processes into the health care organization’s structures (systems and tools) and culture (working climate and organizational barriers to change) [17, 18]. Spear [19] documented an implementation model known in manufacturing as “Lean,” noted by Gamm [20] as successfully applied in hospitals. However, few studies have focused on its application to provider practices. [21]

[In September 2012, the Institute of Medicine issued a report on Best Care at Lower Cost, highlighting a need for strategies, *specifically including Lean*, to redesign and implement change in health care systems [22]. Lean coordinates complex work across organizations (including clinical, operational, and financial processes), and directly affects the delivery of care and patient outcomes. Lean supports the culture of learning in health care organizations that the IOM finds imperative for long term success (see Appendix for tools). Figure 2 is a conceptual model of the expected impact of Lean process improvement, based on Helfrich's determinants of effective implementation in health care [23] and its relationship to patient outcomes [22], adapted from a model by Klein and Sorra [24].]

Figure 2: Conceptual Model of Implementation Effectiveness, Determinants, & Patient Outcomes



3.b Innovation

Lean presents a new, systematic approach to the implementation of PCBH. The AHRQ 2008 Evidence Report/Technology Assessment [25] reviewed PCBH ("collaborative care") and identified resistance to change and challenges that affect care as barriers to change. The Toolkit will provide an approach to effective implementation that addresses these barriers.

The Lean Method: The Toolkit will adapt an implementation method in development for over 50 years in the manufacturing sector, known as "Lean Management." Organizational theory suggests that combining a body of structured tools of quality improvement (for example, checklists) with a team- based approach (work process diagramming) improves processes and outcomes [26]. Whether in the manufacturing sector [19] or in health care [27], the result is better achievement of organizational goals [20]. While PCBH-based checklists have been developed [28], a toolkit that systematically combines checklists, decision guides, and a team-based problem solving approach to address organizational barriers does not yet exist. [Lean provides a previously unavailable systematic approach to PCBH planning and implementation and responds to the call for new methods in implementation science with a more effective and faster translation of research into practice [29]. The Lean approach steps the team through the method of defining the issue being addressed, identifying background concerns, analyzing the current process, and searching for root issues that cause waste in the practice. It then assists the team in defining the elements of a redesigned process, developing a patient-centered model that will fit the practice environment, identifying the costs and benefits, producing an implementation plan, and initiating that plan, including approvals, measures of success, and follow up actions. See Appendix for examples.]

The Lean method addresses barriers to change through a site-specific implementation plan in which front line staff analyze and eliminate waste, integrating new processes into workflow. [An early version of the PCBH Toolkit includes the lessons learned from Kessler and van Eeghen's previous work, identifying a set of key decisions that focus on clinical, operational and financial issues involved in PCBH (Table 2).]

Table 2: Examples of PCBH Lean Methodology Implementation Issues [30]	
Clinical	• Will all MHSHB referrals go to PCBH specialists or elsewhere via pre-existing referral patterns? • Will PCBH specialists' responsibilities include follow-up after out-referral?
Operational	• Will PCBH specialist share the clinical documentation system with all other clinicians? • Will PCBH specialist refer to all available community based MHSHB providers?
Financial	• What are the applicable coding rules for PCBH services in this setting? • Are there payer specific expectations of PCBH services and billing?

Implementation of PCBH using Lean method: The PCBH Toolkit uses Lean to plan the implementation of PCBH, integrating clinical data collection into practice workflow for patient care and clinical research. The toolkit exists in alpha (preliminary) version and has not yet undergone extensive testing.

Simultaneously addressing clinical, operating, and financial challenges: The PCBH Toolkit supports changes in clinical practice, but also includes elements sometimes considered outside the domain of the clinician: the practice's operations and its finances [1]. The Toolkit incorporates components of the clinical program (Table 1) and a method to address implementation issues (Table 2).]

3.c Approach

Preliminary Studies

Starting in 2000, a Fletcher Allen Health Care family medicine practice piloted an on-site behavioral health psychologist specializing in primary care as a part of the medical care team [31], based on Strohsahl's model [32]. Building on this experience, an internal medicine practice adopted a full scale model of integrated, collaborative care (PCBH) in 2009 [33]. These experiences afforded key lessons on how to change clinical practice and identified critical operating and financial issues.

[We piloted a third PCBH site in 2010, using Lean to support implementation. This practice demonstrated success in improving access to care within six months of implementation. See Table 3. This implementation used 8 hours of Lean sessions over 3 months to create an implementation plan for PCBH in an academic, internal medicine practice. Nine months following implementation, staff reported improved scores for all work process measures, such as ease of work and practice efficiency [34]. Such implementation can reduce overall cost and improve outcomes [35] [22]. This pilot produced the alpha version of the PCBH Toolkit.]

Table 3: PCBH Preliminary Results with Lean Implementation: 2/2010 to 6/2011

Results	*Pre-Project*	*Post-Project*	*P*
Referrals per 1000 PCP visits	21.9 n=22,808	41.5 n=9,419	< 0.0001
Days to treatment initiation (sd)	33.1 (30.1) n=341	20.6 (28.6) n=292	< 0.0001
Referrals w/ Visit Scheduled	68% (341/500)	75% (292/391)	0.037

This pilot demonstrated that Lean implementation addresses the redesign of clinical, operational, and financial processes. Similarly, Lean has been effective in two other provider practice settings conducted by one of the researchers [34]. Furthermore, observational data collected from health care providers and staff demonstrate support for the Helfrich model of effective implementation [23] in these settings, producing improvements in outcomes. This study will measure all three indicators of success of the Toolkit: opinions regarding PCBH implementation; changes in patient clinical outcomes; and measures of accessibility.

Study Team

This study will be conducted by a mental health and health behavior expert, Rodger Kessler PhD, with past success in implementing integrated primary care behavioral health in multiple settings and EHR-based data collection and extraction; Constance van Eeghen DrPH, an expert in quality improvement methods; Cynthia Gerstl-Pepin PhD, an experienced qualitative researcher familiar with mixed methods approaches; Peter Callas PhD, statistician; and Benjamin Littenberg MD, a clinical researcher experienced in the implementation of innovative systems of care in practice settings. (See Budget Justification and BioSketches for additional details.)

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