Study Protocol and Statistical Analysis Plan
Community Partners in Care (CPIC)

Principle Investigator: Kenneth B. Wells, MD, MPH

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Note: Materials in this file were presented in previous publications (5/7/2013 for 6 months, 11/18/2014 for 12 month, and 7/17/2017 for 3-years). This protocol integrates those materials and was edited for CT.gov in January 2021.

1. Introduction

This document describes the study protocol and general analytic approach for the primary objectives of 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 this document 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 5 (pages 39-40) major features of the protocol, highlighting changes in response to community input. Please see the Appendix A for information on detailed technical handling of issues for the analysis of 6-month client data as well as 12-month and 3 years follow-ups. 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

Under-resourced 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 under-resourced 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 under-resourced communities in implementing QI programs for depression. To address this information gap, we proposed Community Partners in Care (CPIC), a group-level randomized, controlled trial, with randomization at the level of an agency site or "unit." The trial is 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.[5, 6] The Institute of Medicine defines quality as the effectiveness, efficiency, client-centeredness, timeliness, and equity of care. [6] 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.[7] There has also been increasing attention to disparities in access, quality, and outcomes including for psychiatric disorders.[1-3, 8] While appropriateness of care among treated patients is low across geographic regions and demographic groups,[9, 10] underserved minorities, including African Americans and Latinos, have lower access to appropriate care for depression overall and in primary care.[4, 11-14] 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.[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.

While there has been increasing attention to workforce impacts of mental health conditions including depression,[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.[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.[18-21] Employment outcomes of such programs among minorities were reported in PIC.[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[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.[28, 29] 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.[30-33]

Community engagement is one strategy within community-based participatory research, the leading paradigm recommended for health intervention in underserved communities.[34-39] Recent recommendations for revitalizing clinical research call for increased public participation and community engagement,[40-42] while management sciences have produced similar calls for "action research"[43, 44] and "engaged scholarship."[45] 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.[37] Following this framework, we piloted a community engagement approach [31, 38, 46] 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.[30, 32] 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 [4, 13, 47] including in African Americans and Latinos [2, 3] and on the effectiveness of treatments. [4, 48] 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[49] 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 [50-52] and major depressive disorder is a top contributor to the total, worldwide disability-burden of disease.[53, 54] Further, evidence-based treatments exist, including brief, structured psychotherapy such as Cognitive Behavioral Therapy and antidepressant medications. Further, standards for appropriate care are formulated [55-61]. Depressive symptoms below the threshold of depressive disorder are even more common than depressive disorders and substantially affect functional status. [62, 63] While the efficacy of standard treatments for depressive disorders among persons with minor depression is uncertain,[64] 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.[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.[11, 65, 66] Primary care clinicians often do not detect depression[62, 67] and many patients do not receive evidence-based treatments.[13, 66, 68] Depression was selected by the Institute of Medicine as one of ten conditions for tracking quality of care nationally. [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.[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.[66] The poor and ethnic minorities are particularly unlikely to receive needed care.[14, 29, 73] There are many barriers to provision of evidence-based psychotherapy such as lack of criteria for licensing providers in such treatments.[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.[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[74] suggesting that: 1) collaborative care[75] improves quality of care and health outcomes for depressed patients[14, 76-83]; more efficient methods, such as telephone case management improve outcomes[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 (caremangementfordepression.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.[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.[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.[31] CPPR is strength-based and celebrates community capacities, and can support use of evidence-based programs within a participatory approach.[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.[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),[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.[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.[101] Supporting Wellness focused on policy and advocacy, and secured membership in Los Angeles County's planning for

the Mental Health Services Act.[102] Talking Wellness sought to reduce stigma and promote community strength.[103] Building Wellness developed a pilot randomized trial of community outreach and linkage to appropriate depression services.[32] 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,[46] 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,[104-106] and communication and health behavior change,[34, 107] healthcare organization, financing, and management,[108, 109] provider education and behavior change,[110, 111] chronic disease and health promotion literatures.[34, 75, 112] Implementation involves various stakeholders, and studying it requires concepts from diverse frameworks.[113]

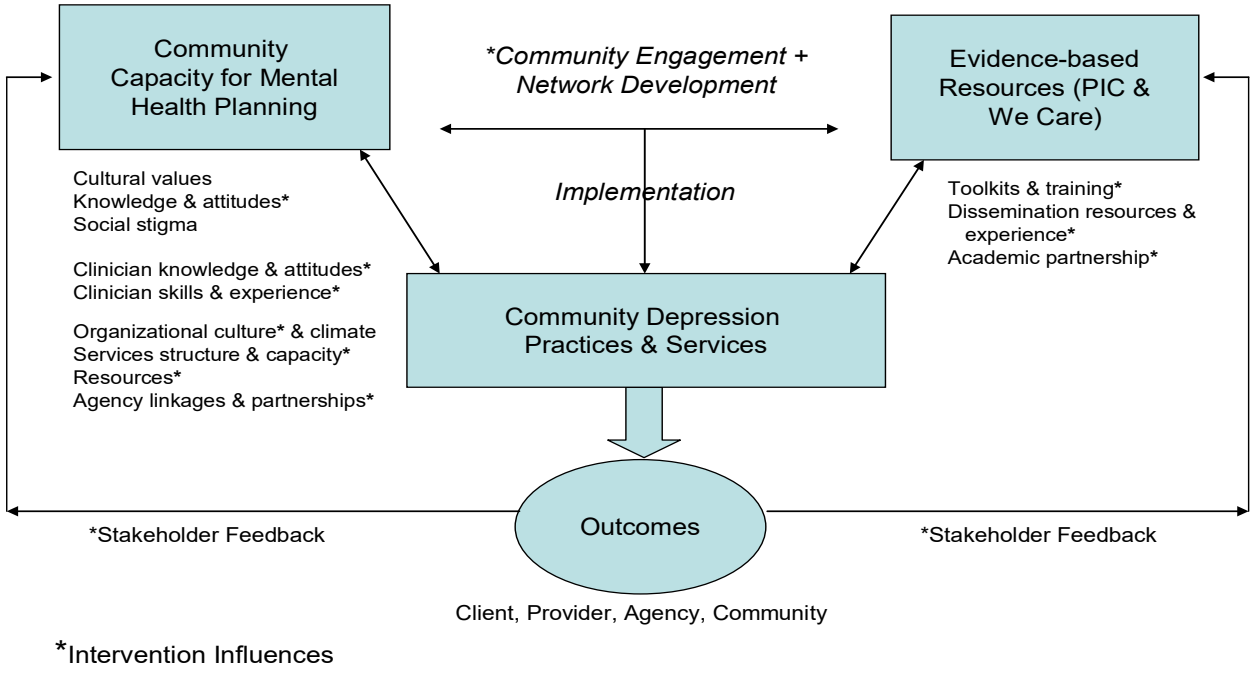
Figure 1 presents a framework for this study. It specifies factors that can influence implementation of evidence-based QI programs for depression through a community-engagement approach. Community capacity for mental health planning includes individual and organizational capacities that affect their 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.[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[45, 104] organizational learning[114, 115 116] and network theories[117, 118] social movement theory,[16, 119, 120] social learning theory,[121] a community engagement framework[31] and a community intervention model for fitting intervention needs to agency capacity.[3] PIC applies the collaborative care model of chronic disease management,[75] which is based on diverse theories including social influence theory[110, 122, 123] and social learning theory,[124] CBT, one of the treatments promoted by PIC/WE Care, is based on social cognitive learning theory.[59]

Figure 1: Framework for Community Engagement Implementation of Evidence-Based Depression Quality Improvement Programs



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[125] and Assertive Community Treatment,[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[65, 74] and less intensive models.[84] A similar assumption underlies initiatives to promote use of depression QI programs in primary care through financing and other innovations.[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[128] 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 While 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.[128] **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.[129] This area has the highest uninsured rates and highest percentages of adults and children with no regular source of care.[130]

Agencies: The agencies to be included in the study will be those who participated in the Community Partnership Initiative and their partners.[131] 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).* Consenting 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 6,000 adult clients to be approached and 4,200 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.

Sample size: 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.)

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 1. Quality Improvement Intervention Materials Available for CPIC

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

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 members[30] 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.[135] 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. *The toolkits and other intervention features for CEP and RS are summarized in Table 2.*

Table 2. Community Partners in Care Interventions and Training Features by Condition		
	Resources for Services (RS)	Community Engagement and Planning (CEP)
Initial Model	1) Depression care collaborative care toolkit (manuals, slides, medication pocket cards, patient education brochures and videos) via print, flash drives, and website. 2) Trainings via 12 webinars / conference calls to all programs and site visits to primary care 3) Expert trainers: nurse care manager, licensed psychologist cognitive behavioral therapy trainer, three board-certified psychiatrists for medication management, experienced community service administrator supporting cultural competence and participation 4) Community engagement specialist for up to 5 outreach calls to encourage participation and fit toolkits to programs 5) Study paid for trainings and materials at $16,333 per community.	1) Depression care collaborative care toolkit (manuals, slides, medication pocket cards, patient education brochures and videos) via print, flash drives, and website. 2) Expert trainers: nurse care manager, licensed psychologist cognitive behavioral therapy trainer, three board-certified psychiatrists for medication management, experienced community service administrator supporting cultural competence and participation 3) 5 months of 2-hour, bi-weekly planning meetings for CEP councils to tailor materials and develop and implement a written training and depression service delivery plan for each community, guided by a manual and community engagement model. The goal of the plan was to support increased capacity for depression care through collaboration across a myriad of community programs. 4) Co-leadership by study Council following community engagement and social justice principles to encourage collaboration and network building 5) $15,000 per community for consultations and training modifications
Implemented		
Overall	21 Webinars and 1 primary care site visit	Multiple one-day conferences with follow-up trainings at sites; webinar and telephone-based supervision
Cognitive Behavioral Therapy (CBT) and clinical assessment	Manuals (Individual and group) and 4 webinars offered for licensed physicians, psychologists, social workers, nurses marriage and family therapists	1) Manuals (Individual and group) 2) Tiers of training: For licensed providers plus substance abuse counselors: a) intensive CBT support included feedback on audiotaped therapy session with one to two depression cases for 12-16 weeks, b) 10 week webinar group consultation, and for any staff trainee, c) Orientation workshops for concepts and approaches.

Table 2. Community Partners in Care Interventions and Training Features by Condition		
	Resources for Services (RS)	Community Engagement and Planning (CEP)
Case management	Manuals, 4 webinars and resources for depression screening, assessment of comorbid conditions, client education and referral, tracking visits to providers, medication adherence, and outcomes, and introduction to problem solving therapy and/ behavioral activation; for nurses, case workers, health educators, spiritual advisors, *promotoras*, lay counselors	1) Manuals 2) In-person conferences, individual agency site visits, and telephone supervision for the same range of providers. 3) Modifications included a focus on self-care for providers, simplification of materials such as fact sheets and tracking with shorter outcome measures. Similar range of providers and staff as RS. 3) Training in active listening in one community; training of volunteers to expand capacity in one community 4) Development of an alternative "resiliency class" approach to support wellness for Village Clinic
Medication and clinical assessment	1) Manuals, medication pocket cards. 2) For MD, Nurses, Nurse practitioners, physician's assistants; training in medication management and diagnostic assessment; webinar and in-person site visit to primary care	1) Manuals, medication pocket cards. 2) Two-tiered approach with training for medication management and clinical assessment coupled with information on complementary / alternative therapies and prayer for depression, through training slides; and second tier of orientation to concepts for lay providers.
Administrators/Other	Webinar on overview of intervention plan approaches to team building/management and team-building resources	1) Conference break-outs for administrators on team management and building and team –building resources; support for grant-writing for programs 2) Administrative problem-solving to support "Village Clinic" including option of delegation of outreach to clients from RAND survey group, identification of programs to support case management, resiliency classes, and CBT for depression
Training events	21 webinars and 1 site visit (22 hours) (combined communities) CBT (8 hours) Care management (8 hours) Medication (1 hours) Implementation support for Administrators (5 hours)	144 training events (220.5 total hours) (combined communities) CBT (135 hours) Care Management (60 hours) Medication (6 hours) Other Skills (19.5 hours)
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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 [136]) 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.[137] 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[138] life stress events, patient treatment preferences,[139] the presence of comorbid panic,[140] and post-traumatic stress disorder[141] and alcohol problems[142] use of avoidant and/or active coping strategies,[14] patient beliefs about depression, and perceived stigma concerns (e.g., difficulty in getting a job, getting health insurance, or social relationships).[143] 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[49, 65, 147] 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 3: Client Measures*

Client Characteristics	Process of Depression Care	Outcomes of Care
Sociodemographics *(0)* Insurance status *(0,6,12)* Family members *(0,6, 12)* *Physical comorbidities *Psychiatric comorbidities * Lifetime schizophrenia, *hospitalization for psychosis*(0)* * One year PTSD screener (0) Panic screener *(0, 6, 12)* Alcohol screener *(0, 6, 12)* Use of illicit substances (0) Stressful life events *(0,6, 12)* Social supports *(0)* Active/passive coping *(0,6, 12)* Ethnicity/acculturation *(0)* Depression knowledge *(0,6)* Stigma concerns *(0)* Treatment Preferences *(0,6*) Readiness for treatment *(0)*	**Treatment** *Use of psychotropic medications *(0,6,12)* *Primary care counseling *(0,6,12)* *Specialty care referral and counseling *(0,6,12)* **Services Use** **Hospitalization for mental health or substance abuse** **Emergency Room Use** **Outpatient Services** **Mental Health Specialty** **Primary Care** **Social Services/Substance Abuse** **Other Community Services** Satisfaction with treatment *(6,12)* *Unmet Need *(6,12)*	Primary pre-planned: *Mental health related quality of life (0,6,12) *Probable depression *(0,6,12)* Secondary/community priorities: **Physical activity (0,6,12)* *Employment status (0,6,12)* **Current work status* **Missed days from work* **Personal work productivity (0,6,12)* *Homelessness Risk Factors (0,6,12)* *Currently homeless or 2 or more nights homeless in 6 months* *Food insecurity (perceived)* *Severe financial crisis* *Eviction from major residence*
**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).[148] 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.

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.[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[161] Tobit-type sample selection models[163]; split-sample techniques to distinguish between different functional forms and to avoid overfitting[161]; and dynamic models, such as episodes of care analytic models, duration analysis, and count models.[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)[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 6-12months 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.[34] Further, the community-engagement intervention utilizes many principles of social-science theory that support behavior change such as practice and skill development[104, 124,

[167]; development of opinion leaders,[110] and stimulation of network development [118] and cross-organizational "communities of practice" that promote identification with common goals and sharing of knowledge,[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 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)

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 [155, 168] and wave-level [169] 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.[170-173] 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 units. To perform multilevel analyses, we will use special software such as the MIXED and GLIMMIX procedures in the SAS System V9, HLM6,[170] MLWin[159], Mplus[174] 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): $Y_{ij} = b_{0j} + b_{1j}X_{ij} + e_{ij}$ $e_{ij} \sim N(0, s^2)$,

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

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 jth 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:

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

The random intercept model can be generalized to a random intercept, random slope mode 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, … t, i=1, …, n_j, j=1, …, 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.[175] 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[176, 177]. 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[176, 177] to adjust the standard errors by the variance inflation factor (VIF) defined as VIF=1+(m-1)×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[177] 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.[177] 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 [176, 177] 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 4. Minimum detectable effect sizes for main analyses (80% power (alpha=0.05), two-sided test)*

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

†Detectable effect size (mean difference between two groups divided by the standard deviation)[178]. §Detectable percentage point difference for two groups.

6. CPIC 3-Year extension (PCORI award # 1845)

<u>*Background:*</u> Depression is a leading cause of morbidity with disparities in care. Depression collaborative care, a team-based approach supporting care management, patient activation and evidence-based treatments, is effective relative to usual care but often unavailable in under-resourced communities. Community Partners in Care (CPIC) randomized 95 programs in healthcare and community-based (e.g., social services, faith-based) service sectors in two communities to Resources for Services (RS) for individual program technical assistance versus

Community Engagement and Planning (CEP) for multi-sector coalition support for depression collaborative care. For depressed clients, CEP relative to RS reduced having poor mental health-related quality of life (MHRQL) and behavioral health hospitalization over 6-12 months. Longer-term outcomes are unknown.

Aims: This extension study of CPIC aims to:

1. Compare CEP and RS effects at 3-year follow-up, 2-years after intervention support, on primary (depression and MHRQL), community-prioritized outcomes of physical health-related quality of life (PHRQL) and behavioral health hospitalization, and outpatient services use (secondary);
2. Compare effects of CEP and RS at 6, 12, and 36 months for CPIC participants enrolled in healthcare or community-based service sectors;
3. Describe outcome priorities for African American and Latino depressed clients, and as perceived by providers.
4. Describe views of stakeholders planning the Los Angeles County Health Neighborhood Initiative (HNI) informed by CPIC; and national stakeholders briefed on CPIC and HNI.

We hypothesized that CEP relative to RS would improve long-term mental and physical health and reduce hospitalization nights, overall and within sector. We expected stakeholders to prioritize social factors and mental health.

Methods: Extension Study (Aims 1-3): Between 1/2014-10/2014, we approached 1004 CPIC clients initially screened as depressed from 89 programs and eligible for 3-year surveys; 600 participated (60%; RS 293, CEP 307). Aim 3: For client qualitative interviews, we approached 163 consecutive 3-year survey participants stratified by depression, race/ethnicity, gender and intervention; 104 participated (64%). For staff, we notified 289 completing 12 month surveys and used purposive follow-up stratified by community, service sector and intervention, to complete 51 interviews. Aim 4: We interviewed 49 county and community leaders planning HNI and 14 of 34 leaders attending a national briefing.

Data Sources: Self-report surveys (Aims 1 and 2) and semi-structured interviews (Aims 3 and 4).

Measures: Client outcomes are poor MHRQL (MCS-12 $\leq$ 40) and depression (PHQ-8$\geq$10) (primary); PHRQL (12-item physical composite score (PCS-12), mental wellness, and behavioral-health hospitalization nights (community-prioritized); and use of outpatient services

(secondary). Clients and providers were asked about priorities for care and national stakeholders for responses to CPIC findings and related policy initiatives.

4-year follow-up of the 3-year sample (extension study).

The CPIC 4-year follow-up was added based on *community-stakeholder input that additional follow-up of the 3-year sample was desired to show longer-term effects on depression remission*. This follow-up built on the 3-year extension study as well as an opportunity to explore of using an existing funded cohort to recruit potential subjects into the Community and Patient Partnered Research Network (CPPRN).

Analyses plan: We will conduct 3-year end-status intent-to-treat analyses, and for 4-year follow-up of the 3-year sample, 4-year end status, with intervention status as the main independent variable, adjusted for baseline status and covariates, with response weights and multiple imputation (Aim 1); subanalyses of intervention effects within service sector at each follow-up (Aim 2); sensitivity analyses (raw data, longitudinal modeling and sector-by-intervention interactions); and thematic analyses of qualitative data (Aims 3 and 4)

7. 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.

8. Protection of Human Subjects

8.1. RISKS TO THE SUBJECTS

8.1a. Human Subjects Involvement and Characteristics

The proposed research will involve five groups of human subjects, agencies/administrators; clinicians/case workers; clients of these clinicians, and community members and civic leaders, and the research team itself. The study is a randomized controlled trial of a community-engagement, network building implementation intervention versus a low-intensity dissemination approach using a conference and access to a website with Partners in Care (PIC) toolkits. The

study supports post-trial, wait-list intervention training for controls supported by intervention leaders.

Communities: We selected by convenience two of the largest communities in Los Angeles with substantial, low-income, and largely uninsured and predominantly minority populations, for which we had established partnerships.

Agencies: We will contact the community agencies participating in the Community Partnership Initiative interviews (66 to date, 2 more to be completed; plus 10 attending the Feedback Conference). We will ask them to participate in a websurvey in which we will identify other potential partners. We expect 15-20 new agencies to be identified and we will ask the new agencies to also complete a Community Partnership interview, and to complete the websurvey. The websurvey will describe the goals and activities of CPIC with contact information for study staff, and follow-up activities by study staff, including study presentations as desired and follow-up calls. We expect 80 agencies to agree. These agencies will include social service and faith-based community agencies, primary care clinics, and mental health specialty outpatient settings, serving low-income clients or community members. Lead agency administrators will be asked to participate in a series of follow-up web surveys at 24, 36, and 48 months after their baseline survey, to participate in conferences, and if their agency is selected for the trial, in the main study activities.

All 80 participating CPIC agencies will be asked to identify service locations in the community areas, for which they have at least one full-time equivalent clinicians/case workers that serve adults; and to provide the number of eligible clinicians or case workers in those locations. These units will be the focus of clinician recruitment (see below). We expect most participating agencies to have 1-4 eligible units, but some will have more than 10. We will explore the feasibility of splitting some units into distinct teams. We expect to identify 150-200 eligible units across agencies.

All participating agencies' eligible units (150-200) will be considered for selection into the main trial. We will select a stratified sample, by agency type, to achieve 50-60 participating units (25-30 per community) for the main study, but expect to have another 25-30 participate in the ongoing administrator and clinician surveys but not in the main study.

Among the participating organizational units, we will randomly assign them (stratified by community and type of agency) to participation in the 2 study conditions; for very large, well-

established, multi-agency networks (such as QueensCare), we may randomize units within that network to preserve network ties. Agencies and organizational units will be informed of their randomization status by letter prior to the study's Phase 1 Kick-Off Conference. Some agencies may have units in both Phase 1 intervention conditions in the trial, and for this purpose, will identify a lead administrator for that agency for each intervention condition, and ask the additional administrator to complete the baseline administrator survey. This will increase the administrator pool across the 80 CPIC agencies to about 100.

All agencies will be asked to commit to participate in the administrator/agency web surveys, clinician surveys, and Feedback Conference. Agencies selected for the main trial will be asked to send 1-2 representatives to a Kick-Off Conference in their community, participate in the relevant intervention planning and implementation activities for each condition, and participate in a client outcomes study. Intervention agencies will be asked to assist training for the controls in the wait-list training after the main trial.

Agencies/units assigned to community engagement implementation will participate in 4 months of planning and training for use of PIC/WE Care and to design an approach to fit the programs to their resources, priorities, and sites, with support of community members serving as co-intervention planners. Then they will participate in 12-18 months of implementing PIC/WE Care, including training the clinicians within participating units and supporting access to evidence-based treatment treatments for depressed clients enrolled into a client study. Those assigned to low-intensity, standard dissemination will attend a conference and have access to PIC toolkits on a website, but will not be asked to participate in other intervention planning or implementation at that time. Agencies/units in both conditions will be asked to participate in client enrollment within each unit, designed to achieve screening of a defined client pool for depression and enrollment of several depressed clients for each unit into baseline surveys and 6-month and 12-month follow-up surveys. In community-engagement practices, those clients will be identified to the practice so that they can initiate PIC/WE Care intervention activities to facilitate access to evidence-based depression treatments, following the approach developed within their implementation planning period. Following the 6-month outcomes data collection for the client study, the agencies in the community engagement condition will be asked to identify representatives to participate in collaborative analyses and preparation of findings for presentation at the Community Feedback Conference, attended by all participating Agencies, to

formulate recommendations for the field and for future community implementation, and initiate wait-list training for controls.

Administrators: The administrator sample will be recruited from all participating CPIC agencies (see above), including those from the original respondents to the Community Partnership Initiative, those for agencies joining CPIC after being nominated for inclusion (i.e., primary care and specialty care partners of social service agencies in CPIC), and the additional lead administrators for those agencies with units in both Phase 1 conditions. We expect to have 100 administrators in the study. Administrators will be asked to complete baseline, 12-month, 24-month, and 36-month follow-up websurveys on behalf of their agency, and to participate in the other relevant study activities for their agency, see above.

Clinicians: We will ask administrators to complete a form for each selected unit for the study within their agency (see above), listing the number of full-time providers of services to adults within that unit. Using lists of providers we will select 5 at random, using other providers (including part time or 50% working clinicians) for replacements as needed, using random selection from the remainder. We will send recruitment packets with follow-up telephone contact/fax, and as needed, and for larger agencies make presentations to units to explain the study. Clinicians/case workers will be asked to complete a baseline websurvey on the background and knowledge of and treatment practices for depression. All clinicians will be asked to participate in follow-up websurveys at 12, 24, and 36 months. Clinicians will be informed that there will be different types of participation depending on whether they are in an organization in the main study, and whether in the main study, in the community engagement intervention or low intensity dissemination condition. Clinicians will be informed of their participation status by letter at the time that their agencies are notified. We expect about 200-250 clinicians/case workers to enroll in the units participating in the main trail and another 100-150 in nonparticipating units.

Clinicians in units assigned to the main study will be asked to participate in the client outcomes study. One or two clinicians for each participating unit will be identified by their agency as “lead” clinicians for purpose of participating in planning and assuming roles of trainers of other clinicians in interventions. These lead clinicians will be nominated by their agencies, not selected by the study. The lead clinicians for their unit, may be asked by their agency to attend the Kick-off Community Conference and Feedback Community Conference.

Lead clinicians (and key administrators) may be asked to participate in semi-structured interviews about implementation at the end of the trial.

When participating in the community engagement intervention (initial trial or wait-list period for controls after main trial), clinicians/case workers will be asked to participate in PIC/WE Care training activities relevant to the scope of their practice (care managers, therapists, medication specialists, outreach workers, educations, etc.), using training materials from the study, with help from their agency's lead clinician(s) and study investigators.

Clinicians will be free to participate or not in CPIC, and in the training activities, conferences, expert leader roles, and other activities of the project. They will be able to select treatments with their clients or not use treatments. There is no control by the study over their activities. Clinicians will not be paid for their participation but will receive token gift certificates or comparably small thank-you tokens.

Clients: The clients will be recruited from a consecutive sample of adults visiting each participating clinician/case worker, over a one to two month period for that site. Agencies will be given fliers and other materials to advertise the study and screening days if they wish. Agency staff at the unit will ask clients if they would be interested in participating in a research study in which the agency/clinic is participating. If interested, the client will be referred to the study field interviewer. The interviewer will ask the client to complete a screening survey. Clinicians can also refer to the study. We expect 6000 clients to be referred for screening across the 50-60 units, and expect 4200 to complete the screener survey. This phase will not require written consent, because we will not obtain client identifiers. Those with a positive depression score (840), which indicates probable (but not certain) depression, will be asked to consent to participate in a baseline assessment and two follow-up surveys at 6 and 12 months. The client baseline survey will be completed on the same day at the agency/unit or, if this is not feasible for the client, in a follow-up telephone call from RAND survey staff. An estimated 540 subjects identified as depressed on the screener will sign the study consent and complete the baseline survey. The clinician visited that day will be asked to complete a brief post-visit encounter form describing the process of care for the same visit, collected by the survey staff. All depressed patients completing the screener, at the time of enrollment, will receive a list of local mental health agencies in case they perceive a need for care.

Clients from agency units/clinicians in the community engagement condition will be identified to their practice for initiation of the PIC/WE Care program, and clients will be given contact information for a care manager in the intervention group. Depending on the scope of practice for the agency unit in which they were screened, clients may be asked to participate in developing a strategy for education and referral, clinical assessment for depression, or counseling or medication management, and to work with a case manager for follow-up; for some of these activities, clients may be referred to other agencies within the intervention network, for example, to receive medication management or Cognitive Behavioral Therapy. Clients and clinicians will be able to select their choice of treatments and fit them to client needs. Clients will be able to select other resources available to them, outside of the study or network, or other services within the network, and remain in the study.

Clients from agencies in the low-intensity dissemination condition (control) will be given the standard referral information and encouraged if they are concerned about their mental health or welfare to talk to their agency clinician or other provider. Further, their participating CPIC clinician or case worker will have previously had exposure to PIC/WE Care materials, through an initial conference presentation and discussion and access to toolkits on the website. Clients from the low-intensity control will be able to receive medication or counseling supported through usual community services.

Client participants in both intervention conditions will be asked to complete a follow-up telephone survey at 6 months and again at 12 months from baseline. All participants at 12 month follow-up will be given the same mental health referral information from baseline. We expect 85% response at 6 months (N=500) and 80% at 12 months (N=470).

Collaborating Institutions and Sites: The lead collaborating institutions for the research will be RAND, UCLA, Healthy African American Families, QueensCare, and Los Angeles County Department of Mental Health. In addition, research activities conducted by study staff, and intervention activities by community providers, will occur in the participating agencies. Because those agencies are not yet recruited, we cannot identify those agencies at this time. Agencies recruited may have their own Internal Review Board, and we will support submissions of the study as needed to those IRBs, and otherwise these agencies will be asked to assign their IRB needs to RAND. We will collect information on whether the organization has its own IRB for

participating in research, during the baseline agency administrator survey and the recruitment activities for that survey.

UCLA and RAND executed a Memo of Understanding and filed necessary documents permitting deferred review, such that studies involving both institutions have only one institution as the sole IRB for that pair of institutions. For research not involving human tissues, requiring FDA approval, or involving UCLA HIPPA issues (i.e., involving UCLA patient records), the reviewing institution is RAND. This policy went into effect September 1, 2006. Thus for CPIC, RAND will be the lead IRB; separate UCLA IRB review will not be required.

Community Leaders and Advisors: For intervention groups, key agency leaders participate in the 4-month implementation planning, serve as leaders in the community conferences, help provide oversight during implementation, and participate in the collaborative analyses of data from each stage. Along with agency leaders, we will include community members who will serve as key community advisors, representing the community voice outside of formal agencies. In addition, there will be representation from key civic agencies, such as the Los Angeles County Board of Supervisors and the Los Angeles Mayor's Office (Dr. Patel, and representatives from local neighborhood planning councils), as part of the advisory group for planning. This addition of grass-roots community members and civic leaders, helps make the overall project a community-wide project, supports the community-engagement model, and builds community support for implementation. These are public roles, but the participants are also research subjects because they will be asked to complete conference surveys; notes of planning meetings are project data; and training and planning meetings and conferences, may be attended by study research staff making observations and taking field notes as qualitative research data for the project. For these activities, the community leaders and advisors are also research subjects and will be asked to sign a consent form for participation in the research activities of the project. Community members will be recruited for their advisory roles by the lead CBOs for the project, through advertising among the community contacts for these roles. The Community members participating in these roles will receive thank-you stipends from the CBOs. The civic leaders will be recruited from the mayor's and Board of Supervisor offices (see support letters), with additional nominations from those offices and the lead CBOs, as they have broad knowledge of community leadership in their areas. Civic leaders will not receive a stipend for participating, as it is assumed to be within the scope of their usual duties.

Research Investigators and Staff: Project research investigators and staff participating in training, implementation planning meetings, and conference activities including the collaborative research analyses of data with agency administrators, will also be research subjects as they will be involved in minutes from meetings and subject to observation and other qualitative data collection activities, just like the community members and civic leaders. Those project staff serving in those collaborator/consulting roles with community agencies, will be asked to sign a consent form as a research participant, as in Witness for Wellness.

8.1b. Sources of Materials

Data Sources: Data on agencies and units derives from reports from lead administrators from the pre-study Community Partnership Initiative and four longitudinal web-surveys at baseline, 12, 24, and 36 follow-up. Data on clinicians/case workers is obtained through four self-report web-surveys at the same time points. Data on clients is obtained through screening surveys with a follow-up baseline face-to-face or telephone-administered interview for those screening positive for depression; and, for enrolled depressed clients only, at 6-and12-month follow-up telephone interviews. Other sources of data are minutes and action plans from planning meetings and conferences, field notes of conferences, meetings, and training sessions, before-after surveys for conference participants (for Kick-Off, Feedback, and Quality Assurance Conferences), and other qualitative interviews for the process evaluation, conducted periodically (such as at trial exit for administrators) as part of the implementation process evaluation.

8.1c. Potential Risks

Administrators and Clinicians: There is some minor risk of social harm (embarrassment) to administrators or clinicians due to the evaluation process (for example, through feeling compared with other administrators or clinicians). Also, there will be an increase in the caseloads of the providers in the intervention agencies, but a given provider will only have a few enrolled depressed patients in the study, that load is not great. Thus, we think it unlikely that agencies will assume an undue burden in selecting the scope of implementation. Over time, this may or may not translate into economic risk for the agencies or providers, since improved patient outcomes may well reduce intensity of services over time for some clients, and increase it for others.

Providers will help define the implementation plans for use of service delivery interventions that support use of evidence-based treatments. None of the treatments supported by the study, and none of the service delivery interventions (PIC/WE Care), are new interventions; they are not "experimental" treatments or interventions, as their evidence-basis is already well-established. Providers and clients are not mandated to use particular treatments, i.e., they are assigned to resources to support care decisions, not mandated to particular treatments; and providers can refuse to use study materials and remain in the study, and clients can refuse treatments or select others, and remain in the study. Providers face potential malpractice suits for adverse treatment outcomes under usual practice, and while there is always a risk for an adverse treatment outcome (such as a side effect, or no treatment response), these are less likely with evidence-based care, so if anything the overall chances of malpractice suits for treating depression should be less for providers supported by the study to consider evidence-based care strategies. In the unlikely event that a malpractice claim is brought (for example, because of a complication from medication), treating providers would be covered by their own malpractice insurance or that of their agencies.

Clients: Potential risks to clients participating in this study, from the study itself, are minimal, and chiefly consist of the embarrassment of revealing personal information to a stranger or neutral party. There is also some risk that information on a mental health condition, if entered into the medical record or reported on an insurance claim form, could establish a history of a pre-existing condition making it more difficult to be covered by insurance for that problem, but only in some companies, should the client change jobs or try to change insurance. Consents will suggest that clients discuss such concerns with their providers, and providing training will alert providers to this standard concern in clinical practice. The interventions will be in addition to the patient's usual course of treatment, not a replacement for it, and clients can choose to use any study materials, such as the PIC client brochure, or use a treatment (such as Cognitive Behavioral Therapy that was supported by study-training of a community provider), or to not use these resources, and stay in the study. Clients are not assigned to treatments, and all treatment decisions will be up to clients and the providers they choose to visit. The client's usual provider will continue to be responsible for treatment and will be responsible for application of the protocols, or providers to which the client is referred.

Because the treatments the study interventions support are not experimental, side effects from them (for example, normal side effects of antidepressant medications) experienced by clients, would not be considered "adverse events" of the study itself, but expected side effects of standard practice treatments.

We will collect data from the clients about lifetime and current depression and other psychiatric disorders (alcoholism, panic disorder, psychotic symptoms). If a life-threatening situation is encountered during screening, telephone interviews or other contact with project staff, emergency protocols similar to those developed for PIC will be followed. Depending on whether the situation comes up in the agency/unit or through a study telephone interview, clients with an emergency will either be walked to a clinician in their agency and the study staff will assist the client in explaining the situation; or the telephone survey staff will contact the PI (or if an urgent life-threatening situation, either contact 911 or if feasible have the respondent contact 911, which greatly speeds up the response). In over 10 years of conducting depression studies, emergency protocols are activated for 1-3 out of 500 depressed clients per wave; in the last (8-year) follow-up of PIC participants, there were no emergency events; but in tests of the PI's response time through randomly selected times for calls, the PI responded to the telephone survey center on average, with 2 minutes of the call from survey staff. Thus, we are very experienced with facilitating activation of and effective use of an emergency response system for studies of depressed clients.

Clients will be paid $20 for the baseline survey and $30 for the 6-month follow-up survey. Clients will receive a small gift certificate for completing the screener.

Community Members, Civic Leaders, and Researchers: For other participants in implementation planning and collaborative research activities, we expect individuals to agree to serve these roles who are comfortable with public visibility. Community members will be supported in their roles by the lead CBOs. Community members are in a more vulnerable position and will receive stipends for their roles by the CBOs, but civic leaders and researchers will not receive stipends. The main risks to these participants is embarrassment or insecurity in serving in a public role.

8.2. ADEQUACY OF PROTECTION AGAINST RISKS

8.2a. Recruitment and Informed Consent

Lead administrators from the participating agencies will be asked to review a description of CPIC on the web survey, and will review that description with appropriate leaders within their agency. Agencies will submit a signed letter to initiate their participation. The composition and recruitment procedures are provided in detail above, but briefly include agencies participating in the Community Partnership Initiative; and additional primary care and specialty care agencies identified by social service agencies as their main partners of that type. There will be 80 organizations that participate. The organizations will be invited by mail to enroll as a participating agency and the subsequent study activities. Organizations will be free not to participate.

Administrators and Clinicians: We will ask each participating agency to identify 1 administrator, supplemented in agencies with organizational units in both intervention conditions, by administrators that support the additional intervention, for an approximate sample of 100 administrators. Administrators identify organizational units with full time clinicians/case workers for adults, and these units will be arrayed by the study to select 50-60 for random, stratified assignment to the intervention conditions in the main study. To have alternative sites and due to the timing of obtaining the information to select units and recruiting clinicians, we expect to have some clinicians participating in units that are not selected for the study.

Clinicians/Case Workers: Using lists of all full-time clinicians or case workers for adults within selected units, we will use recruitment packets and follow-up calls to recruit 5 clinicians per unit, replacing as necessary from remaining clinicians; and if necessary replacing units with others from the remaining nonselected pool. In PIC, all but 2 clinicians agreed to participate in selected clinics, so we expect a similarly high rate here given high agency interest and cooperation. We expect 200-250 clinicians in the 60 main study units and another 100-150 from other units. Clinicians will be free to choose not to participate in the study or in particular activities of the study.

Clients: We will recruit a consecutive sample of adult clients visiting participating clinicians, over a two week period for that site. Following posting of notices for the study or sending fliers, the agency's staff will ask their clients if they are interested in participating in a research project in which the agency is participating. If the client is interested, he/she will be directed to see the RAND field staff person assigned to that agency. We hope to talk to 6000 clients across the 48 units, and expect to complete 4200 screeners. Those with a positive

depression score, an estimated 840, will be asked to complete a baseline survey at the agency or if this is not feasible, in a follow-up telephone call. An estimated 500 will agree to the survey and sign consent forms to participate in the study. The field staff who do the screening give the client a written study summary and a question and answer booklet, review these materials with the client, and get written consent from the client. In addition, clients will be asked to give permission for their clinician to complete a post-visit report. Enrolled, depressed clients will also be asked to consent to a 6-month follow-up telephone survey and a 12-month survey. We expect 500 enrolled participants to complete the 6-month interview and 470 to complete the 12-month survey. Clients are free not to participate, receive referrals to mental health providers whether or not they are in the higher intensity condition, and all clients will be free to accept treatments or referrals or not.

8.2b. Protection against Risk

Subjects will know that they are free to refuse to participate in each stage of the study, and to leave questions or issues unanswered. Subjects will know that they will have the option of completing a survey at the agency or by telephone. If a life-threatening situation is encountered during the telephone interview or other contact with participants, emergency protocols similar to those developed for PIC will be followed. For example, for life-threatening physical emergencies, subjects are instructed to call 911 and assisted if necessary. The main other emergencies are a patient becoming disoriented or severely confused, or disclosing that they are currently suicidal. Project interviewers will be trained in protocols for contacting the project on-call physician who can make contact with the participant and/or provide referrals to a specific doctor or clinic identified for this purpose within each geographical area. During PIC telephone interviews there were no instances where interviewers encountered life-threatening physical health situations. However, there were about 2 instances per survey wave where the interviewer was concerned because a subject suggested they might have been recently suicidal (out of about 1000 interviews per wave). Following the approved protocol, the study PI contacted these participants (usually within 24 hours or as soon as they could be reached by telephone) and discussed the situation. In all instances, the patients were well aware of their options for treatment, all were in active treatment, and all were discussing their symptoms with their providers and felt they did not need additional assistance contacting their doctor. Most subjects

in this category had already seen their provider that day or were scheduled to see their provider the following day. All appreciated the contact by the PI.

Responding to mental health emergencies by telephone is challenging, particularly at some distance where there is no current rapport with a treating provider, or where there is no active treatment provider. Because of this, we will increase the chances the subjects will have information needed to avoid emergencies. In our recently completed 8-year follow-up of PIC participants, we had no telephone emergencies. To assure responsiveness in the case of an emergency, we developed a protocol to have test the PI's responsiveness by having calls at random times, and the response to the telephone center was within 2 minutes over 10 calls.

All patient-identifying information will be kept confidential. RAND's Survey Research Group (SRG) will use one set of identifiers (Field IDs) in their contacts with participants. Our senior programmer will receive field data from SRG and transform the Field IDs to another set of IDs (Analytic IDs) before the data are available to the investigators. The file that links the 2 IDs will be secured and accessible only to the senior programmer and RAND's privacy office. Identifiable hard copy data will be maintained separately by SRG with limited access and kept only as long as needed to maintain consent files or to contact patients for follow-up surveys. A detailed data safeguarding plan will be developed for the study and submitted to the IRBs at RAND and UCLA for approval. See section on Data and Safety Monitoring Plan below.

All field staff who interact with clients will receive at least 4 days of paid training at RAND and are required to complete the UCLA online course for social behavioral training in the protection of human subjects. General training includes general interviewing skills such as maintaining neutrality and use of non-leading probes, use of the interview software, SRG confidentiality, data safeguarding and quality control policy and procedures, and how to handle emergency situations such as intent to harm self or others. During PIC clinician training, clinicians are encouraged to review potential side effects of treatments with patients, and to elicit their treatment preferences and negotiate with clients to receive their treatments of choice.

8.3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

Many national studies have shown that underserved minority populations have low rates of access to mental health services and lower access in particular to appropriate care for depression.

Depression is a leading cause of disability worldwide, and improving access to appropriate services can improve health outcomes and functional status, and improve employment. Our prior work in PIC has shown that evidence-based service delivery programs for depression can improve health outcomes in depressed patients, and especially in minorities, largely overcoming disparities in outcomes from care between whites and minorities. Yet in safety-net systems that are the main sources of healthcare for low-income, communities of color, such evidence-based programs have not been available, because of poor resources, competing priorities, and poor infrastructure to support evidence-based quality improvement programs. Determining how to best support safety-net agency networks in implementing these service delivery programs, is a critical issue for improving the health-related quality of life of depressed persons in underserved communities.

The proposed study offers participants an opportunity to receive their care in systems, whether social service agencies or health clinics, that can support a network approach to evidence-based care. This study focuses on determining whether a community-engagement, network-building approach to implementation is more effective than a standard, low-intensity dissemination approach.

Overall, we think that the benefits of the study, in achieving a better knowledge base and network structure for service delivery interventions that support provision of evidence-based care, are potentially very substantial, and will benefit clients and their families. The risks are embarrassment, some having side effects from treatment whereas they might not have had treatments (and not gotten better), and for clinicians, administrators, and other participants, embarrassment, extra efforts, or for agencies, the possibility of increased costs; but all participants are free to participate or not in the study and activities within the study, and the study is designed to adjust implementation of the services delivery interventions to the priorities and resources of the agencies, and the treatment preferences of providers and clients. The more serious risks of clients having difficulty with insurance in future jobs from a history of treatment are rare compared to the common risks of untreated depression. Further the implementation strategy being studied, community engagement, is specifically designed to provide the empowerment and flexibility for participate meaningfully in social planning, such as improving healthcare delivery.

This study will provide several types of new knowledge: 1) the effectiveness of a community-engagement based implementation intervention relative to standard, low-intensity dissemination; 2) strategies that community agencies and members use to learn about implementing evidence-based interventions; and 3) the process of implementation of evidence-based depression quality improvement programs in underserved communities of color.

These knowledge gains for the field, will likely help develop a stronger focus on dissemination and implementation for a stigmatized condition such as depression.We believe that the gains of the study, in terms of knowledge and substantive gains to the community, exceed the risks for participants.

9. Data and Safety Monitoring Plan

The administrator and clinician website will be maintained by UCLA. Most of the data collected from administrators and clinicians will be entered into a secure web data base that is password protected. Access to this data base will be limited to a senior programmer and Ruth Klap, the data manager at UCLA. Field IDs will be replaced with Analytic IDs before data are released for analysis. Contact information and contact histories for administrators and clinicians will be shared with the RAND survey group, to enable their contact of all participants for further surveys, conferences, etc. A program, such as PGP, that provides RSA level security will be used to encrypt files before sending them by email. The passwords for encrypted files will be transmitted directly to the intended recipient over the telephone (no messages will be left) or by US mail. Hard copy administrator and clinician agreements and interview forms will be kept at RAND. All client data will be maintained at RAND. RAND will initiate all written contacts, telephone or other personal contact with participants; UCLA initiates contact with administrators and providers through the web survey or emails to cue them to complete a web survey. Hard copy administrator and clinician agreements and interview forms will be kept in locked file cabinets with limited access.

The use of Web-based technology presents additional concerns in relation to loss of confidentiality. To ensure the security and integrity of our data, we use technology similar to that used to protect credit card information in e-commerce applications: all exchanges between a user's browser and the server are two-way encrypted with the secure sockets layer (SSL) protocol to prevent eavesdropping, tampering, or data forgery. SSL protocols use 128-bit cryptography

algorithms, such as RC4, which have emerged as standard approaches to high-grade online privacy protection. As a further safeguard, access to all data on the server is controlled by password protection. Different user profiles allow access to relevant sections of the database. For example, study clinicians can view and edit data on their own patients only. Investigators can see recruitment and intervention data for their study site and de-identified summary data for all study sites for comparison. For additional security of the data, we use only unique study identification numbers to identify study patients on data forms, and we do not transmit patients' names, medical record numbers, or other identifying information over the Internet.

Hard copy patient participation agreements will be sent to the Survey Research Group at RAND on a weekly basis from each of the screening sites. They will be logged in and put on-line by designated person(s) and then stored in locked file cabinets. The screening forms will be sent to data entry after which the hard copy will be stored in locked file cabinets. Judy Perlman, SRG, will be responsible for the safeguarding of the hard copy of these forms while they are in the field and once the forms are at RAND.

Baseline surveys will be collected on laptop computers sing Computer Assisted Personal Interviewing (CAPI). Access to the notebook computer will require a password. An additional password will be required for access to the survey data. Data will be transferred from the laptops to network drives with restricted access regularly. The follow-up surveys will be conducted using Computer Assisted Telephone Interviewing (CAPI) by the RAND survey Research group. This data will be safeguarded at RAND. Only de-identified data will be shared with UCLA.

Worksheets, logs and call records that contain the patient names and RAND IDs used by operations staff are needed for monitoring the flow of the field work during the data collection period. After the field period, the worksheets will be kept in locked file cabinets. As much as possible, Field IDs will be used as identifiers on worksheets rather than patient identifiers.

We will have an on-line file of patient names and telephone numbers during the data collection period. This system will track the status of each patient and provider until the data collection is completed and will help in the scheduling of cases. These files have access restricted by passwords to interviewers and supervisors who have a need to use them to operate the study and who have signed the oath of confidentiality. Judy Perlman will be responsible for safeguarding these files during the data collection period. When data collection is completed,

these data files will be handled as described in below before being turned over to the analysis team.

Bernadette Benjamin will create analytic IDs to replace the IDs assigned during the data collection. A file that links the analytic IDs and data collection IDs will be kept by Bernadette. This linking file will have read and write access restricted to Bernadette. The analytic ID for participants and/or other RAND-assigned identifiers will replace the identifying information in all fields that would identify individuals or clinics before primary data are made available to the analysis team. Following analysis, reports will be prepared. These reports will not contain any data that could identify individual clients or providers.

The raw data and the computer data files will be kept for at least one year following the publication of the final reports on the study. Upon the completion of the study, the link files, and the survey data files will be turned over to the RAND Privacy Resource Team for safeguarding.

Employees who will be handling any participant-identifying computer files, worksheets, or medical record information as well as the survey interviewers and their supervisor will sign an oath of confidentiality. As part of their training, they will be instructed in the rules of confidentiality and data safeguarding for the study.

Process for Handling and Reporting Adverse Events (AEs): If an AE in the nature of threat to harm self or others occurs in the agency during the screening, consenting, baseline survey interaction, the client's provider or a provider designated by the clinic will be notified with the client's consent. Events occurring during telephone interviews with clients will be reported to the SRG supervisor who will immediately contact the Principal Investigator, Dr. Wells or a project clinician designated by Dr. Wells (Dr. Miranda, Dr. Ong). Dr. Wells (or a designated backup clinician) will be always on call during the field period. Dr. Wells decides how the event is to be handled (e.g., phones a suicidal patient, reports elderly abuse). When the event is resolved, Dr. Wells will write a summary of the occurrence and submit it to the IRB. The IRB determines whether further notification is warranted.

Data Safeguarding and Management Board (DSMB): The DSMB is charged as an external, independent oversight board, to monitor the conduct of the study for ongoing feasibility, data integrity and safety. NIMH has its own DSMP for clinical trials. If determined that the study requires a DSMP, we will use the NIMH DSMP. However, we think this study may not require a DSMP. The reason is that it is a randomized, controlled trial of an intervention to implement

evidence-based services delivery programs that support use of evidence-based treatments, relative to a low-intensity, standard dissemination approach. Neither approach increases patient risks appreciably in that they both support improved treatment approaches if implemented. The study does not promote use of new treatments or unproven treatments, except for the value of the implementation approach itself, which is directed at a network and organizational unit level.

If recommended for DSMP, CPIC will work with the selected DSMB members identified by NIMH; they will be selected to have appropriate expertise and no conflicts of interests. These members will monitor the study and ensure that monitoring is timely and effective. The PI will provide necessary data to the DSMB, respond to any DSMB queries or suggestions and submit the DSMB reports to all IRBs after DSMB meetings.

Data to be Reviewed: Prior to the start of the study, the board would review the protocol and overall plans for data and safety monitoring. The board then will review patient flow and subject entry to ensure adequate recruitment and retention of subjects and will monitor the occurrence of adverse events related to participation in the protocol. However, we point out that the main adverse events relevant to a study of this nature, are likely to be either expected complications of depression or of treatments. Overall in clinical trials of depression, adverse events may include: deaths, suicide attempts, study dropout, psychiatric hospitalizations, and clinical deterioration defined as emergent suicidal or plan, development of serious substance abuse, or emergence of a new psychiatric or medical diagnosis or behavior posing significant risk to the subjects or others.

Relative to clinical treatment trials, this study has infrequent monitoring of patients and is mainly able to identify clinical problems at the time of the subject being in a screening visit when a social service worker or clinician will be present; and at telephone follow-up, when emergency procedures are handled by the PI on notification by survey staff. During main community-wide implementation, community organizations are implementing the protocols under their own priorities and resources, and the study does not monitor their patient care, except through a sample of clients in the second cross-sectional survey, i.e., it is real community implementation, and that phase is not randomized. This study is more like a “fifth” or “sixth” level trial, and is not of treatment per se, or services delivery per se, but of implementation of evidence-based interventions at these levels.

Schedule of Meetings: If recommended for a DSMB, we suggest teleconferences for the meetings, once in the first year; at 6-month intervals years 2 and 3, and once in year 4, when clients are participating in the study.

10. Inclusion of Women and Minorities

This study will focus on communities of color and will have predominantly minority participants at the client level; 2/3 of depressed clients are women and we should accordingly address important issues for women in communities of color. The project will use bilingual interviewers and all instruments will be available in English and in Spanish.

11. Summary of Initial Design, Community Input, Modifications, and Final Design

Table 5: Summary of Initial Design, Community Input, Modifications, and Final Design

Design Feature	Initial	Community Input	Modified	Final
Communities	South Los Angeles/Hollywood-Metropolitan Los Angeles	Include Downtown Los Angeles with Hollywood	Affirmed	Same as initial
Services Sectors	Mental health specialty, primary care, substance abuse, social services	Include public health, homeless-serving, prisoner re-entry, family preservation, faith-based, senior centers of parks and recreation, exercise clubs, hair salons	Expansion to meet community goals, required modification of expected retention for client surveys and of client recruitment plans	Mental health specialty, primary care, public health, substance abuse, social services, faith-based, senior centers, exercise clubs, and hair salons
Providers	Professional staff and case workers	Include all staff, paid and volunteer with direct patient contact	Invitation to all staff	Staff with patient contact
Clients	Persons on designated days showing to sites for services (adults), consecutive sample	Include parents of child clients that accompanied child if they could also be supported; expand to events/food lines	Clients and parents of child clinics; events/food lines included	Adult clients and parents of child clients in waiting rooms (consecutive selection) and events (random selection)
Depression Quality Improvement Toolkits	Toolkits for clinician assessment, medication management, Cognitive Behavioral Therapy, case management, patient education from Partners in Care and We-Care	Modify for lay staff, simplify language and forms, available on-line, expand health worker tools	Modified clinician assessment and case manager tools; added health worker guide and team leader tools from Mental Health Infrastructure and Training	Modified PIC, We-Care and MHIT materials, simplified and offered on web site, hardcopy, and flashdrives
Resources for Services	One-day conference and written/posted	Expand to meet Los Angeles County	Offer of up to 12 webinars on all toolkit	"Standard" technical assistant to individual

Table 5: Summary of Initial Design, Community Input, Modifications, and Final Design

Design Feature	Initial	Community Input	Modified	Final
Intervention	toolkit materials	standards for training support for evidence-based practices	components plus site visit to primary care; plus toolkits online, flashdrive/hardcopy	agencies as described in modifications
Community Engagement and Planning Intervention	4 months of planning followed by 2 day training and follow-up supervision led by research/QI experts supported by written toolkits	Trainings coled by community leaders; follow community specifications; resources to match RS ($15K/Council); network innovation	Modified 4 months of planning with written plan, coled training, monthly oversight of implementation, network innovations	4 months of capacity building and network development to re-engineer toolkit training as partnered training and innovation
Randomization	Group-randomized at program level (agency site/team)	Develop trust in randomization/explore alternatives	Community forums on Tuskegee legacy and scientific advantages of randomization; Council supplies seed numbers to initiate randomization	Group-randomization implemented with trust-building activities
Outcomes	Risk for depressive disorder, mental health-related quality of life, physical functioning, access and use of services, quality of care	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	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;	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
Sampling	Initial: 50 programs and screening of 6000 clients to identify and enroll and complete outcomes on 500	To add employment outcomes, 30% increase in sample size required; homeless sample would reduce expected retention from 80% to 65-70%	Expand expected sample size to achieve power for employment analyses; expand enrollment 20% more due to expected attrition	80-100 programs; with screening to enroll 1200 depressed clients yielding 780 at last follow-up
Analysis Approach	Intent to treat; control for baseline value of outcome and covariates; nonresponse weights; adjust for clustering; impute missing data	Include raw data	Conclusions based on modeled data and raw presented to confirm modeling	Modeling as planned plus raw data presented

12. Human Subjects Protocol

Human Subjects Study Protocols were approved by RAND's Institutional Review Board (HSPC) prior to study initiation in 3/18/2008. HSPC id: w2812-06-01; Federalwide Assurance number (FWA): FWA00003425; IRB number: IRB00000051.

Client components including informed consent forms for screener, enrollment, baseline, 6 months, and 12 months follow-up were approved in 10/22/2009 through 10/21/2010 (w2812-06-01-CR02), with extensions through 10/3/2014 (w2812-0601-AM09, w2812-06-01-CR03, w2812-06-01-CR04, w2812-06-01-CR05, w2812-06-01-CR06).

Partner agencies approved the referenced research by signing an authorization agreement letter, or if requiring their own IRB, through approval by their IRB, prior to client recruitment at their agency. For agencies with their own IRB, the IRB focused on initial client recruitment into the study. The initial consents covered screening for eligibility and enrollment in the trial, including baseline through 12-month follow-up, in the enrollment consent. All longer-term follow-up human subjects approval was through RAND IRB with the recruited clients .

Three-year extension was approved by HSPC in 10/3/2014 through 10/3/2016 (w2812-06-01-CR07, w2812-06-01-CR08). An amendment was approved in 2/29/2016 (w2812-06-01-AM25) for contacting the 600 CPIC clients who completed the 36-month follow-up interviews by phone, for the 4-year follow-up survey and enrollment into a new program (CPPRN).

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Appendix A

This report provides information on detailed technical methods for handling of issues for the analysis of 6-month client data as well as 12-month and 3 years follow-ups.

A1. Analytic Sample

Enrollment

The study settings were South Los Angeles and Hollywood-Metro. Participant sampling (program and client recruitment) and randomization are described in greater detail in prior publications. Within enrolled programs, clients were screened for eligibility in waiting rooms (consecutive selection) or events (random selection) between March 2010 to November 2010 by community members blinded to intervention condition and supervised by RAND. Staff approached 4,645 adults (age≥18) over 2-3 days per program; 4440 (96%) agreed to screening. Study eligibility was limited to clients providing contact information and depressed based on a score of 10 or greater on a modified 8-item Patient Health Questionnaire (PHQ-8) (3). Of 4,440 screened, 1,322 (30%) were eligible and 1246 (94%) consented. In our previous publications,(1-3) we created enrollment weights based on propensity weighting adjustment, by fitting logistic regression models to predict the enrollment among those eligible. The reciprocal of the predicted response probability was used as the enrollment weight for each participant. See Supplementary Materials in publications. [1-5]

Telephone survey

Baseline survey. Between April 27, 2010-January 2, 2011, we approached 1,246 consented clients for baseline telephone survey conducted by survey staff blinded to intervention condition and 981 clients (79% of 1246 consented, RS: 492, CEP: 489) completed the baseline, 36 refused (RS: 17, CEP: 19), 227 were unable to contact (RS: 96, CEP: 131), and 2 deceased (RS: 1, CEP: 1).

6 month follow-up survey. Between November 2, 2010 and August 11, 2011, we approached 1093 participants (RS: 540, CEP: 553) for 6-month follow-up telephone survey; 153 enrolled participants were excluded from the contact list because their baseline survey response status was in one of following categories: final refusal, ill or incarceration, unable to contact, or deceased. Of 1093 attempted for 6-month follow-up, N=759 (69% of attempted, RS: 380, CEP: 359) completed the survey, 12 refused (RS: 3, CEP: 9), 321 were unable to contact (RS: 157, CEP: 164), and 3 deceased (RS: 1, CEP: 2).

12 month follow-up survey. Between May 10, 2011 and March 12, 2012, we approached 974 participants for 12-month follow-up telephone survey; 272 enrolled participants were not attempted for 12-month follow-up based on their baseline or 6 month survey status. Of 974

attempted for 12-month follow-up, N=733 (75% of attempted, RS: 364, CEP: 369) completed the survey, 7 refused (RS: 4, CEP: 3), 229 were unable to contact (RS: 109, CEP: 120), and 5 deceased (RS: 3, CEP: 2).

3 year follow-up survey (extension study). Between 1/14/2014 and 10/14/2014, we attempted to contact 1004 participants for 36-month follow-up with exclusion who deceased (RS: 4, CEP: 4), who made final refusal in previous wave (RS: 22; CEP: 27), or who had no data on baseline, 6, and 12 months (RS: 84; CEP: 101). Of 1014 attempted for 36-month follow-up, 600 (600/1014=59%) participated (RS 293, CEP:307), 24 were deceased (RS:14, CEP:11), 10 refused (RS:7, CEP:3), 3 were too ill/incapable (RS:2, CEP:1), and 367 (RE:180, CEP:186) were not able to be reached.

4-year follow-up of the 3-year sample (extension study). The CPIC 4-year study was added to explore longer-term outcomes for the sample completing the 3-year follow-up, based on community stakeholder interest. In addition, this follow-up offered CPIC participants the opportunity to be participants in an additional project, the Community and Patient Partnered Research Network (CPPRN). Between 3/31/2016 and 5/26/2016, we attempted to contact 598 clients (RS: 292, CEP: 306) who completed CPIC 3 years interview participants excluding 2 that declined follow-up (RS 1, CEP 1). The telephone interview took about 15-20 minutes. At the end of the interview, a respondent was asked "Would you like to hear about the CPPRN program?" and "do you agree to be part of the CPPRN?" if answered 'yes'. Of those, 283 (47.3%) participated (RS 143, CEP 140), with 308 not reached (RS 143, CEP 165), 1 deceased (RS 1, CEP 0), 5 refused (RS 5, CEP 0), and 1 too ill to participate (RS 0, CEP 1). [5]

A2. Weighting

Enrollment The enrollment weight was intended to make the enrolled sample (n=1,246) representative of a specific target population. [6, 7] That target population was defined as people who were: age 18 or older, visited a participating CPIC sties during our screening window, screened positive for PHQ-8, and provided contact information. We created enrollment weights based on propensity weighting adjustment, by fitting logistic regression models to predict the enrollment among those eligible. The reciprocal of the predicted response probability was used as the enrollment weight for each participant. Five versions of the enrollment weight were created corresponding to five imputed screener data, because imputed predictors from the

screener data were used in fitting logistic regressions. Common predictors of age, community, and type of programs were used in all models.

Attrition The analytic sample for 6 months is comprised of 1,018 participants who completed baseline, or 6-month telephone follow-up surveys. We used nonresponse weighting to address missing data for subjects who did not who did neither complete baseline nor 6 months follow-up telephone surveys. We started with a large set of independent categorical variables to be considered for a logistic regression on the outcome of response among enrolled participants. The final model included predictors that were significant ($p<0.05$) for either intervention arm (age, gender, ethnicity, living situation, income, US born), as well as for two design variables (community and sector of the screening program). The final weights defined on the analytic sample were the product of the two adjustment factors for enrollment and nonresponse. See Supplementary Materials in publications. We applied the weights to the 36-month outcome analysis excluding 24 deceased cases (1,004 attempted - 24 deceased = 980). The weights for 3-year main analysis defined on the analytic sample were the product of the two adjustment factors for enrollment and nonresponse. See Supplementary Materials in previous publications. [1-3]

For 4-year follow-up, we tested bivariate associations between an indicator for responding at the 4-year survey and demographic and clinical characteristics at baseline and 3 years. [5] The weighting model to predict follow-up status from 3-year sample included screener sector, age, education, working for pay, PCS-12, poor mental health-related quality of life at baseline, and risk for homelessness at 3 years.

A3. Multiple Imputation

Item-level Missing Data We used an extended hot deck multiple imputation technique to impute missing values for item-level nonresponse. [8, 9] The procedure was based on cycling through each missing-data pattern on each variable with incomplete items. This method involved two steps: 1) forming imputation classes based on the predicted mean of the variable being imputed from a multiple regression model, and 2) drawing imputations at random from observed data within each class based on an approximate Bayesian bootstrap. To reflect the uncertainty of donor cells we created bootstrap weights and then used the product of the bootstrap weights in the multiple imputation model. Five imputed datasets were created. Each of the imputed data sets differs by the bootstrap weight and the seed used to obtain the random number employed in the hot deck

imputation. Data on several hundred, multi-item scales were collected at screener, baseline and follow-up time points. Most variables had item-level missingness rates of less than 5% except for baseline income and MINI variables. With imputations stratified by intervention arms, 5 alternative imputed datasets were produced for screener, baseline, 6 month, 12 month, and 3 year follow-ups, and multiple imputation inferences were used in all analysis. [10, 11]

The approach for selecting variables for multiple regression models was intended to preserve the associations and relationships among variables. In general, we identified common predictors for all imputation models including design variables (community, type of programs), social demographic variables (age, gender, ethnicity, marital status, education, living situation, income, and working status), and PHQ-8 score. For baseline, 6 months, 12 months, and three year data, baseline health variables (count of chronic medical conditions, PCS12 and MCS12) were included. In addition to these common predictors, each imputation model also included other predictors to be used in later analyses of interest. The order in which variables were imputed was determined based on a judgment of the analytic importance of the variables and the degree of missing data. Earlier imputed values were used during subsequent imputation steps, implying some dependence on the order in which variables were imputed.

Unit-Level Multiple Imputation We used a hot deck multiple imputation procedure based on an approximate Bayesian bootstrap method for unit-level missing data. [12, 13] This model assumes that both missingness and dropout arise from mechanisms that are missing at random (MAR) in the sense defined by Rubin. Our imputation techniques attempted to include information related to the missing values whenever possible. We first modeled the propensity of response at a given time point (coded 1 if response and 0 if nonresponse). In Step 2, we stratified cases based on the quintiles of the propensity scores and used the approximate Bayesian bootstrap to select donors. In practice these procedures were applied in sequence for the baseline, 6-month, 12-month, and 3-year data, with imputations stratified by two intervention arms. We started with imputing baseline. For each of the 5 item-level imputed screener datasets, we imputed a unit-level imputation baseline dataset. Limited to the analytic sample of 1,018, we then used baseline variables as predictors for modeling 6 and 12-month follow-up data and produced unit-level imputation datasets. In modeling the logistic regression of predicting response propensities, we started with a large set of independent variables. The final baseline model included the predictors: age, gender, ethnicity, income, living situation, US born, community, and type of

screening program. The 6-month models included participants characteristics assessed at screener (age, gender, ethnicity, health insurance, and type of screening program.), and baseline clinic and service variables (multiple chronic conditions, alcohol abuse or use of illicit drugs, any depression care). The 12-month models included additional variables: community, PHQ-8 assesses at screener, mental wellness, homeless status at baseline. The 3 years models included age, gender, ethnicity, employment status, ≥3 chronic conditions, homeless, 12-month alcohol abuse or use of illicit drugs, no place to stay for at least two nights in the past 6 months, type of screening program, and community with additional stratum variable sector (social-community screening sector vs healthcare Screening Sector) in Step 2. Values for participants who were deceased were not imputed.

A4. Analyses

For all study components (including supplement components discussed below), we convened working groups co-chaired by academic and community members to review analysis plans, data output and discuss findings.

Analyses for 6-month outcome: We conducted intent-to-treat, comparative-effectiveness analyses with intervention status as the independent variable, using logistic regression for dichotomous measures and Poisson regression models for count variables. Covariates were selected to account for known associations of sociodemographic and clinical status indicators with primary outcome measures. We adjusted for baseline status of dependent variables and covariates (age, sex, ≥3 chronic general medical conditions from a list of 18, education, race/ethnicity, family income < federal poverty level, 12-month alcohol abuse or use of illicit drugs at baseline, 12-month depressive disorder at baseline, and community). All analyses were conducted using SUDAAN Version 10.0 (http://www.rti.org/sudaan/) and accounted for clustering (clients within programs), weighting, and multiple imputations. Significance of comparisons by intervention status was based on regression coefficients. Results of logistic regression models are presented as odds ratios (OR) and Poisson models as rate ratios (RR) with 95 % confidence intervals. We illustrate results for intervention groups adjusted for covariates using standardized predictions generated from fitted regression models. [14] We present Cohen's effect size index h, defined for dichotomous variables,[15] where h=0.20 is small, h=0.50 is medium and h=0.80 is large. We supplement adjusted models with unadjusted raw data to assess

robustness. We applied a Bonferroni adjustment considering two primary outcomes (Poor mental health qualify of life MCS-12<=40, and at least mild depression PHQ-9>=10) and compared the proportion of results across outcomes favoring one intervention to an assumed null-hypothesis of 0.5.

Analyses for 12-month outcome: We conducted intent-to-treat analyses of repeated measures including all participants with available data at baseline, 6-, or 12-months by using SAS software version 9.2 (SAS Institute). We used a model-based approach with unweighted data. Initial explorations of 3-level, random-effects logistic models using SAS PROC GLIMMIX for binary outcomes yielded unstable estimates for program-specific random effects. [16, 17]

We analyzed dichotomous and count outcomes by using a generalized estimating equation (GEE) framework. [18] Specifically, we fitted logistic regression models for binary outcomes and Poisson models for count data using SAS PROC GENMOD, specifying exchangeable correlation at the program level, with regression adjustment for baseline covariates (age, sex, >=3 chronic conditions, education, race/ethnicity, family poverty, alcohol abuse or use of illicit drugs in the past 12 months, depressive disorder in the past 12 months, and community). We then developed a contrast involving a linear combination of coefficients to test intervention effects at each end point (baseline, 6 months, and 12 months) and tested differences between intervention groups in change from baseline to 6 and 12 months.

The results of analyses of binary outcomes are presented as odds ratios, and the results of Poisson regression analyses of count data are presented as rate ratios. We treated time as a continuous variable and examined the fixed effects for time and intervention, and their interactions. We included quadratic terms (squared effect of time and its interaction with the intervention) which allowed insight into whether changes are greater from baseline to 6 months or subsequent months.

In analyzing continuously scaled MCS-12 as the dependent variable, we used a 3-level, mixed-effect regression model by using SAS PROC MIXED. We accounted for the multilevel data structure with clients nested within pro-grams and repeated measurements nested within clients. To account for the intraclass correlation expected in the data, we specified random effects at the program level and an autoregressive covariance structure within clients to account for within-client correlation over time.

We conducted sensitivity analyses for alternative representations of time as a continuous or class variable and for alternative weighting approaches. To investigate possible nonignorable effects, we used 2 methods. For continuous measures (such as MCS-12 and number of service visits), we multiplied ignorable-model imputations alternatively by 1.1 and 0.9 to reveal sensitivity to 10% departures from ignorable-model predictions with dichotomized versions of continuous measures (MCS-12 <= 40) based on the imputed continuous value. For categorical imputations where reference cells were based on an underlying continuous measure (that is, predicted response propensity) including an indicator for any utilization and adjusted Bayesian bootstrap imputations reflecting unit nonresponse at a particular time point, nonignorable imputations for cases in nonboundary reference cells were generated by borrowing values from the reference cell with either the next higher or next lower value of the underlying continuous measure. [19] We also conducted 12-month endpoint analysis controlling baseline with weighting adjustment and presented standardized predictions. [2, 14]

Analyses for 3-year outcome:

We conducted 3 years endpoint analysis controlling baseline with weighting adjustment (see analysis strategy for 6 months). Given multiple secondary outcomes, [19] we built on the false-discovery-rate (FDR) framework [20] as extended by Yekutieli and Benjamini [21] and used both standard and FDR-adjusted p values (pFDR) in interpreting results across a large number of regression analyses. Results with pFDR <.05 are viewed as convincing evidence of a difference, and higher pFDR thresholds are considered as suggestive evidence. We separately calculated pFDR for the two primary outcomes, the community-prioritized outcomes, service use in the health care sector, service use in the social-community sector, medication use, and summary utilization indicators.

We conducted a longitudinal sensitivity analysis using all waves of data (baseline, 6-months, 12-months, 3-years) without response weights, adjusting for baseline covariates as in the primary analysis. We specified a spline model, with a linear segment between baseline and the first follow-up for initial improvement and another linear segment for the subsequent follow-ups; the two linear segments were specified to join at the first follow-up. In analyzing continuously scaled PCS-12 as the dependent variable, we used a 3-level, mixed-effects regression model by using SAS PROC MIXED. To account for the intraclass correlation due to the multilevel structure, we specified random effects at the program level and a spatial power covariance

structure at the client level to account for unequal spacing of waves. Initial explorations of 3-level, random-effects logistic models using SAS PROC GLIMMIX for binary outcomes yielded unstable estimates for program-specific random effects. We utilized a generalized estimating equation (GEE) framework with logistic regression models for binary outcomes and Poisson models for counts using SAS PROC GENMOD, specifying exchangeable correlation at the program level. From the estimated spline models, we developed a contrast involving a linear combination of coefficients to test intervention effects at each end point (baseline, 6-months, 12-months, and 3-years) and tested differences between intervention groups in change from baseline to 6 months, 12 months, and 3 years.

Exploratory analyses. The CPIC study had 2 primary outcomes: poor MHRQL (12-item mental health composite score, MCS-12<=40), and depressive symptoms (PHQ-8 >=10 or PHQ-2 < 3 for 4-year follow-up); and a community-prioritized outcome of mental wellness (a response of at least "a good bit of the time" in the previous 4 weeks to feeling calm or peaceful, having energy, or being happy), based on community input matched to the 36-item short-form health survey quality-of-life items. We developed 2 indicators: "clinical remission" (PHQ-8 < 10 or PHQ-2 < 3) and, with stakeholder input, "community-defined remission" (PHQ-8 < 10 or PHQ-2 < 3 or MCS-12 > 40 or any mental wellness). We also used a count of survey periods in remission from baseline up to 3-year follow-up. Intervention status was the client's program assignment at enrollment to CEP or RS.

For time (survey period) to first remission, we used Cox proportional hazard models for the full sample with any survey data (n = 1018), limited to those at risk for subsequent clinical (n = 995) and community-defined (n = 408) remission at baseline. We used linear regression for number of periods in remission during the course of 3 years for the full sample (n = 1018). We developed models including intervention status, adding social determinants, then depression treatment. [5]

<u>Analyses for 4-year outcome:</u>

We conducted intent-to-treat analyses with intervention status as the main independent variable, using logistic regression for probability of remission (clinical, community-defined) for the sample with 4-year data (n = 298). We conducted analyses parallel to the 3-year analyses noted previously, using the same covariates plus base-line measure of the outcome and the 1 baseline item differing by intervention status among 4-year completers. [5]

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Study Name:	Community Partners in Care (CPIC)
NCT Number:	NCT01699789

HSPC (RAND's Institutional Review Board)

HSPC Project ID:	w2812-06-01
Federalwide Assurance number (FWA):	FWA00003425
IRB number:	IRB00000051

Content:	**Informed consent forms**

Dates of Document

Screener:	2/16/2010
Enrollment:	2/16/2010
Three years:	10/2/2013
Four years:	2/29/2016

CLIENT ID

SCREENER CONSENT

We are asking you and over 7,000 other adults in Los Angeles County to participate in a 10 minute interview. The purpose of this interview is to see who may be asked to participate in a new research project.

WHO IS LEADING THIS RESEARCH PROJECT?

The name of the project is Community Partners in Care (CPIC). The project is carried out by community-based organizations led by Healthy African American Families, QueensCare Health and Faith Partnership, and the Los Angeles County Department of Mental Health Services, as well as the RAND Corporation and UCLA.

WHAT IS THIS INTERVIEW ABOUT?

- This short interview is a screening to see who may be asked to participate in a research project.
- During the interview, I will ask you about how you have been feeling and services you may be getting. I will also ask you questions to see if you have symptoms of depression or too much stress. By depression, we mean feeling sad, blue, feeling down, feeling less than, or feeling stressed almost all of the time and having other symptoms like poor concentration or poor appetite.

WHAT WILL WE ASK YOU TO DO?

- If you agree, we can complete the interview right here in a private place and it will take 10 minutes. You can either read it yourself or I can assist you if you would like. As a thank you, I will give you $5 in cash for completing this interview.
- There are no right or wrong answers. Based on your answers, we will know right away if I will talk with you about participating in the next part of the research project. I will explain that project and you can agree or refuse to participate in it at that time.

POTENTIAL BENEFITS

If you agree to be interviewed today:

- After the interview, we give everyone a CPIC Resource Guide which provides information on mental health and other services available in the community.
- The results of the research may help improve understanding of how to help people in the community who have depression.
- I will give you $5 as a thank you.

RISKS OF PARTICIPATION

- Answering some questions might upset or embarrass you. However, you can skip any questions you do not want to answer.
- If the results suggest you may be depressed, you might become concerned or worried; but this is only a screening. To determine if you might have depression or another problem that needs treatment, you would need to visit a provider for a clinical assessment.

CONFIDENTIALITY

- Any information you give us will only be used to a) find out if we might ask you to continue in the project and b) to help us describe the different types of people who agreed to be interviewed.
- Information you provide will be kept in locked file cabinets and in secure computer files. Only research staff will have access to these files.
- I will NOT ask for your name for this interview except for certain emergencies described below.
- If you are asked to participate in the main project and agree, I will ask for your name at that time.

While we don't ask about this subject, if you tell me that a child or elderly person is being abused, I will ask for your name and must report this to my supervisor who may then report it to the appropriate authorities. If you tell me you might harm yourself or others, I will ask for your name and I may give information about you to people who could help protect you from that harm, which could include needed medical attention. A project clinician or provider might also call you if you tell me you might harm yourself or others.

COSTS

There is no cost to you for participating in this interview.

PARTICIPATION IS VOLUNTARY

You do not have to participate if you do not want to. You can skip any question or stop the interview at any time. You may drop out of the project at anytime. Your choice about being in this project will not affect the care or services you are receiving in any way. Participation will have no effect on decisions about probation, parole, detention or sentencing, if any apply to you.

WHO CAN YOU CONTACT?

- Judy Perlman is the CPIC Survey Director at RAND and can be reached at (310) 393-0411 x7811. Our toll free number for CPIC is (877) 499-7411.
- Dr. Kenneth Wells is the Principal Investigator at RAND and can be reached through the CPIC project coordinator, Esmeralda Ramos and can be reached at (310) 794-3719.
- If you have questions regarding your rights as a research subject, contact Marilyn Yokota at the RAND Institutional Review Board at (310) 393-0411 x6369.
- You may contact the LA County Department of Mental Health Research Committee at (213) 738-4600.
- You can have a copy of this information sheet.

CPIC STAFF USE ONLY

My signature indicates that I have explained the research to the person and answered all of his/her questions and that I believe he/she understands the information described in this document.

NAME:_____ SIGNATURE:_____

DATE:_____

CLIENT ID

ENROLLMENT CONSENT
CONSENT PROVIDED BY SIGNATURE ON-SITE OR ORALLY BY PHONE

WHY HAVE YOU BEEN SELECTED?

You were selected for the main project because you reported some symptoms of depression or stress in the short screening interview. Many problems and stresses can cause similar symptoms. Only a provider who has done a clinical assessment can tell whether you have depression or another health issue that might benefit from treatment.

WHAT WILL WE ASK YOU TO DO?

For this research project we will ask you to:

1. Complete a 1 hour telephone interview in the next two weeks for which we will give you $15 to thank you for your time.
2. Complete another interview in 6 months and one more in 12 months. You will receive $20 for the 6-month interview and $25 for the 12-month interview to thank you for your time. We may ask you to participate in additional interviews past 12 months but you can choose whether or not you wish to at that later time.
3. Give us your telephone number and other ways to contact you so we can do the telephone interviews.
4. We may ask you to participate in related research regarding services you received, but you can choose whether or not you wish to at that later time.

WILL CPIC GIVE YOU TREATMENT AS PART OF THIS PROJECT?

No, the project does not provide treatment. The project can only give you a list of places where you can go to receive treatment. It is up to you to decide if you want treatment. We cannot guarantee that any agency on this list can take you for treatment, or take you quickly.

If you get assessed or treated for depression, it may be important for you to discuss what goes into your written record with your provider. This is important because some private insurance companies sometimes deny coverage or set prices based on an individual's treatment history.

BENEFITS OF PARTICIPATING IN THIS PROJECT

- Some people find the interviews interesting and helpful in their understanding some of their feelings.
- You might receive information about depression that might help you or someone you know.

RISKS OF PARTICIPATING IN THIS PROJECT

- If you participate in this project, you might seek services that you did not consider before.
- You might be embarrassed by some of the questions we will ask you during the interview.

CONFIDENTIALITY

- All the information you give us for this project will be kept confidential. Information you provide will be kept in locked file cabinets and in secure computer files. Only research staff will have access to these files.

- The only exceptions are: while we don't ask about this subject, if you tell me that a child or elderly person is being abused, I must report this to my supervisor who may then report it to the appropriate authorities. If you tell me you might harm yourself or others, I will give information about you to people who could help protect you from that harm, which could include needed medical attention. A project clinician or provider might also call you if you tell me you might harm yourself or others.
- The project has received a Certificate of Confidentiality from the National Institutes of Health which gives participants the added protection that we do not have to release information about individuals from this project even under court order.
- In some cases, we may give your contact information to a staff person at a service agency. This person may contact you about a visit with them or refer you to another agency.

PARTICIPATION IS VOLUNTARY

You do not have to participate if you do not want to. You can skip any question or stop the interview at any time. You may also drop out of the project at anytime. Your choice about being in this project will not affect the care or services you are receiving in any way. Participation will have no effect on decisions about probation, parole, detention or sentencing, if any apply to you.

WHO CAN YOU CONTACT?

- Judy Perlman is the CPIC Survey Director at RAND (310) 393-0411 x 7811. Our toll free number for CPIC is (877) 499-7411.
- Dr. Kenneth Wells is the Principal Investigator at RAND and can be reached through the CPIC project coordinator, Esmeralda Ramos at (310) 794-3719.
- If you have questions regarding your rights as a research subject, contact Marilyn Yokota at the RAND Institutional Review Board at (310) 393-0411 x 6369.
- You may contact the LA County Department of Mental Health Research Committee at (213) 738-4600.
- You can have a copy of this information sheet.

SIGNATURE OF RESEARCH PARTICIPANT

My signature indicates that I have read (or someone has read to me) this consent form and that I understand the information. Any questions that I have asked have been answered, and I agree to take part in the telephone interviews.

YOUR NAME: _____

YOUR SIGNATURE: _____

DATE: _____

Community Partners in Care

- **Please check off each statement after you read it.**
- **YOU CAN KEEP THIS FORM**

Things you should know about the project:

☐ **1. We are asking you to complete a one hour telephone interview in the next two weeks, another in 6 months, and another in 12 months. Each interview will last about an hour. We will pay you $15 for the first interview, $20 for the second, and $25 for the third.**

☐ **2. We are asking you to participate in CPIC because you reported symptoms of feeling sad, depressed, or stressed.**

☐ **3. You don't have to be in this project. You can leave the project at any time.**

☐ **4. If you do not want to be in the project, the care or services you are receiving will not change.**

☐ **5. Participation in CPIC will have no effect on decisions about probation, parole, detention or sentencing, if any apply to you.**

☐ **6. We might tell a provider or staff member at the agency where you completed the short interview that you are enrolled in CPIC.**

☐ **7. You could be contacted by someone at that agency or a partner agency about further services available to you.**

☐ **8. You will be given a CPIC Resource Guide for places to go for services. It is up to you to decide whether to go and where to go.**

☐ **9. CPIC cannot guarantee that you will get an appointment for an assessment or what services you will receive.**

☐ **10. Do you have any questions?**

☐ **11. Do you agree to be in this project?**

Want to Know More?

We are only asking you to participate in telephone interviews, but you may be wondering why we are doing this project or what is going to happen during the project. This sheet will give you more information about CPIC.

WHAT IS THE MAIN PROJECT ABOUT?

This project compares **two different ways** of supporting community-based agencies in providing services for depression. All participating agencies are being provided with some help. Some agencies are supported independently by the project to provide care for depression. Other agencies are supported to **work together** as a group to improve services. For example, they might share resources or staff.

Agencies are placed in the individual support or group planning by chance, like a coin toss, also called randomization. Regardless of which support program they are in, all agencies are free to use or not to use the resources provided by the project.

The resources provided by the project support education, assessment, and treatments that are proven to help people with depression. There are no new or experimental treatments being supported in the project.

The agency that you are in now has been assigned to one of the two ways we mentioned above for improving services.

- You are free to tell a provider or staff member at this agency about your participation in this project if you wish.
- The provider or staff member at this agency is free to work with you using resources from the project or to follow their usual procedures.

If this agency has been assigned to the **group planning** model for improving services, you may receive a follow-up call or be asked to return for a visit at either this agency or another agency from the group of agencies working together. That is the main way that you will learn that your agency is in the group-support program.

Regardless, you will be able to visit or use agencies in your community and receive services as you normally would. You and your providers will also be able to choose whether or not to use any resources from this project that are offered to you. That is, these resources may be new options that you can choose to use or not.

Either way, all agencies have support from the information and resources provided by the project to help people with depression in some way. We hope to learn whether it is better for agencies to do their best by **themselves** or to spend the time **working together**, and that is why the project is being conducted by community and academic partners. We will use the results of the project to share what we learned together about how to improve depression services in the community.

Community Partners in Care
40-Month Interview Consent Script

Hello, my name is [INTERVIEWER NAME] and I'm calling from RAND about Community Partners in Care to speak with [NAME].

You may remember that you completed a telephone interview with us some time ago. Thank you for doing that. I am calling now to conduct another interview with you. The interview will take about 30-35 minutes depending on your experiences and we will send you a $40 gift card as a thank you.

We sent you a letter to let you know we would be calling. Did you receive that letter?

IF YES: Great. First I need to confirm that I'm speaking to the right person. What is your date of birth?

IF MATCHES → GO TO intro
IF DOB DOES NOT MATCH → GO TO dobprob

IF NO: No problem. The letter explained that in the interview, we will be asking you some questions about your health and how you have been feeling lately, as well as your experiences using community services.

First I need to confirm that I'm speaking to the right person. What is your date of birth?

IF MATCHES → GO TO intro
IF DOB DOES NOT MATCH → GO TO dobprob

>dobprob<
That does not match the date listed in our records. Is this (RESPONDENT NAME)?

<1> YES, DOB MATCHES → GO TO intro
<2> YES, BUT DOB DOES NOT MATCH → GO TO dobprob2
<3> NO, WRONG PERSON → END CALL.

>dobprob2<
I cannot continue the interview if the dates do not match. I need to speak to my supervisor. Someone will call you back when we have more information. → END CALL.

>intro<
Thank you. Next, I need to go over a few important points with you.

You were selected for this interview because you reported some symptoms of depression or stress in a past CPIC interview. Many problems and stresses can cause similar symptoms. Only a provider who has done a clinical assessment can tell whether you have depression or another

health issue that might benefit from treatment. Because you participated in a past interview, we want to follow up with you and see how you are doing now. We want you to know that the information you can give us is important, but you do not have to take part in this study. Everything you tell us is confidential. The only exceptions are: although I will not be asking questions about this, if you tell me that a child or elderly person is being abused, we may report it to the appropriate authorities. If you tell me that you might harm yourself, I will give information about you to people who could help protect you from that harm, which could include needed medical attention. A project clinician or provider will likely call you if you tell me you might harm yourself or others.

You can skip any question you do not want to answer or stop the interview at any time. Information you provide will be kept in locked file cabinets and in secure computer files. Only research staff will have access to these files. That means we will not tell anyone outside of the study your answers.

* The project has received a Certificate of Confidentiality from the National Institutes of Health which gives participants the added protection that we do not have to release information about individuals from this project even under court order.
* In some cases, we may give your contact information to a staff person at a service agency. This person may contact you about a visit with them or refer you to another agency.

There are phone numbers to call if you have questions about this study or your rights. Would you like me to give you those numbers now?

IF YES: Judy Perlman is the CPIC Survey Director at RAND. You can reach her at 310-393-0411 x 7811. Dr. Kenneth Wells is the Principal Investigator at RAND and can be reached through the CPIC project coordinator, Esmeralda Ramos, at (310) 794-3719.

IF NEEDED: If you have questions regarding your rights as a research subject, contact the RAND Human Subjects Protection Committee at (310) 393-0411 x6369. You may also contact the LA County Department of Mental Health Research Committee at (213) 738-4611.

Do you agree to take part in the telephone interview?

IF YES → START INTERVIEW.

CPPRN Enrollment Consent Script

Hello, my name is [INTERVIEWER NAME] and I'm calling from RAND about Community Partners in Care to speak with [NAME].

You may remember that you completed a telephone interview with us some time ago. Thank you for doing that. I am calling now to conduct another interview with you. The interview will take about 15-20 minutes depending on your experiences and we will send you a $20 gift card as a thank you. We also would like to discuss another project with you, and will send you an additional $5 gift card as a thank you for taking the time to consider that project, regardless of whether you agree to participate.

We sent you a letter to let you know we would be calling. Did you receive that letter?

IF YES: Great. First I need to confirm that I'm speaking to the right person. What is your date of birth?
IF MATCHES → GO TO intro
IF DOB DOES NOT MATCH → GO TO dobprob

IF NO: No problem. The letter explained that in the interview, we will be asking you some questions about your health and how you have been feeling lately, as well as your experiences using community services.

First I need to confirm that I'm speaking to the right person. What is your date of birth?

IF MATCHES → GO TO intro
IF DOB DOES NOT MATCH → GO TO dobprob

>dobprob<
That does not match the date listed in our records. Is this (RESPONDENT NAME)?

<1> YES, DOB MATCHES → GO TO intro
<2> YES, BUT DOB DOES NOT MATCH → GO TO dobprob2
<3> NO, WRONG PERSON → END CALL.

>dobprob2<
I cannot continue the interview if the dates do not match. I need to speak to my supervisor. Someone will call you back when we have more information. → END CALL.

Thank you for participating in CPIC! Because you participated in a past interview, we want to follow up with you and see how you are doing now. This interview will take about 15-20 minutes.

We want you to know that the information you can give us is important, but you do not have to take part in this interview. Everything you tell us is confidential. The only exceptions are: although I will not be asking questions about this, if you tell me that a child or elderly person is being abused, we may report it to the appropriate authorities. If you tell me that you might harm yourself, I will give information about you to people who could help protect you from that harm, which could include needed medical attention. A project clinician or provider will likely call you if you tell me you might harm yourself or others.

You can skip any question you do not want to answer or stop the interview at any time. Information you provide will be kept in locked file cabinets and in secure computer files. Only research staff will have access to these files. That means we will not tell anyone outside of the study your answers.

The project has received a Certificate of Confidentiality from the National Institutes of Health which gives participants the added protection that we do not have to release information about individuals from this project even under court order.

START INTERVIEW.

END INTERVIEW

Now, we would like to take a few minutes to invite you to participate in a new program of research called Community and Patient Partnered Research Network, or CPPRN for short. CPPRN is part of a national network called PCORnet, working to improve through research the information available to patients, providers and communities, about health and healthcare decisions that affect them. CPPRN is focused on under-resourced communities and behavioral health and social issues such as stress, sadness, resiliency, housing, and jobs. CPPRN is a joint effort across Los Angeles and New Orleans. If you can take a few minutes to hear our invitation to participate in CPPRN, we will send you a $5 gift card as a thank you. This is in addition to the $20 gift card you will receive for participating in the interview. Would you like to hear about the CPPRN program?

IF NO: [Proceed to questions about contact information and sending the $20 gift card, if they completed an interview.]

IF YES: CPPRN is setting up a program of research to understand people's priorities for health and healthcare about behavioral health and social factors like housing. People can participate in CPPRN by providing information on their priorities as well as some information about their background and health.

If you agree to participate in CPPRN, we will ask you to let us use the contact information you gave to CPIC, your information from today's CPIC survey and some data from prior CPIC surveys for the new CPPRN. We will use these data to determine if you are eligible for other

studies of ours or of other PCORnet programs, as they come up, and then contact you either by our CPPRN staff or lead investigators of the other PCORnet programs about those studies. We also may contact you in the future to ask permission to obtain information on services use from your providers for any health, mental health, or social services. For any of these requests, you can choose whether or not to give us permission at that time. While this will take some of your time to participate, we hope it may be meaningful to be part of a new national set of programs working to provide better information for patients, providers and communities. Any information we obtain will only be used for research purposes and will be presented anonymously, that is without naming you.

Do you agree to be part of the CPPRN?

IF YES: Great.

Do you have any questions about CPPRN?
Just to confirm, you have agreed to be part of CPPRN, are willing to be contacted for future studies, and agree that we can use your information from CPIC in combination with other's information, without naming you. Correct?

IF NO: OK, thanks. Would you still like to be on a contact list for other activities in the CPPRN, such as having access to our website or giving opinions on health issues? IF NO THANK RESPONDENT AND GO TO SECTION ON SENDING THE $20 AND $5 GIFT CARDS.

IF YES: Great. (ASK FOR UPDATED CONTACT INFORMATION)

GET CONTACT INFORMATION

I really appreciate your patience and honesty. I need to get some information to help us contact you in the future.

NAME
We have your name as [FILL R NAME]. Any other names you go by?

@a_____OTHER NAMES/ALIAS

MAILADD
What is your mailing address? This is the address we will send your gift card to. Please allow 3-4 weeks for processing.
_____ STREET ADDRESS
(C/O, Apt.)
_____ CITY

_____ STATE
_____ COUNTRY
_____ ZIPCODE

SAMEADD
Is your mailing address the same as your home address?

1 YES à GO TO HPNUM
0 NO

HOMEADD
What is your home address?
_____ STREET ADDRESS
(C/O, Apt.)
_____ CITY
_____ STATE
_____ COUNTRY
_____ ZIPCODE

HPNUM
What is your correct home telephone number, including area code?

|__|__|__| (Area Code) |__|__|__| - |__|__|__|__|

ENTER 000-000-0000 IF NO PHONE
ENTER r if REFUSED

HPLIST
Is this telephone number listed in your name?
INTERVIEWER: IF NO HOME PHONE CODE YES
1 YES à GO TO CPNUM
0 NO

HPNAME
In whose name is the telephone number listed?
[INTERVIEWER: WRITE FULL NAME VERBATIM. CHECK WITH R TO MAKE SURE YOU HAVE FULL NAME AND CORRECT SPELLING]
_____ (VERBATIM-LIMITED)

CPHONE

Do you also have a separate cell phone number?
1 YES
0 NO à GO TO EMAIL

CPNUM
What is your correct cell number, including area code?

|__|__|__| (Area Code) |__|__|__| - |__|__|__|__|
ENTER r if REFUSED

HEMAIL
Do you have an e-mail address you use?
1 YES
0 NO à GO TO CONT1a

HEMAILAD
What is this e-mail address?
_____@_____ (END SHOULD BE .com, .edu, .gov, .net, .org)

CONT1a
In case we have difficulty getting in touch with you in the future, could you give me the name, address, and phone number of one person not currently living with you who will always know your whereabouts? PROBE: This might be a family member or a close friend or someone else who knows where you are. IF NECESSARY: We would only get in touch with this person if we could not reach you.

What is this person's name?

_____NAME

ENTER 0 IF REFUSED AND GO TO INPUT

CONT1b
How is this person related to you?
DO NOT READ ANSWERS. CODE R'S RESPONSE.
INTERVIEWER NOTE: THIS SHOULD BE A PERSON NOT CURRENTLY LIVING WITH R
1. MOTHER
2. FATHER

3. STEPMOTHER
4. STEPFATHER
5. GRANDMOTHER
6. GRANDFATHER
7. DAUGHTER
8. SON
9. AUNT
10. UNCLE
11. SISTER (INCLUDING HALF SISTER, STEP SISTER)
12. BROTHER (INCLUDING HALF BROTHER, STEP BROTHER)
13. OTHER RELATIVES
14. FRIEND
15. COWORKER
16. OTHER, SPECIFY-LIMITED _____

CONT1c
What is his/her address?
_____ (ADDRESS)
(C/O, Apt.)
_____ (CITY)
_____ (STATE)
_____ (COUNTRY)
_____(ZIP)

CONT1d
What is his/her home phone number?
(__ __ __) __ __ __ - __ __ __ __ EXT. __ __ __ __ (PHONE NUMBER)

CONT1e
How about a cell phone number?
(__ __ __) __ __ __ - __ __ __ __ (CELL PHONE NUMBER)
ENTER 000-000-0000 IF NO CELL NUMBER
ENTER r IF REFUSED

INPUT
Those are all the questions I have for you. Thank you for participating.

GET INFORMATION ON BEST WAY TO SEND GIFT CARDS

I also wanted to let you know that there are phone numbers to call if you have questions about the CPPRNs study or your rights. Would you like me to give you those numbers now?

IF NEEDED: Dr. Kenneth Wells is the Principal Investigator of CPPRN at RAND and UCLA and can be reached through the CPPRN project coordinator, Krystal Griffith, at (310) 794-2967.

IF NEEDED: If you have questions regarding your rights as a research subject, contact the RAND Human Subjects Protection Committee at (310) 393-0411 x6369.