Community Partners in Care
6-Month Client Outcomes

PROTOCOL

December, 2012
# Table of Contents

<table>
<thead>
<tr>
<th></th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Introduction to Protocol</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>Specific Aims</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>Background and Significance</td>
<td>6</td>
</tr>
<tr>
<td>4</td>
<td>Research Design and Methods</td>
<td>15</td>
</tr>
<tr>
<td>4.1</td>
<td>Sampling</td>
<td>16</td>
</tr>
<tr>
<td>4.2</td>
<td>Intervention Assignment</td>
<td>19</td>
</tr>
<tr>
<td>4.2a</td>
<td>Masking of Intervention Assignment</td>
<td>20</td>
</tr>
<tr>
<td>4.3</td>
<td>Intervention Conditions</td>
<td>20</td>
</tr>
<tr>
<td>4.4</td>
<td>Data Sources and Measures</td>
<td>23</td>
</tr>
<tr>
<td>4.5</td>
<td>Statistical Analyses Plan and Power Analyses for Client Outcomes Analysis</td>
<td>27</td>
</tr>
<tr>
<td>5</td>
<td>Limitations</td>
<td>34</td>
</tr>
<tr>
<td>6</td>
<td>Summary of Initial Design, Community Input, Modifications, and Final Design</td>
<td>35</td>
</tr>
<tr>
<td>7</td>
<td>Literature Cited</td>
<td>37</td>
</tr>
</tbody>
</table>
1. Introduction to Protocol

This appendix provides the protocol for Community Partners in Care, including changes that were implemented over the course of the design phase post funding but prior to client enrollment, in response to planned community input, budget reductions, and additional grants obtained to support supplemental components. Specifically, there was an initial funded National Institute of Mental Health proposal and modifications due to budget reductions. A key feature of the project was participatory collaboration in developing the design with community co-leadership and input. This led to further changes in the design, including an expansion of outcomes to include employment status and homelessness risk factors and prioritization among other outcomes; expansion of the scope of agencies, provider types, and client populations to include a wider range of community-based agencies and vulnerable client populations such as the homeless and prisoner re-entry clients, seniors, substance abusers, and neighborhoods with high concentrations of African Americans. To respond to these community priorities, a competing supplement proposal was submitted and two of four requested years were funded, which resulted in an expansion in expected client sample size and restoration of some data collection elements dropped with budget cuts (e.g., 12-month client outcomes). Subsequently, there was a second wave of community input with final changes in outcomes to include homelessness risk factors as outcomes resulting in a decision to increase client enrollment by a further 20% because with inclusion of the homeless and criminal justice populations there was an expected decrease in follow-up response from 80 to 65-70%. In addition, at this stage community input led to some changes in intervention design, including: 1) inclusion for both intervention conditions of materials to support lower level staff in providing education, case management, screening and tracking outcomes; and resources for team management; as well as: 2) an increase in the intensity of the technical assistance intervention to be comparable to best-available technical assistance for evidence-based practice in public sector agencies. The final protocol that was implemented remains broadly consistent with the original aims of the project but with outcomes more consistent with community priorities for functional status, wellness, and avoiding homelessness; a more intensive comparison intervention; a more diverse agency sample with more emphasis on community agencies; and greater planned client enrollment. Because the paper that this Appendix supplements concerns client outcomes only, we present information in
this Protocol only on aims, measures and analyses concerning client outcomes, rather than administrator or provider outcomes.

To present the protocol and its evolution, we followed this strategy: 1) present the original funded proposal, modified to remove components that were eliminated with budget cuts but including components added or restored with the second revision proposal; 2) notation in italics in the text for each section changes due to community input. We then summarize in Table 4 (pages 19-20) major features of the protocol, highlighting changes in response to community input. Please see the technical appendix for information on detailed technical handling of issues for the analysis of 6-month client data. By ignoring italicized information in the protocol the reader can understand the original protocol. By including italicized information the reader can understand the evolution of protocol changes in response to planned community input and budget changes.

**Acronyms and glossary of terms:**

QI = Quality improvement or quality improvement program
PIC=Partners in Care (a prior research study evaluating depression QI relative to UC care in primary care practices)
WE Care (a prior research study evaluating treatments for depression in low-income, minority women)
CPIC=Community Partners in Care
CBPR=Community-based participatory research
CPPR=Community-partnered participatory research (a form of CBPR emphasizing co-equal leadership in all phases of research through two-way knowledge exchange and a structure including a Council and workgroups following three development phases of Vision or planning, Valley or work, and Victory or products and celebration).
CEP=Community Engagement and Planning Intervention for CPIC
RS=Resources for Services (Technical Assistance) Intervention for CPIC
2. Specific Aims

Underserved communities of color in low income, largely ethnic-minority neighborhoods face an excessive burden of illness from depression due to higher prevalence of depression and lower access to quality care.\(^1\) Evidence-based quality improvement (QI) programs for depression in primary care settings—where many low-income and minority patients receive their only mental health care—can enhance quality of depression care and improve health outcomes. These programs are under-utilized in community-based health care settings, and have not been adapted for use across diverse agencies (social service, faith based, primary and specialty care) that could partner to support disease management for depression. Partners in Care (PIC)\(^2,3\) and WE Care\(^4\) are interventions designed to improve access to evidence-based depression treatments (medication management or psychotherapy) for primary care patients and, in WE Care, social service clients. PIC evaluated a services delivery intervention while WE Care was an effectiveness trial with study-provided treatments. Both studies promoted use of the same evidence-based treatments. Both PIC and WE Care programs improved use of evidence-based treatments for depression and health outcomes for African Americans and Latinos. The PIC interventions reduced health outcome disparities evident in usual care in the first follow-up year and at five-year follow-up. While these findings offer hope to underserved communities, such communities have poor resources to support implementation of these programs, and may have historical distrust in research and health care settings. There is no evidence-based approach to support agency networks in underserved communities in implementing QI programs for depression. To address this information gap, we propose Community Partners in Care (CPIC), a group-level randomized, controlled trial, with randomization at the level of an agency site or “unit.” The trial will be fielded in two underserved communities, Hollywood and South Los Angeles, and conducted through a community-participatory, partnered research (CPPR) approach. The specific aims are:

1. To engage two communities of color in improving safety-net care for depression.
2. To examine the effects on three levels of stakeholders of an innovative, community-engagement and network capacity building intervention that implements PIC and WE Care QI toolkits, compared to low-intensity dissemination (i.e., control). The control condition that includes review of findings and toolkits in a conference followed by access to PIC toolkits on a website. The stakeholders and outcomes of interest are:
a. Agency adoption of QI toolkits and depression treatments. (Not discussed in this Protocol).
b. Provider participation in QI trainings in each intervention condition; and intervention effects on provider attitudes and knowledge toward depression care and adoption of PIC/WE Care toolkits and depression treatments. (Not discussed in this Protocol).
c. Client mental health-related quality of life and depressive symptoms, access to care and quality of care, employment status and work days lost, and risk factors for homelessness. (Discussed in this Protocol).

This study builds on our extensive prior work in PIC/WE Care and pilot work in the Witness for Wellness initiative to apply a model of community engagement in under-resourced communities of color to depression QI, and in the Community Partnership Initiative to develop agency networks in under-resourced communities in Los Angeles that are concerned with mental health and substance abuse issues. The proposal initiates a long-term research agenda, by developing evidence on the relative effectiveness of a community engagement approach and a more standard time-limited technical assistance approach to implementing community-wide quality improvement programs for depression in under-resourced communities.

3. Background and Significance

Overview: In the last decade, there has been increasing attention by policymakers, providers, the public, and scientists to the “quality chasm” or gap between the promise of clinical research and the realities of clinical practice, including for psychiatric conditions such as depression. The Institute of Medicine defines quality as the effectiveness, efficiency, client-centeredness, timeliness, and equity of care. McGlynn and her colleagues found that only 55% of persons with a chronic health condition received appropriate care; and quality of care for depression was close to this mediocre average. There has also been increasing attention to disparities in access, quality, and outcomes including for psychiatric disorders. While appropriateness of care among treated patients is low across geographic regions and demographic groups, underserved minorities, including African Americans and Latinos, have lower access to appropriate care for depression overall and in primary care. We propose to address this disparity-related gap in access to quality care, through evaluating the effectiveness of a community-engagement intervention, relative to a time-limited, individual program technical assistance intervention, to implement evidence-based QI programs for depression, originally
developed for primary care settings but modified in this study to be applicable potentially to a broad range of community-based health and social services agencies.\textsuperscript{4,13} We hypothesize that the community engagement approach will be more likely to increase agency and clinician use of the programs across the network, thereby increasing client access to appropriate care and health outcomes. We also expect that the community engagement approach, through increasing access, will increase services use across health and social services sectors.

\textit{While there has been increasing attention to workforce impacts of mental health conditions including depression,\textsuperscript{15} few data are available on the effects of improving care for depression on employment in underserved communities, particularly on entry into employment for the unemployed. Employment and work productivity losses comprise 62\% of the economic burden of depression, and are estimated to be 51.5 billion dollars in 2000.\textsuperscript{16,17} QI programs for common mental disorders in primary care or through employer-managed programs can improve employment outcomes, either for employed subgroups, or across patients including employed and unemployed.\textsuperscript{18-21} Employment outcomes of such programs among minorities were reported in PIC.\textsuperscript{22} While intervention effect sizes were qualitatively similar or larger for minorities than for whites, they were statistically significant only among whites or whites and minorities pooled, owing to limited precision for analyses among minorities. The present study also offers an opportunity to determine, in a largely low-income minority depressed group, whether a community engagement approach to implementing quality improvement for depression, compared to a more standard individual program technical assistance approach, leads to improved employment outcomes, addressing an important gap in the literature.}

The existence of a quality gap and outcome disparities constitute evidence of a “science dissemination” gap\textsuperscript{23-27} The NIH has proposed to address this gap through PAR-06-039, stimulating an improved science of dissemination and implementation for evidence-based practice. Our trial proposed in response to this PAR features a community engagement intervention that promotes community commitment and leadership to form a network committed to evidence-based, quality improvement intervention approaches. We suggest that a sound framework to improve depression care in underserved communities should incorporate effective interventions at three levels: evidence-based treatments; quality improvement strategies; and community-based implementation strategies that can be applied across the diverse agencies supporting underserved clients. Underserved communities of color often have poor resources to...
implement comprehensive programs, and may have historical issues of distrust in science and healthcare services. Community engagement promotes organizational and community member participation and leadership in goal setting, program development, implementation and evaluation by shifting the authority for action to the community.

Community engagement is one strategy within community-based participatory research, the leading paradigm recommended for health intervention in underserved communities. Recent recommendations for revitalizing clinical research call for increased public participation and community engagement, while management sciences have produced similar calls for “action research” and “engaged scholarship.” We have proposed an approach to implement evidence-based QI programs in mental health, in which community agencies divide up the roles and functions required for evidence-based QI programs, among different network partners. Following this framework, we piloted a community engagement approach to building depression-related networks, and developed a manual for community members and a companion guide for academic leaders in the skills of community engagement. We have not formally tested the effectiveness of this model relative to an alternative, however. Previously, we provided evidence on the effectiveness of the QI interventions including in African Americans and Latinos and on the effectiveness of treatments. This proposal takes the next step by testing the community engagement implementation model relative to a more standard, individual agency technical assistance model.

Depression as a Tracer Condition: Depression, i.e., unipolar depressive disorder, is an excellent “tracer” condition for studying quality of care because of its high prevalence (at least 8-10% of the population in a year and associated morbidity. Our prior work has shown that depression is associated with as much or more limitation in daily functioning and well-being as most major chronic conditions such as diabetes and major depressive disorder is a top contributor to the total, worldwide disability-burden of disease. Further, evidence-based treatments exist, including brief, structured psychotherapy such as Cognitive Behavioral Therapy and antidepressant medications. Further, standards for appropriate care are formulated. Depressive symptoms below the threshold of depressive disorder are even more common than depressive disorders and substantially affect functional status. While the efficacy of standard treatments for depressive disorders among persons with minor depression is uncertain, we found that QI programs for depression that support care decisions over time improved
outcomes for persons with initial depressive disorder or subthreshold symptoms, and improved outcomes for those with subthreshold symptoms at 5-year follow-up.\textsuperscript{2, 3} We use a broad definition of depression for this proposal, “probable depressive disorder” that includes persons with depressive disorder and those with depressive symptoms without having a current depressive disorder, because that full range can benefit from disease management.

Many persons with depression do not receive mental health care, and most receive such care through primary care or community agencies, such as faith-based settings.\textsuperscript{11, 65, 66} Primary care clinicians often do not detect depression\textsuperscript{62, 67} and many patients do not receive evidence-based treatments.\textsuperscript{13, 66, 68} Depression was selected by the Institute of Medicine as one of ten conditions for tracking quality of care nationally.\textsuperscript{69} Delivering evidence-based care for depression is challenging, owing to organizational and financing factors, such as limited psychotherapy coverage or diversity in third-party management of services; clinical features of depression such as social withdrawal; societal factors such as social stigma and limited public knowledge; and clinician factors such as limited knowledge or experience.\textsuperscript{5, 14, 29, 70-72} For example, while antidepressant medication use rose over the last decade, many in need of depression care did not receive counseling, medications, or referral.\textsuperscript{66} The poor and ethnic minorities are particularly unlikely to receive needed care.\textsuperscript{14, 29, 73} There are many barriers to provision of evidence-based psychotherapy such as lack of criteria for licensing providers in such treatments.\textsuperscript{5, 38} Outside of organized group practices, coordination between primary and mental health care is often difficult, given widespread use of “carve-out” behavioral health management companies that operate largely independently of health plans or medical practices.\textsuperscript{5, 26} Public sector mental health agencies prioritize clients with severe and persistent illness, while public primary care agencies are not organized or financed to support ongoing mental health care. The proposed community engagement intervention is designed to help compensate for these factors by developing networks that can share depression management and treatment responsibilities and roles.

Quality Improvement for Depression: There have been several demonstrations of the effectiveness of QI programs for depression in primary care\textsuperscript{74} suggesting that: 1) collaborative care\textsuperscript{75} improves quality of care and health outcomes for depressed patients\textsuperscript{14, 76-83}; more efficient methods, such as telephone case management improve outcomes\textsuperscript{84-86}; 3) multimodal strategies that include case management tend to be more effective than improving clinician knowledge or
skills alone[^87-89]; 4) such programs can improve outcomes for adolescents[^90] and the elderly[^81, 91]; and 4) active outreach strategies help engage low-income and minority groups in such care[^4, 92].

The President’s New Freedom Commission on Mental Health recommended implementing QI programs for depression, citing the IMPACT study as a model[^93]. We lead or participated in a number of these trials. Other groups have been stimulating dissemination through financing innovations[^94, 95], information technology[^81, 96], clarifying gains for purchasers ([carenagementfordepression.org](http://carenagementfordepression.org)),[^18] or developing private sector networks[^97].

**Partners in Care (PIC)** was a group-level randomized trial in which managed, primary care practices were randomized to usual care or one of two QI programs that provided resources to encourage use of evidence-based treatments for depressed adults. Both interventions were implemented by local practice teams with study support and featured toolkits for educating clinicians, patients, and intervention staff. One intervention facilitated use of evidence-based medication management through supporting nurse care managers for 6-12 months, while the other facilitated access to evidence-based therapy for depression through lowering the copay for sessions with therapists trained in Cognitive Behavioral Therapy (CBT) for Depression.[^60] The interventions improved quality of care, depression and quality-of-life outcomes and employment status over two years; and they generated cost-effectiveness ratios relative to usual care within the range expected for a widely-used medical therapy.[^13, 14, 47] African Americans and Latinos improved more in clinical outcomes than did comparable whites in the first follow-up year[^4] and at five-years, particularly under the therapy-resource model[^3]. The PIC interventions facilitated use of evidence-based treatments following practice priorities and resources and patient and clinician preferences[^14, 98, 99], and thus are suitable for use with a community-engagement approach because they permit the flexibility to fit implementation to network needs. The PIC therapy-based QI is the proposed services intervention for this study because it was effective over time among Latinos and African Americans[^3]. WE Care is unique among depression interventions in encouraging and facilitating access to evidence-based treatments for depression among low-income, minority women who visited community social service agencies or health clinics. The study found that active outreach was necessary for increasing the engagement of low-income women in care, and that efforts to decrease structural barriers to care by facilitating transportation and childcare increased adherence to treatments[^4]. WE Care used an individual-level randomized, controlled designed to compare enhanced community usual care to medication...
management or CBT; and the treatments improved outcomes relative to usual community services over the first year.\textsuperscript{4} WE Care has the social service setting and client activation approaches to complement the PIC services delivery approach. The two studies used consistent treatment protocols.

**CPPR and Community Engagement Depression Initiatives:** Community Participatory Partnered Research promotes equal partnership of community and academic partners while building capacity for partnered planning and community implementation of research-informed programs.\textsuperscript{30} This is accomplished through a process of community engagement and sharing of resources and expertise. A CPPR project involves identifying a health issue that fits community and academic priorities; developing a coalition of stakeholders who inform and support the initiative; engaging the community through activities that provide information, determine readiness to proceed, and obtain input; and initiating work groups that develop, implement, and evaluate action plans.\textsuperscript{31} CPPR is strength-based and celebrates community capacities, and can support use of evidence-based programs within a participatory approach.\textsuperscript{31, 38, 100} This project is conducted within a CPPR framework, not just because it evaluates a community engagement intervention, but because the study was designed and will be implemented with community input and co-leadership. We use the term community to refer to persons who work, share recreation or live in a given area. Community engagement refers to values, strategies and actions that support authentic partnerships, including mutual respect and active and inclusive participation; power sharing and equity; mutual benefit; and flexibility in pursuing goals, methods, and timeframes to fit priorities and capacities of communities.\textsuperscript{30, 36}

Because we found long-lasting outcome gains for depressed minorities in PIC and WE Care, we initiated pilot studies of CPPR and community engagement concerning depression in the communities for this proposal. One pilot, Witness for Wellness (W4W), led by Healthy African American Families (witness4wellness.org),\textsuperscript{31} developed a coalition of 40 community agencies and academic institutions to assess, in the community, the salience of depression and the PIC/WE Care interventions. The coalition sponsored a conference attended by over 500 community members and providers, in which support for this focus emerged.\textsuperscript{31} Data from surveys and field notes of discussion groups framed the charge for 3 working groups that formulated action plans that were approved by community members.\textsuperscript{101} Supporting Wellness focused on policy and advocacy, and secured membership in Los Angeles County’s planning for
the Mental Health Services Act. Talking Wellness sought to reduce stigma and promote community strength. Building Wellness developed a pilot randomized trial of community outreach and linkage to appropriate depression services. Community members and researchers have been adapting PIC toolkits to promote screening, education, and referral through social service agencies and have negotiated a partnership for collaborate care between a free clinic and a public mental health clinic. We also used a community partnered approach to develop an evidence-based intervention for youth exposed to community violence through QueensCare, and we initiated a pilot study of the use of parish nurses to screen community members for depression and refer to safety-net clinics. We adapted Cognitive Behavioral Therapy for non-mental health practitioners and piloted the intervention with parish nurses, substance abuse counselors, and social workers. These pilots inform CPIC.

Conceptual Framework: The field of implementation and dissemination research is emerging in mental health. The relevant literature derives from diffusion of innovation theory, and communication and health behavior change, healthcare organization, financing, and management, provider education and behavior change, chronic disease and health promotion literatures. Implementation involves various stakeholders, and studying it requires concepts from diverse frameworks.

Figure 1 presents a framework for this study. It specifies factors that can influence implementation of evidence-based QI programs for depression through a community-engagement approach. Community capacity for mental health planning includes individual and organizational capacities that affect their willingness and ability to implement and maintain QI interventions, and provide information and resources for learning about, assessing, and reinforcing them. Individual factors include knowledge and attitudes toward depression treatment and clinician training, values and skills. Organizational factors include organizational culture and climate, such as receptivity to innovation and commitment to improve depression care, and structural features that affect capacity to deliver programs, such as care routines, funding, skilled personnel, information technologies, or agency linkages. Figure 1 suggests that features of evidence-based programs such as training resources may affect depression services delivery. According to diffusion theory, ‘complexity’ and ‘trialability’ may affect adoption. In addition, resources for dissemination may interact with community priorities and capacities to influence practice. The arrow between these constructs represents the community-engagement
process that draws agencies and communities into dealing with depression and supports them in finding a feasible fit between the requirements of programs and the priorities and resources in the network, while building community leadership to support implementation. The downward arrow represents the implementation plans, their adoption, fit to network, and sustainability. Care influences outcomes of stakeholders, which influence capacities for community planning, iteratively. Our design mirrors this framework.

In Figure 1, we indicate by a star areas potentially affected by the proposed interventions. We stimulate community engagement through a participatory, network development model.\textsuperscript{31, 32, 38} We introduce into these partnerships the PIC/WE Care toolkits and training and their adaptations for the capacities of diverse safety-net agencies. The proposed study design experimentally varies organizational exposure to the community engagement intervention versus low-intensity dissemination. During the study, the lead community agencies (QueensCare, HAAF, DMH), host a conference that facilitates feedback on the outcomes of implementation. The proposed planning process may affect organizational commitment, a component of culture, and receptivity to innovation, a component of climate. By asking organizations to work as a network, we hope to increase partnership capacity. By stimulating leadership for implementing evidence-based toolkits, we hope to improve knowledge, attitudes, skills, and commitment to sustained change.

Figure 1 is a framework and not a specific theory, but is suited to applying concepts from theories to guide hypotheses. We rely on concepts from diffusion of innovation\textsuperscript{45, 104} organizational learning\textsuperscript{114, 115, 116} and network theories\textsuperscript{117, 118} social movement theory,\textsuperscript{16, 119, 120} social learning theory,\textsuperscript{121} a community engagement framework\textsuperscript{31} and a community intervention model for fitting intervention needs to agency capacity.\textsuperscript{3} PIC applies the collaborative care model of chronic disease management,\textsuperscript{75} which is based on diverse theories including social influence theory\textsuperscript{110, 122, 123} and social learning theory,\textsuperscript{124} CBT, one of the treatments promoted by PIC/WE Care, is based on social cognitive learning theory.\textsuperscript{59}
We suggest that stakeholder trust, ownership, and commitment generated by a community engagement approach is a necessary but not sufficient step to promoting implementation and sustainability of evidence-based programs in underserved communities. Resources to support use of programs and their availability and flexibility for adaptation to network capacities are required. We rely on organizational learning and network theories to explicate how agencies learn to establish “communities of practice” by identifying common goals, sharing knowledge, and developing that promote social support and information flow among stakeholders. We use diffusion of innovation theory to understand the process of implementation and the characteristics of interventions that promote adoption and sustainability. In particular, we introduce systematic variation in organizations’ support for implementation. How organizations “fit” evidence-based programs to their structures, the structures they create, and the experience of participants in doing so, will be the subject of an implementation process evaluation. We will use concepts from these diverse theories and frameworks and project data to specify a conceptual model of the process of implementation.
For some services delivery interventions, such Multisystemic Therapy\textsuperscript{125} and Assertive Community Treatment,\textsuperscript{98, 126, 127} a high degree of fidelity is necessary to improve outcomes. We think that variable adherence to PIC/WE Care will be effective, because positive outcomes have been observed across diverse QI programs\textsuperscript{65, 74} and less intensive models.\textsuperscript{84} A similar assumption underlies initiatives to promote use of depression QI programs in primary care through financing and other innovations.\textsuperscript{66, 95, 97}

4. Research Design and Methods

We propose a group-level, randomized controlled trial to assess the effectiveness of a community engagement intervention, compared to an individual program technical assistance intervention, in increasing community agency and clinician use of quality improvement interventions for depression; and improving client quality of care and outcomes. The project is longitudinal at three levels of stakeholders: agency/administrator, clinicians/case worker, and client. The study is conducted in two, underserved, largely minority communities in Los Angeles: Hollywood and South Los Angeles. We considered alternative designs, including an observational (pre-post) design and randomizing at the individual client or provider level. An observational study has less internal validity; individual-level randomization risks contamination of conditions.

We will recruit agencies (social service agencies, primary care agencies, and mental health agencies, and community partners such as faith-based organizations), using the Community Partnership Initiative sampling frame, and their “units,” or service locations or teams, which we also refer to as “programs.” 50-60 units or programs (expanded in the revision to 70-80; and then considering addition of homeless/prisoner re-entry to 80-100 programs), balanced across the two communities and including diverse agencies, will be selected and randomized to the community engagement or low-intensity control dissemination condition. The first year is a planning phase for agency and provider recruitment and intervention and measures modification and documentation with community input. (With community input the planning year was expanded to 2 years to accommodate recruitment of the larger program and client sample; all benchmarks and timelines discussed below were shifted to one year later). Between months 6-12, we will field the baseline web surveys for administrators and clinicians. Agencies will be recruited in batches, South Los Angeles followed by Hollywood. We will host Kick-Off Conferences to explain the study to agencies and their representatives and introduce the quality improvement toolkits that are common to both intervention conditions to all agencies/programs.
Each conference is followed by planning and training for the intervention condition, followed six months later by client screening and recruitment of depressed patients into a panel study with baseline and 6- and 12-month measures. Administrators in all agencies and clinicians in sites participating in the trial, as well as some sites not in the trial, will complete an 18 month follow-up survey. After several months of collaborative analysis involving community agency partners, the project will sponsor a community feedback conference to share the outcomes findings and provide assistance in use of intervention materials based on evidence for their effectiveness. Final analyses and feedback conference will occur in the last year of the study.

4.1. Sampling

Communities: We selected by convenience two communities in Los Angeles (Hollywood and South Los Angeles) with large, low-income, mainly minority populations, where we have strong existing partnerships.

The County of Los Angeles, with nearly 10 million people, is one of the most populous and diverse counties in the United States: of the population, 43.9% are Latino, 33.5% white, 12.3% Asian, 10% Black and 0.3% American Indian. Over 20% live below the federal poverty level\(^1\) with ethnic minorities over-represented among the poor. South Los Angeles has a population of about 1.5 million, with 60% Hispanic, 35% African American, 3% non-Hispanic White and 2% Asian American. The communities of South Los Angeles suffer from some of the highest rate of morbidity and mortality and the lowest rate of educational attainment, family income and insurance coverage in Los Angeles County.\(^2\) Hollywood-Metro has a population of almost half a million: 60% Hispanic, 3% African American, 17% non-Hispanic White and 17.3% Asian American. Over half are foreign born and less than half have a high school diploma. A little over a quarter live in poverty and the median household income is 25% less than the county as a whole.\(^3\) This area has the highest uninsured rates and highest percentages of adults and children with no regular source of care.\(^4\)

Agencies: The agencies to be included in the study will be those who participated in the Community Partnership Initiative and their partners.\(^5\) The CPI frame of 94 organizations, which was developed through publicly available, comprehensive lists of services agencies in Los Angeles County coupled with recommendations from lead community partners, included mental health, substance abuse, primary care, social service, and homeless and other community agencies. Other agencies participated in the community feedback conference and expressed
interest in further activities. We will invite agencies to participate through letters and phone calls and ask them to complete a web survey, review a description of the study, and suggest additional partners. Each consenting agency will provide a list of their sites or ‘units’ that provide services to adults and have at least one full-time equivalent clinician or case worker. Agencies will be enrolled in a rolling fashion over six months, grouped into two main batches, one for each area. We will recruit clinicians from this pool of units and finalize unit selection at the conclusion of agency/clinician enrollment by month 13.

(Note: With community input in the design period, the definition of agencies was expanded to include homeless-serving, prisoner re-entry and “community-trusted locations, including parks and recreation centers, senior citizen centers, faith-based programs, hair salons, and exercise clubs. In addition, to incorporate community priorities for vulnerable populations into account, each community was invited to nominate two vulnerable groups for over-sampling. South Los Angeles selected substance abuse agencies and neighborhoods with high concentration of African Americans. Hollywood-Metro selected homeless clients and senior citizens.)

Units or Programs: Sampling will be carried out with sites or autonomous divisions within sites as the units to be sampled. We expect to identify at least 100-150, with some agencies having over 10-15 units while others have one. We may divide large primary care and mental health specialty clinics into teams as the units. We will stratify units by agency type and randomly select within strata to obtain a sample of unit sample that is 30-40% primary care, 30-40% social service, and 20-30% mental health units that serve more “general community” populations, such as CalWorks contract agencies. In this way, we anticipate having at least 10 units from each category to facilitate fitting statistical models. We will attempt to enroll about 20-30% more units than needed, to allow for withdrawal/attrition. We will include those units in the administrator/clinician surveys even if not selected for the main trial to track spill-over of intervention activities or parallel types of program exposure from the market. Social service agencies are included to participate in screening, education, referral, and case management. Primary care settings can play roles in screening, assessment, case management, and treatment. Mental health specialty clinics provide treatment, consultation and supervision, and some units may participate in screening. We will replace units with others in the same stratum as needed. Units are the “unit of randomization” for this study. We will enroll units in batches (groups of
units) with “batch” as a blocking factor, randomizing units within batches to intervention or control.

**Administrators:** Each participating agency will identify a lead administrator. Some agencies will have a second administrator if they have units assigned to both study conditions. Administrators in all agencies will be asked to complete web-surveys at baseline and 12-18 months. They will be asked to facilitate agency participation in the intervention study and conferences.

**Case Workers and Clinicians:** Using lists of providers/case workers serving adults in participating units in the main study, we will randomly select up to 5 full-time case workers or clinicians per unit; but we will allow part-time (at least 50%) clinicians if necessary. We will provide them with recruitment packets, followed by phone calls or site visits. We will randomly select from the remainder in the same site/agency to replace refusers/drop-outs. *(NOTE: With community input, the definition of “provider” was expanded to all staff with direct client contact, including volunteers. We offered an invitation to all such staff to participate if they wished. In addition, we permitted staff of participating programs to participate in intervention activities, whether or not they enrolled as providers in the study).* Consent providers will be asked to complete baseline and follow-up web surveys at 18 months and to participate in implementation for PIC/WE Care, depending on their intervention assignment. In PIC, 2 providers declined participation, and over 90% participated in 18-month surveys. Providers will learn of their unit’s participation status by letter before the Kick-off Conference for their community. We expect to have 175-225 case workers and providers in the main trial *(Note: expanded with expansion of the overall study to 250-300).*

**Clients:** In social service, community-based, and primary care units selected for the main trial, we will advertise the study with posters and fliers. On designated screening days, clinic staff will invite a consecutive sample of adult clients (over 18) visiting participating clinicians to discuss study participation with RAND field staff. *(Note: With community input, community members were hired and supervised by RAND).* Screening will occur over a one-month period for each unit. We expect 6000 adult clients to be approached and 4200 to complete screener surveys. Those over 18 with a positive depression score will be asked to enroll and complete a baseline interview that day or by follow-up telephone call and to participate in a 6-month telephone survey. Clients who do not speak English or Spanish, or who are too confused or agitated to complete the screener will be excluded. We expect 20% of clients to be eligible, due
to the low-income of the communities. Some of the community agencies at the CPI feedback conference reported that 75% of their population had mild to moderate depression. Of 840 depressed adults, we expect 70% to enroll and complete baseline (588), 500 (85%) to complete 6-month, and 470 (80%) to complete 12-month follow-up, based on PIC experience.

(NOTE: Client screening protocols were changed in several ways. First, because the type of programs was expanded to include homeless-serving programs and other programs for vulnerable populations that did not necessarily have traditional ‘waiting rooms’ we also planned to screen at events such as food lines, but for those locations used a random selection rather than consecutive selection strategy. Second, all client targets were increased by more than 30% for the expanded sample for employment analyses and to compensate for lower follow-up retention rates due to inclusion of homeless clients. However, because depression rates were much higher on average than expected (18-50% depending on the sector) and because acceptance of screener and study enrollment offer was higher than expected (greater than 90%), we were able to use the same expected number of completed screener surveys to achieve both the necessary increases in enrollment and analytic sample for the expanded study.)

4.2. Intervention Assignment

Within each community and stratified by type of agency, we will randomly assign, using a computerized random number generator, the intervention conditions (community engagement implementation or low-intensity control dissemination) to the 50-60 units (programs) for screening clients. We will randomize additional units only providing implementation support (and not supporting client screening) to the two conditions. Within large networks (e.g., QueensCare), we may assign common conditions to collaborating units to maintain network ties. We will consider randomizing units that are matched based on program size and client sociodemographics, to improve client comparability by intervention status, as in PIC.132 Agency administrators and participating clinicians will be informed of their intervention status by letter.

(NOTE: Because of the large number of programs to be recruited, and the very diverse type of sectors recruited, and not all sectors had available up-to-date county lists, we decided to determine program eligibility in stages, in order to randomize a set of probable final programs, after which we planned to conduct site visits to determine final eligibility and final agreement of programs to participate.)
4.2a. Masking of Intervention Assignment

Programs will be informed of their intervention assignment status by a letter to their administrator after their enrollment is finalized. Recruiters of programs, administrators and providers are blinded to program intervention status until program recruitment is finalized. During recruitment, the study Principal Investigator will have access to intervention assignment information on a “need-to-know” basis (such as to answer questions from programs with recruitment finalized and notified of intervention status). Providers will be notified of program assignment through their program administrators. Clients will not be directly notified of their program’s intervention status by the study, but could be notified by their program’s administrator or providers. Survey staff for baseline and follow-up status will be blinded to program intervention assignment status.

4.3. Intervention Conditions

Resources for Services (Individual Program Technical Assistance): The lower-intensity condition is time-limited (3-4 months) technical assistance to individual programs to implement the toolkits of PIC/WE Care at a community conference, with post-conference access to PIC toolkits through a website (Table 1 below). Control units will be invited to the final Community Feedback Conference and offered assistance post-trial in further use of the intervention materials, based on their preferences after reviewing the findings of CPIC.

(NOTE: In the community feedback during the design period, this intervention condition was significantly expanded in scope with increased intensity, to meet the goal of having technical assistance that reasonably approximates the highest standards of implementation of evidence-based practices in the county based on current training practices. The resulting model was offering programs in this condition up to 12 webinars covering all components of the training model as well as offering individual site visits to primary care clinics. In addition, with community input, the RS Intervention had a leadership team of experts in medication management, case management, and Cognitive Behavioral Therapy for Depression; staff support as well as a community engagement and outreach specialist to help assure that individual agencies would participate.

(Note: The originally planned collaborative care toolkit from PIC/We-Care for both intervention conditions was expanded to accommodate the community’s preference to include all staff with direct client contact, including nonprofessional and volunteer staff. We included a
community health worker manual and team management tools from the Mental Health Infrastructure and Training Project using PIC/We-Care and IMPACT toolkits.)

<table>
<thead>
<tr>
<th>Table 1. Quality Improvement Intervention Materials Available for CPIC</th>
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</thead>
<tbody>
<tr>
<td><strong>Introductory Materials:</strong></td>
<td><strong>Training Materials:</strong></td>
</tr>
<tr>
<td>Improving Depression Outcomes in Primary Care: A User's Guide to Implementing the Partners in Care Approach (PIC)</td>
<td>Training Agendas and Materials for Expert Leaders, Depression Nurse Specialists, and Psychotherapists</td>
</tr>
<tr>
<td><strong>To Be Developed:</strong> A Community Network Guide to Implementing Partners in Care</td>
<td>Videotape of Nurse Specialist Assessment</td>
</tr>
<tr>
<td><strong>Materials for Primary Care Physicians &amp; Care Managers:</strong></td>
<td>Resources for Team Management</td>
</tr>
<tr>
<td>Clinician Guide to Depression Assessment &amp; Management (PIC)</td>
<td><strong>Psychotherapy Materials:</strong></td>
</tr>
<tr>
<td>Physician Pocket Reminder Cards</td>
<td>Guidelines for the Study Therapist</td>
</tr>
<tr>
<td>Guidelines/Resources for Depression Nurse Specialist (PIC)</td>
<td>Group and Individual CBT Therapy Manuals for clinicians and clients (PIC, WE Care)</td>
</tr>
<tr>
<td><strong>Materials for Patients:</strong></td>
<td>Modified manuals for nurses, substance abuse counselors, and lay coaches</td>
</tr>
<tr>
<td>Patient Education Brochure in English and Spanish; Patient and Family Education Videotape (English and Spanish); (PIC and WE Care);</td>
<td></td>
</tr>
<tr>
<td>Audio taped testimonials, Fact Sheet (Witness for Wellness)</td>
<td></td>
</tr>
<tr>
<td><strong>Materials for Case Managers and Health Workers</strong></td>
<td></td>
</tr>
<tr>
<td>Case Manager Resources and Website (Building Wellness Pilot): Depression Screener and Scoring; Client Education and Referral Resources</td>
<td></td>
</tr>
<tr>
<td>Community Health Worker Guide (Mental Health Infrastructure and Training Project)</td>
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</tbody>
</table>

**Community Engagement and Planning or CEP:** The CEP intervention condition follows the principles of community engagement reviewed above, and promotes the inclusion of relevant stakeholders in planning and recognizes participants as equal partners, promoting mutual respect, trust, ownership or products, and equal decision making authority. Inclusiveness is thought to be a key factor in the success of coalitions.133, 134 By promoting a negotiation of priorities and resources across academic and community partners, the intervention builds capacity for research-informed action through knowledge dissemination and community leadership.31 To support community engagement, we developed a manual community members30 and guide for academic partners.32 The three main phases of this intervention will include a 4-month planning phase led by a partnered Council including community leaders from the assigned agencies and study QI and depression experts, guided by community engagement principles and activities, an implementation phase following the model of implementation developed in the planning phase, and monitoring and oversight to provide course corrections over that implementation phase. (NOTE: CEP was guided by a written manual developed during the design phase using community and academic partnered input. In addition, because the RS intervention had a more intensive intervention as described above, the CEP Councils were given a budget of $15K per
community to support trainings, roughly comparable to the study’s costs of supporting the model of training in RS).

**CEP Planning and Training:** Intervention activities will be initiated at the Kick-off Conference for each community. Attendees will include administrative and clinicians from units in both intervention conditions, and grass-roots community members supported by HAAF, QueensCare and Behavioral Health Services, the lead community partners. We will provide a study orientation and review PIC/WE Care findings and materials and access to the RAND PIC website and copies of therapy manuals used in PIC and WE Care (see Table 1). Grass roots members and civic leaders will join discussion groups for CE units only. In this session, co-chairs for the CE planning council will be elected. The CE council will meet 1-2 times a month for four months and throughout implementation. Over the planning period, the council will participate in training and ongoing supervision in the CE model, following the manuals, led by HAAF, QueensCare, and Behavioral Health Services. The planning council will conduct an in-depth review of the goals, structure, content, and training requirements for PIC/WE Care and our recently adapted materials, and summarize requirements in a spreadsheet. To develop network implementation capacity, the council will review the mission, services, staffing and resources of participating units, preparing summary tables. Using CE negotiation principles (e.g., inclusion/fairness) the council will develop strategies to fit network capacities to PIC/WE Care requirements. A consensus on the implementation plan will be developed using a modified Delphi approach. The action plan will outline agency roles, provide a blueprint for services coordination, and identify key contacts. For example, social service agencies may be assigned to education or case management roles; community members may be assigned as therapy coaches or educators; clinicians may determine which agency provides therapists or medication consultants. During the planning period, study experts will train agency leaders in use of PIC/WE Care protocols. Therapists will be trained in a 2-day conference followed by audio-taped supervision of a first case when possible, as in PIC and WE Care. Medication experts (primary care, specialty care) and case workers/care managers will be trained in one-day seminars with practice sessions. Community members will receive 1-day training as client advocates/coaches. Manuals supporting activities by clinicians, therapists, caseworkers, and community coaches will be provided. *(NOTE: CEP Councils developed plans for training that fit*
each community and were typically more intensive than outlined above, such as having more training sessions, opportunities for make-ups, and more intensive supervision).

**CEP Implementation:** Agency intervention leaders, supported by study clinicians will train the unit clinicians/case workers in delivering PIC/WE Care protocols and provide consultation and supervision. The council will provide oversight, reviewing monthly reports from lead administrators and intervention experts, with feedback to unit leaders and intervention experts. These meetings will follow the CEP model for inclusiveness and fairness/respect and include grass-root community member perspectives supported by HAAF, QueensCare and Behavioral Health Services, the lead community-based agencies. The monthly reports from intervention leaders will describe progress, problems encountered. As clients are enrolled, program administrative staff will be notified, with client permission. Support for use of depression treatments will be encouraged for 6-12 months at the client level as in PIC. *(NOTE: The training model for this condition was modified with community input to be joint training by study experts and community leaders. We note that the design calls for notification of programs about client enrollment in CPIC but not RS programs).*

**Community Feedback Conference:** The lead CBOs will sponsor a Community Feedback Conference at 40 months (after all client outcomes data are collected), inviting all CPIC agencies as well as civic leaders and community members. The overall study council co-chairs will review outcomes findings, implementation stories, and council recommendations. Break out groups will discuss implications for implementing and sustaining depression services in the community. All participating agencies will be supported in having access to and using the study’s intervention materials.

**4.4. Data Sources and Measures**

Data on agencies include reports from administrators at baseline and follow-up web-surveys at 12-18 months. Data on clinicians/case workers will be obtained through self-report web-surveys at the same time points. Data on clients will be obtained through screening and baseline surveys among those positive for probable depression. Enrolled depressed clients will participate in 6 and 12-month follow-up surveys. Data on implementation process include minutes, field notes, action plans, leader reports, and exit interviews of leaders in both conditions. We will develop each survey with community input into measures selection, based on the fuller measures given below. To do this, the partner community organizations will recruit grass-roots community
participants and some agency leaders that constitute a working group to review and discuss measures, pretest them, and select and suggest modifications or replacements. In this process, academic investigators provide guidance on concepts of measurement construction and identify when measures need to be kept intact for validity and reliability. Table 2 summarizes key client concepts (prior to community input), with a star for priority measures (primary and secondary outcomes). We also include important intermediate outcomes. Client measures will be in English or Spanish.

**Intervention Status:** The main independent variable is intervention status.

**Client Characteristics:** Client demographics and insurance status will be reported at screening and baseline. We will use data from the screener and baseline diagnostic instrument (MINI) to categorize patients as having depressive disorder (i.e., 12-month major depressive or dysthymic disorder plus having 30-day depressive symptoms) versus “subthreshold depression,” defined as not having recent disorder but screening positive on the CPIC screener. The depression screener will be the Patient Health Questionnaire, 8-item version (PHQ8) to permit comparisons to WE Care and other studies. We will use items from HCC to assess self-report of lifetime diagnosis by a provider of schizophrenia or psychosis or lifetime hospitalization for psychosis. We will also include for outcome measurement the full PHQ9, including the suicide ideation item.

Other patient covariates and potential intermediate outcomes include social support, life stress events, patient treatment preferences, the presence of comorbid panic, and post-traumatic stress disorder and alcohol problems use of avoidant and/or active coping strategies, patient beliefs about depression, and perceived stigma concerns (e.g., difficulty in getting a job, getting health insurance, or social relationships). The presence of 19 specific chronic conditions will be assessed as well as prior provider diagnosis of schizophrenia, prior psychiatric hospitalization (including for psychosis) and use of psychotropic medications. We will include a subset of Katon’s self-efficacy for controlling depression items (e.g., how confident are you in your ability to recognize early on when you are starting to get depressed?). Suicidal ideation will be assessed as part of the MINI and PHQ9. Current and past substance use will be assessed at baseline using a modification of the drug section of the MINI. (NOTE: Given community input, the original planned use of the PIC depression screener was switched to the PHQ 8 because it was well-known in some of the practice sites. In addition, one area of
community concern was one item using the word “depression” and the thought was that some clients might not endorsed this item because of discomfort with the word. We created an alternative version without the word depression, included both versions and allowed clients to be counted as depressed on the PHQ8 if they endorsed either version of this item; but Pearson correlation of the 2 versions was 0.99.)

**Process of Care:** Clients will also be asked about perceived need for treatment and how likely they would be to accept treatment or referral if it was recommended. Depressed clients will be asked at baseline and follow-up to report their use of primary care and mental health specialty services, including physician visits, prescription drugs, emergency room visits, and inpatient care over the prior six months. Following AHRQ\(^{13,56,144}\) and prior work we will develop an indicator of two or more months of antidepressant medication or 4 or more counseling sessions.\(^{47}\) We will derive measures of use of services (e.g., primary care, mental health, emergency rooms, social service agencies, faith-based agencies). Clients who improve may not need treatment over time, so we will develop a measure of unmet need for treatment, defined as having probable depression but not receiving appropriate care versus not improved or in care. This measure combines outcomes and treatment data and thus has more power, while preserving intent to treat analyses.\(^{13}\) (NOTE: Based on community input, services use measures were expanded to include services in a wide range of services sectors in the community relevant to depression, such as services in substance abuse agencies, telephone hotlines, self-help groups, community centers and other trusted locations).

**Outcomes of Care.**

**Mental and Physical Health-Related Quality of Life:** Clients will complete the SF-12 at baseline and follow-up. Published results support the validity and responsiveness of the SF-12.\(^{145}\) We found high reliability for telephone and mail-survey administration for the global scale for mental health-related quality of life MCS12 (0.84). The MCS12 is considered the primary outcome of interest as it integrates information on negative states such as psychological distress and on positive states such as wellness of particular interest to community members, and under the hypothesis that the community engagement intervention relative to technical assistance will increase both depression treatment rates, thus lowering distress as well as increase social supports and/or address social determinants of mental health improving mental wellness.

**Depression Status:** We will also include the PHQ9,\(^{146}\) which has different cut-points but
particularly examining whether there is mild/moderate depression (PHQ score greater than or equal to 10). The PHQ9 is a primary outcome measure under the hypothesis that the community engagement intervention would improve through networks access to depression treatments and thus lower symptoms.

(NOTE: Based on community feedback, the highest priority outcome was mental health-related quality of life and the primary measures for the study were designated as the MCS12 (community and academic primary outcome) and the PHQ9 (academic primary outcome). In addition, the community placed a high priority of “peace of mind” or mental wellness, so we created a separate scale using the positive well-being measures available from these measures counting as mental wellness having wellness or any of the 3 items. In addition, the community also placed an emphasis on having good physical activity, especially with the inclusion of senior citizen groups in the study. We included a single-item measure of physical activity to assess this outcome.)

Household and Work Productivity: Current employment status will be assessed at baseline and follow-up as well as self-assessed work productivity (days of work missed; days late to work or left work early; rating of productivity) in the last month. Employment and work productivity measures will be assessed in all client waves, and will use the World Health Organization Health and Productivity Questionnaire, (http://www.hcp.med.harvard.edu/hpq/index.php) a well-validated instrument that has been used to measure effects of depression treatment on employment outcomes (Wang 2007). (NOTE: These measures were added with the Revision proposal, based on the community feedback that employment was a high priority for the community. The study was fielded at the height of the economic recession in the United States).

Homelessness Risk Factors: After the community input prioritized inclusion of homeless populations, and after the prioritization of employment status and expansion of the sample to accommodate studying employment, the partnership determined that it would be important to track homelessness and risk factors for homelessness owing to the inclusion of this group and the possibility that agencies serving the homeless might be able to do so more effectively under the community engagement intervention model. To this end, measures were included, similar to life stress event items, of the presence or absence in the prior six months of 4 factors: Either being currently homeless or living in a shelter or having multiple risk factors for homelessness, including no place to stay for 2 or more nights; being concerned about not having enough to eat
(food insecurity), severe financial crisis, and eviction from major place of residence. These were combined into a simple count as a prioritized secondary outcome, from community interest.

Table 2: Client Measures*

<table>
<thead>
<tr>
<th>Client Characteristics</th>
<th>Process of Depression Care</th>
<th>Outcomes of Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sociodemographics (0)</td>
<td>Treatment</td>
<td>Primary pre-planned:</td>
</tr>
<tr>
<td>Insurance status (0, 6, 12)</td>
<td>*Use of psychotropic medications (0, 6, 12)</td>
<td>*Mental health related quality of life (0, 6, 12)</td>
</tr>
<tr>
<td>Family members (0, 6, 12)</td>
<td>*Primary care counseling (0, 6, 12)</td>
<td>*Probable depression (0, 6, 12)</td>
</tr>
<tr>
<td>*Physical comorbidities</td>
<td>*Specialty care referral and counseling (0, 6, 12)</td>
<td>Secondary/community priorities:</td>
</tr>
<tr>
<td>*Psychiatric comorbidities</td>
<td>Services Use</td>
<td>*Physical activity (0, 6, 12)</td>
</tr>
<tr>
<td>* Lifetime schizophrenia</td>
<td>Hospitalization for mental health or substance abuse</td>
<td>Employment status (0, 6, 12)</td>
</tr>
<tr>
<td>*Stressful life events (0, 6, 12)</td>
<td>Emergency Room Use</td>
<td>*Current work status</td>
</tr>
<tr>
<td>*Social supports (0)</td>
<td>Outpatient Services</td>
<td>*Missed days from work</td>
</tr>
<tr>
<td>PTSD screener (0)</td>
<td>Mental Health Specialty</td>
<td>*Personal work productivity (0, 6, 12)</td>
</tr>
<tr>
<td>Panic screener (0, 6, 12)</td>
<td>Primary Care</td>
<td>Homelessness Risk Factors (0, 6, 12)</td>
</tr>
<tr>
<td>Alcohol screener (0, 6, 12)</td>
<td>Social Services/Substance Abuse</td>
<td>Currently homeless or 2 or more nights homeless in 6 months</td>
</tr>
<tr>
<td>Use of illicit substances (0)</td>
<td>Other Community Services</td>
<td>Food insecurity (perceived)</td>
</tr>
<tr>
<td>Stressful life events (0, 6, 12)</td>
<td>Satisfaction with treatment (6, 12)</td>
<td>Severe financial crisis</td>
</tr>
<tr>
<td>Social supports (0)</td>
<td>*Unmet Need (6, 12)</td>
<td>Eviction from major residence</td>
</tr>
<tr>
<td>Active/passive coping (0, 6, 12)</td>
<td>*Unmet Need (6, 12)</td>
<td></td>
</tr>
<tr>
<td>Ethnicity/acculturation (0)</td>
<td>*Unmet Need (6, 12)</td>
<td></td>
</tr>
<tr>
<td>Depression knowledge (0, 6)</td>
<td>*Unmet Need (6, 12)</td>
<td></td>
</tr>
<tr>
<td>Stigma concerns (0)</td>
<td>*Unmet Need (6, 12)</td>
<td></td>
</tr>
<tr>
<td>Treatment Preferences (0, 6)</td>
<td>*Unmet Need (6, 12)</td>
<td></td>
</tr>
<tr>
<td>Readiness for treatment (0)</td>
<td>*Unmet Need (6, 12)</td>
<td></td>
</tr>
</tbody>
</table>

*0=baseline or screening, 6 or 12 = followup month; * Indicates priority measures

**QI (PIC/WE Care) implementation.** We will assess a variety of implementation processes, including provider/staff exposure to training, specific implementation plans of intervention planning councils, depression QI toolkit adaptation, use of treatment protocols by clinicians, care managers, coaches, and therapists, and strategies to sustain or spread implementation, through reports by administrators and clinicians and from coding of project training logs, contact reports of care managers, session reports of therapists, council action plans and updates, and monthly reports (see Pearson et al 2005). In addition, we will conduct interviews of implementation leaders and administrators in both intervention conditions at the end of client data collection, to triangulate with the quantitative data and ensure validity of the quantitative survey measures. Contamination/exposure to external factors will be assessed through tracking contacts, sharing of information across conditions, and use of other QI programs from the web surveys, contact reports, and meeting minutes. Survey data from non-trial administrators and clinicians will also be used.

**4.5. Statistical Analyses Plan and Power Analyses for Client Outcomes Analysis**

First we review general analysis issues and then analysis plans for the outcomes Aim 2.
Sampling and Nonresponse Weights  We will create weights to account for the sampling design as well as for response. For example, weights at the provider level will be created as products of sample selection weights at the organizational unit and provider level, and response weights, which will be modeled based on logistic regressions of response indicators on provider characteristics.\[^{149, 150}\] Weights for client data will be derived similarly. We will use software that facilitates weighted analysis in multi-level models including HLM, Mplus, and SAS macro developed by Bell and McCaffrey using a bias reduction method for standard error estimation developed,\[^{150, 151}\] as a main analytical tool in PIC. We will also explore alternative robust methods for variance estimation including generalized estimating equations or sandwich variance estimators.\[^{152-154}\] a main analytical tool in PIC. We will use software that facilitates analysis of data from complex sample designs, such as STATA, SUDAAN, PROC ROBUSTREG in SAS V9, and SAS macros developed by McCaffrey at RAND.\[^{150}\]

Missing Data. Missing data can result in response bias. It is known that mixed-effects models handle cases with incomplete follow-up based on an implicit missing-at-random assumption.\[^{155}\] If there are variables that are not included in the mixed-effects model but are relevant to the missing data mechanism, a model without those variables may lead to biased estimates. In addition, many software programs for mixed-effect models drop participants from analyses when any explanatory variable is missing. In CPIC, we will use multiple imputation techniques to account for missing data and the uncertainty in the imputed values.\[^{155, 156}\] The analytic team has extensive experience with multiple imputation.\[^{157-159}\] In line with our earlier findings about the sensitivity of inferences to underlying data distributions,\[^{158}\] we will consider hot-deck and model-based imputation, relying on hot-deck strategies when data distributions are highly skewed but leaving open the possibility of handling several variables simultaneously using model-based strategies if data distributions appear suitably behaved.

Analytic Strategies Our analysis uses an intent-to-treat (ITT) framework. To improve the precision of the estimated intervention effect, we will conduct a series of bivariate analyses to identify the potential covariates to be considered for a multiple regression model. Confounding will be assessed by comparing the unadjusted coefficient for treatment condition with the adjusted coefficient. We will use model-building strategies to obtain final models.\[^{160}\] Assumptions of normality will also be evaluated. For example, we will explore various transformations (e.g., log and square root) for life event variables due to the often skewed
distribution of event counts. Smearing estimates will be used, if necessary, for retransformation, applying separate factors for each intervention group to ensure consistent estimates.\textsuperscript{161, 162} In general, we leave open the possibility of transforming variables with non-normal distributions. In certain cases, the outcome of interest will have a very skewed distribution, either because there will be many zeros (e.g. sick days) and/or because the distribution of observed values has a very long tail (e.g. services utilization). In such cases, we will draw upon statistical models developed for handling these type of data, in particular a two-part model to separately handle zero values and a skewed distribution among non-zeros\textsuperscript{161} Tobit-type sample selection models\textsuperscript{163}; split-sample techniques to distinguish between different functional forms and to avoid overfitting\textsuperscript{161}; and dynamic models, such as episodes of care analytic models, duration analysis, and count models.\textsuperscript{164, 165}

**Multiple Comparisons** We will address multiple comparisons by comparing the proportion of results favoring one intervention to an assumed null-hypothesis value of 0.5. We will consider but will not rely solely on Bonferroni adjustments and related methods that incorporate bounds on the probability of a single false finding of significance. We will also consider the false discovery rate (FDR)\textsuperscript{166}, a framework that offers more sensitive tests of significance when large numbers of tests are carried out by comparing observed significance findings with expected order statistics from a uniform distribution.

**Hypotheses and Analysis Plans for Aim 2:** *To examine the effects on client access to care, quality of care, and depression-related outcomes.*

**Hypotheses:** We hypothesize that the community-engagement approach will lead to greater improvement over 6-12 months in client’s access to care, quality of care, and health outcomes than the technical assistance condition. In underserved communities, greater participation in planning, which community engagement instills, is anticipated to improve uptake of health interventions.\textsuperscript{34} Further, the community-engagement intervention utilizes many principles of social-science theory that support behavior change such as practice and skill development\textsuperscript{104, 124, 167}, development of opinion leaders,\textsuperscript{110} and stimulation of network development\textsuperscript{118} and cross-organizational “communities of practice” that promote identification with common goals and sharing of knowledge,\textsuperscript{119} improving capacity for implementation.

(NOTE: Based on community input this hypothesis was modified to prioritize mental health-related quality of life as the primary outcome because it represents both positive and negative
Overview: The primary goal in this group-level randomized trial is to estimate the difference in effects on outcomes, between intervention arms (e.g., CE condition vs. low-intensity control). To test our main hypotheses (that CEP would be more effective than RS in improving client health outcomes and addressing community priorities for housing and employment, while likely increasing services utilization), we will conduct intent-to-treat, comparative effectiveness analyses using intervention status as the independent variable. We will estimate logistic regression models for indicator variables and loglinear models for counts. Consistent with recommendations for group-level trials, (8) main models will incorporate adjustment for baseline status of dependent variables and covariates: age, sex, >=3 chronic conditions, education, race/ethnicity, family poverty, 12-month alcohol abuse or illicit drug use, 12-month depressive disorder, and community. We will weight data for clients with baseline or six-month data to characteristics of eligible clients. For missing data, we will use item-level and wave-level imputation. Estimates and p-values are calculated using SUDAAN (http://www.rti.org/sudaan/) taking into account clustering within programs and weighting. We supplement findings from adjusted models with results from raw data to assess robustness. We will use two-sided tests with p<.05 for statistical significance.

We will also explore as an alternative approach multi-level models (also known as hierarchical models or random coefficient models) to account for the multilevel data structure with clients nested within units (agencies or relatively autonomous subdivisions thereof), and repeated measurements nested within clients. For this approach, we will apply two-level models for the cross-sectional data with clients nested within units; and three-level models for the longitudinal data with repeated measurements nested within clients and clients nested within

mental health states, and then to separately examine both poor mental health and mental wellness as secondary outcomes; and to expand the include physical activity as both a social determinant of mental and physical health and especially relevant to elderly clients; and also to include employment status, missed work days, and risk factors for homelessness as important outcomes. Further, the concept of quality of care was modified to reflect, in addition to traditional indicators of use of antidepressant medication and/or counseling for depression, use of depression-related case management and counseling services in alternative community services sectors. Services use was hypothesized to increase under the community engagement model relative to the technical assistance model.)

Appendix C: CPIC Protocol 6-month Client Outcomes
units. To perform multilevel analyses, we will use special software such as the MIXED and GLIMMIX procedures in the SAS System V9, HLM6, MLWin, Mplus tailored for these analyses.

Two-level model for cross-sectional data analysis The statistical model for a “cross-sectional” analysis with one observation per client, for example Y=satisfaction at 6 months follow-up, is presented via two regression equations:

Level 1 (individuals): \[ Y_{ij} = b_{0j} + b_{1j}X_{ij} + e_{ij} \quad e_{ij} \sim N(0, s^2), \]

Level 2 (organizational units): \[ b_{0j} = r_{00} + r_{01}V_j + r_{02}W_j + u_{0j} \quad u_{0j} \sim N(0, T), \]

where \( Y_{ij} \) denotes the outcome for the \( i \)-th individual nested within the \( j \)-th organizational unit, \( i=1, \ldots, n_j; j=1, \ldots, J; X_{ij} \) denotes a vector of covariates at the individual level; \( V_j \) denotes treatment status for the \( j \)-th organizational unit; and \( W_j \) denotes a vector of predictors at the organizational-unit level. These two equations can be presented in the mixed model:

\[ Y_{ij} = r_{00} + b_{1j}X_{ij} + r_{01}V_j + r_{02}W_j + u_{0j} + e_{ij} \quad e_{ij} \sim N(0, s^2), u_{0j} \sim N(0, T). \]

The random intercept model can be generalized to a random intercept, random slope model that also specifies \( b_{1j} \) to be random with a multivariate regression for \( (b_{0j}, b_{1j})^T \) at Level 2. For binary outcomes, we will use generalized linear mixed models that use a binomial model and a logit link function at Level 1.

Three-level model for longitudinal data analysis The statistical models for a group-level randomized trial with repeated measures on individuals can be presented via a growth curve model for the trajectory of the outcome measure over time with three regression equations:

Level 1 (Observation level, repeated measurements within individual):

1. \[ Y_{mij} = b_{0ij} + b_{1ij}T_{mij} + e_{mij} \]

Level 2 (individuals):

2.1. \[ b_{0ij} = C_{00j} + C_{01j}X_{ij} + r_{0ij} \]

2.2. \[ b_{1ij} = C_{10j} + C_{11j}X_{ij} + r_{1ij} \]

Level 3 (organizational units):

3.1. \[ C_{00j} = d_{000} + d_{001}V_j + d_{002}W_j + u_{00j} \]

3.2. \[ C_{10j} = d_{100} + d_{101}V_j + d_{102}W_j + u_{10j} \]

where \( Y_{mij} \) denotes the outcome at the \( m \)-th occasion for the \( i \)-th client nested within the \( j \)-th unit, \( m=1, \ldots, t; i=1, \ldots, n_j; j=1, \ldots, J; T_{mij} \) denotes time relative to baseline, \( V_j \) denotes the intervention indicator, \( X_{ij} \) denotes vector of other covariates at individual level, and \( W_j \) denotes
vector of predictors at the organizational-unit level. Our analysis will be focused on the slope coefficient $d_{101}$ that measures the main effect of treatment on the growth rates. Although clustering effects were nearly absent for most PIC analyses, specification of the covariance structure among the random effects will be modeled allowing for covariance between random intercepts and slopes. Given 3 or more repeated measures on individuals and reasonable smoothness assumptions, we will explore curvilinearity through non-linear terms such as a quadratic term in the Level-1 model, allowing insight into whether changes are greater in the first 6 or subsequent 6 months.

We will also apply multilevel models to clinician data, with clinicians taking on the role of “individuals.”

The primary outcome comparisons will be based on client mental health-related quality of life and an indicator of probable depression (see Table 2). Using the clients’ baseline and 6-month follow-up data, we will evaluate the CE intervention effects on primary mental health outcomes, and community priorities/secondary outcomes of physical activity, homelessness risk factors and employment, indicators of quality of care (use of antidepressant medications and healthcare counseling for depression) and services use in all community services sectors. We will take into account the clustered design for a group-randomized trial. We will treat the intervention condition as the primary predictor in an intent-to-treat framework. For a given outcome variable, we will include the baseline measure for that variable as a covariate along with demographic and baseline variables and stratification variables from the study design for additional adjustment. We will also control for other baseline characteristics and stratification variables. To examine intervention effects using longitudinal data (6 and 12 months), we will add individual-level random effects to account for repeated measurements within individuals and include interactions between time and the intervention indicator variable.

**Power for 6-Month Client Outcomes Analyses**

In group-level randomized trials design such as PIC and CPIC, the power analysis is complex because there are many factors that influence power. For a simple group-level randomized trial, the power of a test such as a t-test in comparing two group means is a function of the cluster size ($m$), the number of clusters ($J$), and the intra-class correlation (ICC), the ratio of the between-cluster variability between clusters to the total variability. In our application where cluster is organization unit, we use Kish’s method to adjust the standard errors by the
Variance inflation factor (VIF) is defined as $VIF = 1 + (m-1) \times ICC$, where ICC is the intra-class correlation at the organization unit level. For analysis of repeated measures, we use an extended formula accounting for inter-temporal correlations within individuals and within units. Based on PIC data, outcome analyses on depression care and clinic outcomes have shown that the ICC at the clinic level is either absent or around 0.01, and inter-temporal correlation coefficients within individuals and within units over a 12-month time period are greater than 0.60. PIC provider data shows that ICCs are nearly absent for provider experience and around 0.00-0.05 for knowledge. Taking a conservative approach, we assume that ICC at the unit level ranges from 0.00 to 0.02 for client data and from 0.00 to 0.05 for provider data, and that the inter-temporal correlation is 0.50. In the calculation of power for testing intervention effects from a t-test, we use degrees of freedom equal to $(number\ of\ clusters - 2)$ when ICC>0, which is conservative for assessing significance, although we also explore setting degrees of freedom equal to $N-2$ ($N=total\ sample\ size$) for the scenario where ICC=0 (the optimistic scenario). We also note that regression analyses adjusting for baseline covariates and stratification variables can improve statistical power if covariates explain a substantial portion of the uncertainty. All power analyses are conducted with power of 80% or above as adequate, assuming two-sided tests with significance level 0.05. For client data, we provide detailed power analysis for two primary study variables (appropriate depression care and probable depression).

*Our initial power analyses were based on assumptions about effect sizes derived from prior studies of primary care patients, including ethnic minority patients, and that the main intervention effect would be related to increasing rates of treatments for depression. During the partnered design year, as the community leaders requested inclusion of especially vulnerable populations and services sectors for inclusion expanded, for example to faith-based agencies, senior centers, homeless-serving providers, and prisoner-reentry programs, and outcomes were added such employment, we revisited our estimates of power. First, to accommodate the interest in employment outcomes we submitted a supplemental grant application which was funded, allowing some expansion in sample. However, even after this point, the focus on homelessness and homeless outcomes emerged in planning. This raised several scientific and operations issues, including that we might have greater attrition than planned, necessitating a larger enrolled sample, and that effect sizes might not be as large as planned, because of the greater difficulty in improving outcomes in complex populations. We therefore decided to assume that...*
we needed approximately an increase in enrolled sample relative to our proposed sample for adequate power under more conventional conditions for fielding quality improvement interventions. These adjustments are given in the Table 3 below, including power for originally proposed sample based on prior primary care studies; power for the analysis of the same sample to address employment; and then based on revised assumptions, prior to any recruitment, to capture smaller effect sizes expected for a more clinically and socially vulnerable sample with potentially higher attrition rates. After the participatory design phase, the final study was designed to have a power of .80 with an alpha of .05 (two-sided) and ICC=.00-.02 to detect group difference of 10% to 11% or higher in comparing two proportions and standardized effects size of .20-.22 or higher in comparing two means. Enrolling 557-600 participants per condition (1114-1200 in total) allowed a retention rate of 65-70% at 6 month follow-up.

Table 3. Minimum detectable effect sizes for main analyses (80% power (alpha=0.05), two-sided test)*

<table>
<thead>
<tr>
<th>Note</th>
<th>Analytic sample size at 6 months follow-up</th>
<th>Effect Size†</th>
<th>Point Change§</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original grant</td>
<td>500</td>
<td>0.25-0.27</td>
<td>12.43-13.18%</td>
</tr>
<tr>
<td>With 30% expansion</td>
<td>650</td>
<td>0.22-0.24</td>
<td>10.92-11.78%</td>
</tr>
<tr>
<td>With further 20% expansion, final</td>
<td>780</td>
<td>0.20-0.22</td>
<td>9.98-10.92%</td>
</tr>
</tbody>
</table>

†Detectable effect size (mean difference between two groups divided by the standard deviation)\textsuperscript{178}.
§Detectable percentage point difference for two groups.

5. Limitations
The proposed study is based in two under-resourced communities in Los Angeles; findings may not necessarily apply to other communities. Other limitations include the group-level randomized design, which is quasi-experimental. We rely on self-report measures and for this analysis 6-month client outcomes. This remains an ambitious study in terms of design and scope in the context of a partnered research approach.
### 6. Summary of Initial Design, Community Input, Modifications, and Final Design

Table 4: Summary of Initial Design, Community Input, Modifications, and Final Design

<table>
<thead>
<tr>
<th>Design Feature</th>
<th>Initial</th>
<th>Community Input</th>
<th>Modified</th>
<th>Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communities</td>
<td>South Los Angeles/Hollywood-Metropolitan Los Angeles</td>
<td>Include Downtown Los Angeles with Hollywood</td>
<td>Affirmed</td>
<td>Same as initial</td>
</tr>
<tr>
<td>Services Sectors</td>
<td>Mental health specialty, primary care, substance abuse, social services</td>
<td>Include public health, homeless-serving, prisoner re-entry, family preservation, faith-based, senior centers of parks and recreation, exercise clubs, hair salons</td>
<td>Expansion to meet community goals, required modification of expected retention for client surveys and of client recruitment plans</td>
<td>Mental health specialty, primary care, public health, substance abuse, social services, faith-based, senior centers, exercise clubs, and hair salons</td>
</tr>
<tr>
<td>Providers</td>
<td>Professional staff and case workers</td>
<td>Include all staff, paid and volunteer with direct patient contact</td>
<td>Invitation to all staff</td>
<td>Staff with patient contact</td>
</tr>
<tr>
<td>Clients</td>
<td>Persons on designated days showing to sites for services (adults), consecutive sample</td>
<td>Include parents of child clients that accompanied child if they could also be supported; expand to events/food lines</td>
<td>Clients and parents of child clinics; events/food lines included</td>
<td>Adult clients and parents of child clients in waiting rooms (consecutive selection) and events (random selection)</td>
</tr>
<tr>
<td>Depression Quality Improvement Toolkits</td>
<td>Toolkits for clinician assessment, medication management, Cognitive Behavioral Therapy, case management, patient education from Partners in Care and We-Care</td>
<td>Modify for lay staff, simplify language and forms, available on-line, expand health worker tools</td>
<td>Modified clinician assessment and case manager tools; added health worker guide and team leader tools from Mental Health Infrastructure and Training</td>
<td>Modified PIC, We-Care and MHIT materials, simplified and offered on web site, hardcopy, and flashdrives</td>
</tr>
<tr>
<td>Resources for Services Intervention</td>
<td>One-day conference and written/posted toolkit materials</td>
<td>Expand to meet Los Angeles County standards for training support for evidence-based practices</td>
<td>Offer of up to 12 webinars on all toolkit components plus site visit to primary care; plus toolkits online, flashdrive/hardcopy</td>
<td>“Standard” technical assistant to individual agencies as described in modifications</td>
</tr>
<tr>
<td>Community Engagement and Planning Intervention</td>
<td>4 months of planning followed by 2 day training and follow-up supervision led by research/QI experts supported by written toolkits</td>
<td>Trainings coled by community leaders; follow community specifications; resources to match RS ($15K/Council); network innovation</td>
<td>Modified 4 months of planning with written plan, coled training, monthly oversight of implementation, network innovations</td>
<td>4 months of capacity building and network development to re-engineer toolkit training as partnered training and innovation</td>
</tr>
<tr>
<td>Randomization</td>
<td>Group-randomized at program level (agency site/team)</td>
<td>Develop trust in randomization/explore alternatives</td>
<td>Community forums on Tuskegee legacy and scientific advantages of randomization;</td>
<td>Group-randomization implemented with trust-building activities</td>
</tr>
</tbody>
</table>
Table 4: Summary of Initial Design, Community Input, Modifications, and Final Design

<table>
<thead>
<tr>
<th>Design Feature</th>
<th>Initial</th>
<th>Community Input</th>
<th>Modified</th>
<th>Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcomes</td>
<td>Risk for depressive disorder, mental health-related quality of life, physical functioning, access and use of services, quality of care</td>
<td>Priority for quality of life, wellness and resilience; good physical functioning and physical activity; think of access broadly to include services in alternative locations; add employment and risk factors for homelessness because of economy</td>
<td>Measures re-prioritized, employment and homelessness, food insecurity, financial problems, eviction added as homelessness risk factors; physical activity added to physical functioning for overall good physical health; resiliency items explored;</td>
<td>Mental health quality of life main outcome; mental wellness, life perceived as organized, poor mental health; employment and work loss days; homelessness risk factors primary for community; services use in diverse sectors</td>
</tr>
<tr>
<td>Sampling</td>
<td>Initial: 50 programs and screening of 6000 clients to identify and enroll and complete outcomes on 500</td>
<td>To add employment outcomes, 30% increase in sample size required; homeless sample would reduce expected retention from 80% to 65-70%</td>
<td>Expand expected sample size to achieve power for employment analyses; expand enrollment 20% more due to expected attrition</td>
<td>80-100 programs; with screening to enroll 1200 depressed clients yielding 780 at last follow-up</td>
</tr>
<tr>
<td>Analysis Approach</td>
<td>Intent to treat; control for baseline value of outcome and covariates; nonresponse weights; adjust for clustering; impute missing data</td>
<td>Include raw data</td>
<td>Conclusions based on modeled data and raw presented to confirm modeling</td>
<td>Modeling as planned plus raw data presented</td>
</tr>
</tbody>
</table>
7. Literature Cited


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