Using a Community Partnered Participatory Research Approach to Implement a Randomized Controlled Trial: Planning the Design of Community Partners in Care

Bowen Chung, MD, MSHS, **Loretta Jones, MA**, **Elizabeth L. Dixon, RN, PhD**, **Jeanne Miranda, PhD**, **Kenneth Wells, MD, MPH**, and **Community Partners in Care Steering Council**
and **Kenneth Wells** are affiliated with the RAND Corporation in Santa Monica, Calif. and the Jane and Terry Semel Institute and Dept. of Psychiatry and Biobehavioral Sciences, David Geffen School of Medicine at the University of California at Los Angeles (UCLA). **Loretta Jones** is affiliated with Healthy African American Families II. **Elizabeth Dixon** is affiliated with QueensCare Health and Faith Partnership. **Jeanne Miranda** is affiliated with the Semel Institute and Dept. of Psychiatry and Biobehavioral Sciences, UCLA

Summary

Quality improvement programs for depression in primary care can reduce disparities in outcomes. We describe how community-partnered participatory research was used to design Community Partners in Care, a randomized trial of community engagement to activate a multiple-agency network *versus* support for individual agencies to implement depression QI in underserved communities.

Keywords

Major depression; quality improvement; community-based participatory research; health disparities; intervention studies; minority health

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> *Community…is… about where you live – where there are lots of diverse people — some you like, some not – but you have to respect them all.*
>
> —Participant at dinner sponsored by QueensCare Health
> and Faith Partnership

Depression is a common health condition, associated with limitations in multiple domains of daily functioning.[1-4] Minority groups have lower rates of appropriate care for depression than Whites.[5-12] There are evidence-based programs based on the collaborative care model that improve quality of care for depressed primary care patients. The Partners in Care study found such programs can improve health outcomes for minorities over 5-10 years, leading to reducing outcome disparities relative to Whites, in addition to improving employment over two years. [13-18] Implementation of these interventions is challenging in underserved urban communities due to limited resources.[19] To explore how to promote implementation of such programs to improve depression care in underserved communities, a community-academic partnership was established based on the principles and structure of community-partnered participatory research (CPPR). CPPR is a variant of Community-Based Participatory Research (CBPR) that emphasizes true power sharing and collaboration in all phases of research.[20] CBPR is a well-

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established approach recommended as a method to address health disparities by enhancing trust in research and engaging minorities around health issues.[21-26] The CPIC study is designed to reflect the three phases of a CPPR initiative (Figure 1).[29-32] Such a partnership led to the Witness for Wellness (W4W) initiative, a large intervention development project to develop community-driven strategies to reduce stigma, improve services quality, and promote policies to reduce the burden of depression in South Los Angeles.[27-31] W4W demonstrated underserved, urban minority community members view depression as an issue of collective concern, particularly when information is presented using culturally relevant approaches, such as the arts.[27,31] There are few randomized trials of community engagement compared with other strategies [32-34] and none that we are aware of attempting to improve depression care or outcomes in underserved communities.

In this paper, we describe the design-planning phase (Vision) of a randomized trial, Community Partners in Care (CPIC), which like W4W was also conducted using CPPR principles and structure. At the time of writing this article, the study is transitioning to the implementation of the trial itself (Valley).

The randomized trial, CPIC, compares a low impact intervention, Resources for Services (RS) with a CPPR planning process, Community Engagement and Planning (CEP), as approaches to implement depression care in agencies and programs. The study assesses the impact of the different implementation approaches on community agency administrator, provider and client outcomes for depression. Both RS and CEP groups are exposed to an initial conference that trains recruited agencies, programs, and providers in the CPIC toolkit, consisting of components found in a depression collaborative care model, which includes care management support, medication management training, cognitive behavioral therapy, and administrator support for implementation. RS adds to the initial community conference by providing four, 90 minute technical assistance phone calls to agency administrators and providers on how to implement elements of collaborative care for depression in their agencies. CEP initiates a community planning process to develop a community wide plan for depression care, based on the materials presented at the initial CPIC Conference. The elements of a community plan for depression care are: screening, patient education, care management, and referrals for medications and therapy.

CPPR

CPPR has a structure, a set of principles, and a staged implementation approach assuring equal participation and leadership of community and academic partners while promoting capacity development and productivity. The structure consists of a steering council of relevant stakeholders, co-chaired by community and academic leaders. The council supports several workgroups that develop and implement action plans, approved by broader community input through large community forums. This structure facilitates respect for community and academic expertise ensuring Community Engagement principles (e.g., power-sharing, mutual respect, two-way capacity building) are integrated with scientific rigor. Much effort in a CPPR initiative is spent building and maintaining relationships through sharing perspectives and joint activities. Both partnership structures and principles are reinforced in a memorandum of understanding signed by all partners. CPPR initiatives have three phases. The CPIC study is designed to reflect the three phases of a CPPR initiative (Figure 1).[35-44]

Phase one is the partnered planning of the initiative (Vision), the subject of this article. Phase two is the randomized trial (Valley), which from a community perspective is a pilot to determine what works in the community. Phase three is the initiation of community dissemination beyond agencies in the trial phase based on a partnered analysis of the trial's

results (Victory). Each phase has a cycle of activities that we refer to as the *plan-do-evaluate cycle*.

The community engagement intervention uses a W4W-like structure and set of principles to develop community-based strategies to implement the same toolkits in a culturally appropriate manner. We planned to recruit 60-80 agencies/sites across South Los Angeles and Hollywood-Metro Los Angeles. From these sites, we planned to recruit 60-100 administrators, 150-200 providers. We proposed to approach 6,000 clients in those agencies about being screened for depression, and planned to enroll about 500 that screened as potentially having depression. We plan to examine quality of depression care and depression outcomes at six months for clients and changes in use of toolkits, depression resources and services provision, and attitudes and knowledge about depression care, at 12 and 24 months for providers and administrators.

Leadership structure

The leadership body for the design phase was the CPIC Steering Council, which comprises community-based agencies and academic institutions that agreed to provide the leadership for the initiative. Council members for the Vision phase are listed in the Acknowledgements. The lead academic partners for this initiative were RAND Health (RAND) and the UCLA Health Services Research Center (UCLA). The lead community partners were Healthy African American Families II (HAAF), QueensCare Health and Faith Partnerships (QHFP), the Los Angeles County Department of Mental Health (LAC DMH), and Behavioral Health Services. All study decisions are considered and voted upon by the CPIC Steering Council which meets twice monthly, communicating via conference and e-mail as needed.

The CPIC Steering Council focuses on study goals, project oversight and planning, budget allocation, and partnership development. Much of the work for CPIC is delegated to subcommittees of academic and community partners. The CPPR working groups for the Vision (design) phase were the CPIC Council's design committees. The CPIC committees, meeting frequency, and tasks are summarized in Box 1.

All study protocols were approved by the RAND Institutional Review Board (IRB) including the documentation of the Vision phase. UCLA deferred review to RAND under a joint IRB deferral memorandum of understanding.

Community input into CPIC design

Box 2 summarizes elements of the CPIC design, highlights input from community members (through Council or committee meetings, or the broader community dialogue or policy board input) and describes design adaptations approved by the Council.

Study measures

The study data are from administrators, providers, and clients; they were collected at baseline and two follow-up time points (6 and 12 months for clients; 12 and 24 months for providers and administrators). The study obtained qualitative data on implementation from meeting minutes, items within the main surveys, and other sources (see Figure 1). A summary of key constructs for client, organizational, implementation, and provider measures is found under "Community Capacity for Mental Health Planning" in Figure 2. Council community leaders interest in sustainability of change at the organizational level led to a proposal to add a wave of administrator and provider surveys (changing outcome from 18 months to 12 and 24).

Randomized trials designed under CPPR can enhance relevance and community ownership while maintaining scientific rigor. Over the last six years, our community-academic partnership

developed the design for a randomized comparison trial, using a CPPR approach. Our partnership strove to develop the study to improve the quality of data to inform community planning about how best to improve services for depression in underserved communities and to provide data to the scientific community on the effectiveness of community engagement as an intervention strategy to promote evidence-based care for depression. We found that using a CPPR approach in the design phase (Vision) led to many changes in study design that potentially improve the fit of the study with community priorities (e.g., aligning community boundaries with existing county service planning areas), as well as enrich the study's potential scientific contributions (e.g., through expanded outcomes of community and policy relevance). Moreover, some of the changes, such as shifting the time of randomization to after the kick-off conference introducing the clinical intervention toolkits, improved internal validity by removing a potential source of bias (knowledge of intervention assignment, which could have led to differential conference attendance by intervention condition).

The strengthening of the study's overall focus on community engagement across intervention conditions, while potentially reducing the difference between intervention conditions, has improved the community support for the study. At the time of manuscript submission, we are moving from the Vision (phase 1) to the Valley (phase 2) of this CPPR initiative. To date, we have recruited 110 agency programs and sites, having randomized 74 in South Los Angeles to the two study conditions.

Overall, the changes to the design and measures in response to community input improved the external validity of the study such as including more vulnerable populations (such as people who are homeless), enhancing its relevance for underserved communities, while increasing study scope and costs. By structuring the study to respond to community input regularly, this initiative attempts to fulfill its mission as a community capacity-building and program development activity.

The CPIC design is complex, including multi-level sampling and group-level randomization. Participation in the study places a considerable demand on participating agencies without directly compensating them for services in a declining economy. Even though the scope of the randomized phase of the study in any one agency is relatively small, the economic depression in California, with a record 11.2% unemployment rate, has severely strained safety-net agencies, many of which have lost staff and infrastructure support while facing increased community needs.[45,46] Yet, we have learned while both participating and non-participating agencies are concerned about the implications of participation, most agree with the importance of the study goals and appreciate the spirit of collaboration offered in the project.

The CPIC study is community-owned, in that the community is contributing time and effort and is not directly compensated. Some design features, nevertheless, make CPIC a good fit with community priorities. For example, the study supports a choice-based model, in which agencies, providers, and clients are supported in deciding which depression treatments they prefer, if any. Participants can refuse to use any intervention resources and remain in the trial. This means the study will generate findings about the effects of feasible implementation strategies, a different goal than understanding the effects of optimal treatment under a strict protocol. Because of the community's risk-taking and investment in participation, we hope that the study findings will provide important information to the community about what their collaboration achieves in terms of client and community member outcomes.

Because it takes time to obtain partnership input, studies like CPIC take time to design and revise.[20-25,29-32] Despite the greater complexity of decision making, the colead CPIC committee composition and structure makes the consideration and adjustment of study protocols feasible.

Our partnership's focus has been on clinical depression, a topic that has drawn a high level of interest from all community participants, some of whom have personal concerns about depression. These distinct voices add a personal urgency to the social justice perspective of CPPR, and motivate the partnership to work hard to achieve our goals. Cashman *et al.* suggested that including community partners in data analysis and interpretation can enrich insights on the findings for academic and community partners.[47] Building on this theme, we hope that participation of diverse stakeholders in the CPIC initiative yields findings supporting sustainable improvements in depression outcomes in our communities.[48]

Box 1: CPIC Committees, Meeting Frequency, and Tasks

Committee	Meeting Frequency	Tasks
Steering Council	2 × / month	Study Goals Project oversight and planning Budget Allocation Partnership Development
Design	2 × / month	Sampling Design Randomization procedures
Operations and Recruitment	1 × / week	Day-to-day project management Agency, program, administrator, provider, client recruitment Survey administration and data collection
Implementation Evaluation	2 × / month	Training and Conference Evaluation CEP Workgroup Evaluation Evaluation of agency implementation of CEP & RS Plans
Measures	As needed	Administrator, provider, and client survey development
Community Engagement and Planning	1× / month	Development of CEP manual for use in CEP Workgroups Oversees CEP workgroups, CEP plan development and CEP trainings
Clinical Services Intervention	As needed	Oversees PIC training and supervision for administrator and providers (cognitive behavioral therapy, medication management, care manager)

Box 1: Adaptations to Design Based on Community – Academic Partnered Solutions

Design Component	Original Study Goal	Community Feedback	Partnered Solution
Study Goals	To demonstrate effectiveness of a community engagement and planning approach to disseminating evidence-based programs to improve depression care, versus technical assistance.	The win for agencies is not clear. Technical assistance suggests that study leaders are experts and not the community.	Study re-framed to offer two-way knowledge-exchange: 1) resources (academic and community) for individual agencies to improve services for depression; 2) those resources plus a mulit-agency community-academic planning process to promote sharing resources and adapting programs to the community to expand the reach of programs to all. We also emphasized the

Design Component	Original Study Goal	Community Feedback	Partnered Solution
			post-trial dissemination phase.
Sampling Design and Procedures			
Definition of Community	Hollywood and South Los Angeles.	Base on Los Angeles County service areas but also follow clients along referral lines.	Expand to include full county service planning areas plus surrounding areas; study priorities for agency recruitment based on community knowledge of use and referral patterns;
Agency Sample	Primary care/ community clinics, mental health clinics, Social service agencies	Expand locations to include "community trusted locations"	Expand to include churches and church health fairs, community centers and senior centres of parks and recreation, barber/ beauty shops, women's gyms
Provider Sample	Service providers and case workers in recruited agencies	A range of leaders in the community and staff at agencies can influence clients	Expand to include faith-based leaders, community center program staff, staff at other community locations such as exercise clubs
Patient/Client Sample	Adults receiving services in established agencies.	Include the most vulnerable community members if possible and those not receiving services.	Agencies added that serve transitional age youth, elderly, homeless, and prison/jail release populations.
Randomization Procedure	Group-level (site, program, or clinical team as unit), randomized controlled (comparison) design with assignment to resources and encouragement for services (choice-based model); wait list for effective intervention at dissemination phase; randomization before kickoff conference	Choice-based model (agencies, providers, and clients are free to choose treatments or no treatment) and wait list for resources are valued types of design in the community. Acceptability of randomization in the community remains somewhat uncertain.	Provide clear explanations of this complex design (transparency). Involve community partners in implementing the randomization procedure. All respondents are free to participate or not as they choose. Those who do not want services or choose the treatments can remain in the study. Randomization will take place after kick-off conference.
Theory Basis of Intervention Implementation Evaluation	Diffusion of Innovation Theory, Quality improvement frameworks, Organizational Learning, Communities of Practice	Use community knowledge of services, practice, and populations; select theories that reflect the group or community values	Expand theory to include Collective Efficacy. Expand community input into concepts based on the principles of Community-Partnered Participatory Research.
Intervention Design			

Design Component	Original Study Goal	Community Feedback	Partnered Solution
Resources for Services	Standard components of collaborative care for depression: Resources for primary care providers, nurse care managers, psychotherapists and counselors, patient education and activation, tracking and coordination, and team management/quality review	Resources are limited, especially primary care clinician time for training and services; few community clinics have available nurse or other trained staff for care manager roles	Train-the-trainers approach to training; identify potential community leaders for training early on. Simplify and clarify care manager materials for a range of staff levels
Community Engagement and Planning	Manual to guide use of action plans to review resources and adapt for agencies, plan trainings, and develop a collaboration plan	Communities of color may be reluctant to engage in more traditional or Western treatment models Many value alternative therapies Community-trusted locations such as parks do not have staff with clinical backgrounds; develop outreach.	Collaborate with community agencies to identify cultural competence resources Identify outreach models for mental health and supplement with locally-developed materials for diverse cultural groups
Outcome Measures (Clients)	See Figure One	Relevance of economic stress and strain with job losses Other outcomes of interest such as housing stability	Expand to include employment status/workforce participation outcomes; and housing, recent victimization, and other common sources of stress in the community
Survey payments	Checks	Many community members do not use banks, and check cashing locations charge fees.	Cash or gift cards instead of checks.

Box 2: Timeline of Intervention Planning and Training Activities

CPIC Kick-Off Conference (participants)	Timeframe	Activities	Resources
RS CEP	One day	Overview of CPIC materials	**Introductory Materials:** Improving Depression Outcomes in Primary Care: A User's Guide to Implementing the Partners in Care Approach (PIC); **Training Materials:** Training Agendas and Materials for Expert Leaders, Depression Nurse Specialists, and Psychotherapists, Videotape of Nurse Specialist Assessment; **Materials for Primary Care Physicians & Care Managers:** Clinician

CPIC Kick-Off Conference (participants)	Timeframe	Activities	Resources
			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) including relapse prevention plan. All PIC / We Care materials have been culturally and linguistically adapted for African American and Latinos.
Resources for Services (participants)			
RS	same timeframe as CEP Intervention (18 months)		Training resources from CPIC Kick-Off Conference and technical assistance follow-up phone calls on medication management, cognitive behavioral therapy, care management
Community Engagement and Planning Orientation (Participants)			
CEP	Two hours	Introduction to goals and resources of intervention condition	CEP Manual, Sample Action Plans, CPIC Organizational Plans
Community Engagement and Planning Workgroups (Participants)			
CEP	Two meetings per month for Four to Five months	Workgroups will develop a written plan for coordinated delivery for depression for implementation in the pilot phase.	In addition to the materials in CEP orientation, the workgroups will receive administrative support and small pilot funds to develop plans.
Community Engagement and Planning Training (Participants)			

CPIC Kick-Off Conference (participants)	Timeframe	Activities	Resources
CEP	One day – to be modified by the CEP workgroups	Training based on CEP workgroup planning and adaptation of materials from PIC / WE Care	Community Plan and Adapted materials from Initial CPIC Kick-off Conference
Pilot Implementation (Participants)			
CEP	One year	Refine Interventions based on feedback from agency administrators, providers, community leaders, community members, and patients.	Outcome measures of successful implementation (providing supervision of therapy models such as cognitive behavioral therapy, new outreach roles, adjustments to collaboration agreements)
Community Dialogue			
RS CEP	One day	CPIC Council and Policy Advisory Board	Comparisons of CEP and RS interventions; Discussions of findings; Recommendations for community-wide plan for reducing impact of depression in the community; Sharing of testimonials from leadership of interventions conditions.
Community Dissemination			
RS CEP		CPIC Council and intervention working groups	CPIC plan for dissemination of study findings and resources.

Acknowledgments

Appendix Table One: Outcome Measures

Potential Client Measures		
Client Characteristics	**Process of Depression Care**	**Outcomes of Care**
Sociodemographics *(0)*	**Assessment** [a]	*Depression diagnosis *(0)*
Insurance status *(0,6,12,24)*	*Current symptoms	*Depressive symptoms *(0,6,12,24)*
Family members *(0,6, 12,24)*	Previous episodes	Household or work productivity *(0,6,12,24)*
[†]*Physical comorbidities*	*Suicidal ideation	*Physical and Emotional functioning

Potential Client Measures		
Client Characteristics	**Process of Depression Care**	**Outcomes of Care**
[†]*Psychiatric comorbidities*	*Substance use	*(0,6,12,24)*
[†]*Lifetime schizophrenia,* [†]*hospitalization for psychosis (0)*		*Probable depression *(0,6,12,24)*
[†] *One year*	**Treatment**	Treatment compliance *(0,6,12,24)*
PTSD screener (0)	*Use of psychotropic medications *(0,6,12,24)*	Satisfaction with treatment *(6,12,24)*
Panic screener *(0, 6, 12,24)*	Treatment at index visit *(0)*	*Unmet Need *(6,12,24)*
Alcohol screener *(0, 6, 12,24)*	*Primary care counseling *(0,6,12,24)*	
Use of illicit substances (0)	*Specialty care referral and	
Stressful life events *(0,6, 12,24)*	counseling *(0,6,12,24)*	
Social supports *(0)*	Prior treatment *(0)*	
Active/passive coping *(0,6, 12,24)*		
Ethnicity/acculturation *(0)*		
Depression knowledge *(0,6)*		
Stigma concerns *(0)*		
Treatment Preferences *(0,6)*		
Readiness for treatment *(0)*		
Organizational Measures (baseline,1st, 2nd, 3rd follow-up administrator/clinician surveys as indicated below)			
Organizational Background	**Services**	**Resources**	**Inter-Agency Linkages & Partnerships**
	Structure & Capacity		
*Organization type[a]	*Services offered[c]	*Funding[c]	*Inter-agency linkages [d]
*Ownership/legal status[a]	*Client size and composition[c]	Staffing levels[c]	Experiences & interest in partnering[d]
Organizational structure[a]	*Staff qualifications for depression care[d]	Physical space Information technology[c]	Perceived barriers to partnering[d]
Organizational		*Experience with depression QI interventions[c]	
Culture & Climate			
*Mission and priorities[b]			
Receptivity to innovation[b]			
Support for QI[b] & *PIC/WE Care interventions[d]			
Implementation Measures		
Group dynamics of partnership	Exposure to training materials and roles	
*Perceived level of participation	*Implementation activities	
Communication & decision-making process	*Model adaptation	
*Perceived level of trust	*Clinical use of PIC/WE Care	
Intermediate partnership effectiveness	*Perceptions of PIC/WE Care interventions	

Potential Client Measures		
Client Characteristics	**Process of Depression Care**	**Outcomes of Care**
Perceived accomplishments	Expansion of implementation/intent to spread	
*Perceived empowerment & ownership		
*Network development		
Provider Measures and Timeframe (baseline-0, 12,24,36-month follow-up)		
Occupation background (0)	*Depression treatment practices (0, 12, 24, 36)	Depression treatment proclivity (0,12,24,36)
Demographics: Age, gender, ethnicity (0)	*Depression treatment knowledge (0, 12,24,36)	Readiness to change (0, 12, 24, 36)
Workload (0)	Quality improvement experience (0, 12,24,36)	Perceived barriers to treatment (0, 12, 24, 36)
	Skill level with depression services (0, 12,24,36)	Satisfaction with work environment (0, 12, 24 36)

*
Indicates priority measures.

†
0=baseline or screening, 6 or 12 = followup month.

a
available from CPI study or agency recruitment phase and highly stable;

b
assessed at baseline only and highly stable;

c
assessed at baseline, moderately stable and updated at baseline and 3rd follow-up.

d
assessed at all waves and related to implementation measures

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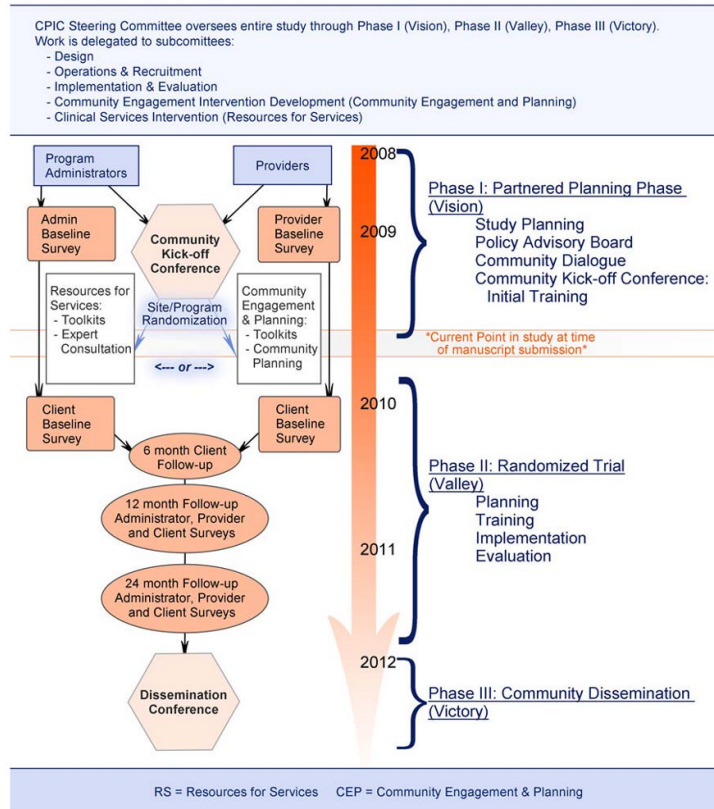
Figure 1. Timeline for CPIC [author: all figures must be provided in black and white]
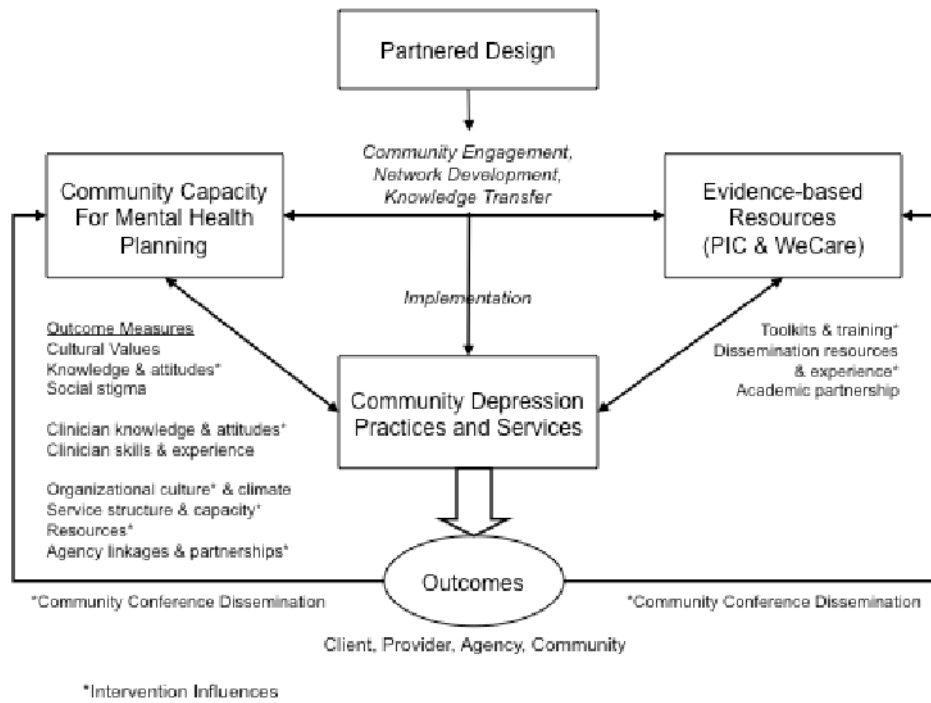
Figure 2. Framework for Partnered Design, Community Engagement Implementation and Dissemination of Evidence Based, Quality Improvement