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Achieving Impact:
Community Partners
in Care and Beyond

Maintaining Internal Validity in Community Partnered Participatory Research: Experience from the Community Partners in Care Study

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Objective: With internal validity being a central goal of designed experiments, we seek to elucidate how community partnered participatory research (CPPR) impacts the internal validity of public health comparative-effectiveness research.

Methods: Community Partners in Care (CPIC), a study comparing a community-coalition intervention to direct technical assistance for disseminating depression care to vulnerable populations, is used to illustrate design choices developed with attention to core CPPR principles. The study-design process is reviewed retrospectively and evaluated based on the resulting covariate balance across intervention arms and on broader peer-review assessments. Contributions of the CPIC Council and the study's design committee are highlighted.

Results: CPPR principles contributed to building consensus around the use of randomization, creating a sampling frame, specifying geographic boundaries delimiting the scope of the investigation, grouping similar programs into pairs or other small blocks of units, collaboratively choosing random-number-generator seeds to determine randomized intervention assignments, and addressing logistical constraints in field operations. Study protocols yielded samples that were well-balanced on background characteristics across intervention arms. CPIC has been recognized for scientific merit, has drawn attention from policymakers, and has fueled ongoing research collaborations.

Conclusions: Creative and collaborative fulfillment of CPPR principles reinforced the internal validity of CPIC, strengthening the study's scientific rigor by engaging complementary areas of knowledge and expertise among members of the investigative team.

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Introduction

Internal validity is a crucial scientific imperative, especially in designed experiments where there is interest in characterizing the causal effects of interventions. Causal inference is founded on viewing an intervention as a replicable set of actions that can be applied to units of analysis and on viewing units as similar enough that they can be regarded as exchangeable in statistical comparisons.[1,2] Public-health research involving community coalitions presents a variety of related complexities and ambiguities in characterizing the units of analysis and the nature of the interventions under study. Additional challenges accompany community partnered participatory research (CPPR), which has emerged as a widely embraced strategy for uniting academic institutions and community-based organizations in pursuing shared research interests.[3-5] In this article, we consider the impact of study design on the internal validity of research findings by focusing on Community Partners in Care (CPIC), a two-arm randomized CPPR-based comparative-effec-

tiveness study investigating dissemination of evidence-based depression care in underserved areas of Los Angeles.

An overarching challenge in CPPR-based investigations is the need to maintain openness and respect for all points of view while strictly adhering to principles that are crucial to scientific integrity. This article, co-authored by academic and community partners who were members of the CPIC Council (the steering committee for the CPIC study), elaborates on how we honored cross-cutting imperatives. We focus on internal validity, by which we mean the correctness, precision, and robustness of inferences drawn from the research, and aiming for the ability to interpret differences in study outcomes as causal effects. External validity, or the ability to generalize findings to other settings, is also crucially important and deserving of examination that goes beyond the scope of this article. As complementary reflections of how the CPPR framework influenced internal validity, we highlight ways that CPIC investigators regarded CPPR principles as having been impactful, summarize the distributional balance on background characteristics across the respective intervention arms, refer to publications that emerged from CPIC, and allude to other peer-review evaluations.

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Methods

Applied Context

The CPIC study grew out of earlier efforts documenting health and social-welfare benefits of "collaborative care" for depression.[6] In Partners in Care,[7] primary-care patients at risk for depression were helped by guidance regarding available treatment, with larger than average benefits found for minority participants. Using a CPPR-based approach, Witness for Wellness[8] documented extensive unmet need for depression care while bridging academic researchers at UCLA and the RAND Corporation with community partners affiliated with Healthy African American Families II, a non-profit agency focused on health in predominantly minority communities, and QueensCare, a public charity providing health services to indigent patients. Promising results led to consideration of disseminating evidence-based depression treatments through social service agencies, substance abuse clinics, primary care clinics, mental health agencies, faith-based entities, or other community-trusted locations (eg, parks and recreation programs, salons or barber shops, fitness centers).

CPPR Principles

Core principles of a CPPR framework include respect for diversity, openness, equality, "redirected power" (referring to channeling the power embedded in communities, a term we prefer to "empowerment" because the latter presupposes a deficit of power in communities), and an asset-based approach.[5] In CPIC, this framework was understood not as requiring all partners to have interchangeable knowledge and abilities but rather as implying a need for trust, for mutual respect regarding the unique strengths that individuals bring to the collective effort, and for all partners to be invested in design decisions.

CPIC Interventions and Sociodemographic Context

CPIC compared two strategies for disseminating evidence-based depression care through programs within agencies. Programs were randomized to either a more intensive Community Engagement and Planning (CEP) intervention, with agency representatives working together in group-planning sessions, or a less intensive agency-specific Resources for Services (RS) intervention exposing staff to depression care training without cross-agency components. Unlike a no-treatment control arm, RS included active intervention components not expected outside the study environment; CPIC was thus a comparative-effectiveness study.

CPIC was implemented across two Los Angeles County service planning areas (Hollywood/Metropolitan and South Central), socioeconomically disadvantaged communities with disproportionate minority populations. After agencies gave approval to participate, clients were recruited from programs within those agencies through a secondary process requiring informed consent from individual clients.

Balance, Equipoise, and the Ethics of Randomization

Ultimately, CPIC embraced the historically successful scientific strategy of contrasting interventions in a randomized controlled trial,[9,10] securing benefits that include protection against confounding due to imbalances in background characteristics, availability of internal estimates of variability to support statistical inference, and reduced sensitivity to modeling assumptions compared with non-random treatment assignment.[1,11,12] But the use of randomization was carefully considered, as early discussions within the CPIC Council noted community concerns with randomization stemming from historical research abuses and associated mistrust of research, as documented in the Belmont Report[13] and elsewhere.[14-16]

In an early CPIC Council meeting, the first author gave a presentation touching on both ethical principles and scientific considerations pertaining to randomization. Delivering interventions with at least some potential benefit was recognized as a reflection of respect for persons, and the importance of starting from a position of genuine equipoise was also emphasized. It was noted that incorporating active intervention elements in the RS arm would have sample size implications, diminishing power to detect a significant intervention effect as compared with having a treatment-as-usual control arm; still, there was broad agreement that ethical considerations demanded offering meaningful potential benefit in the less intensive RS arm.

Additional discussion motivated randomization based on the importance of balance in the distribution of background characteristics. Specifically, it was noted that any substantial imbalance could undermine the validity of interpreting outcome differences as attributable to the intervention. The potential for contamination (ie, exposure to an intervention not assigned) was also considered, along with the feasibility and acceptability of alternative randomized designs. Randomization of entire communities would offer appealingly low contamination potential, but adequate statistical power was not feasible within the project budget. Randomization of individuals within programs offered appealing statistical power but carried substantial potential for contamination. Program-level randomization offered intermediate statistical power with some potential for contamination, though far less than for individual-level randomization, while avoiding different interventions for individuals in the same program, a prospect especially concerning to community stakeholders. A formal vote was taken, with the result favoring program-level randomization.

Once a consensus supporting the use of randomization emerged from the CPIC Council, it was agreed to delegate implementation details to the study's Design Committee. This group included the project's leadership, all study investigators with specialized training in statistics, and other interested academic and community partners.

Experimental-Design Conceptualization

Efforts to gain precision in CPIC outcome comparisons built on experimental design principles such as replication and blocking.[12] The CPIC design was also influenced by the Rubin Causal Model,[1,2] which emphasizes transparency in making underlying assumptions explicit rather than implicit.

Specifically, in the Rubin Causal Model, a treatment is conceptualized as a well-defined set of actions that can be replicated and applied to distinct units, which are the building blocks of a population. The task of inference is greatly simplified when it is possible to invoke the stable-unit-treatment-value assumption (SUTVA), implying that the potential outcomes for an individual depend only on the treatment received by that individual and not on treatments received by others. SUTVA is not valid in some settings (eg, when contamination has an impact, or with epidemic diseases, where an unvaccinated individual's outcome might depend on whether a neighbor was vaccinated). But many scientific studies are premised on SUTVA, and careful study design seeks to preserve its validity to the extent possible (eg, by avoiding communication between participants or guarding against other forms of interference between units that would subvert the ability to attribute effects of exposure to assigned treatments). In CPIC, judgments about whether programs were too closely linked to risk violation of SUTVA guided determinations of whether programs could be assigned different interventions or had to receive the same intervention.

The Rubin Causal Model also imparts that when treatments have multiple components, one cannot isolate the effect of a treatment to a specific component.[1] Such ambiguities, familiar in experimental research, are especially salient when studying community-coalition interventions given the complexity of interpersonal

interactions embedded in intervention activity, making it impossible to know which intervention component might have influenced a client outcome. At the analysis stage, with the number of possible high-order interaction effects overwhelming the ability to estimate such effects with any precision, it made sense in CPIC to focus on the main effect of intervention and low-order interactions such as whether intervention effects differ across geographic or demographic subgroups.

CPIC Sampling Frame

A key practical step in formulating a plan to select units from a well-defined population is the development of a sampling frame.[17] The CPPR-influenced process used in CPIC, described in greater detail elsewhere,[18] drew on a directory of local health and social service agencies, a list of providers treating mental health and substance-use disorders,[19] and recommendations from community partners regarding "community trusted locations" (eg, faith-based organizations, senior citizen centers, exercise clubs, hair salons/barber shops). CPPR principles were reflected in the division of labor between academic partners assembling lists of candidate agencies and community partners reviewing the lists for appropriateness to project goals and feasibility of participation.

Characterizing the Scope of CPIC

As the CPIC sampling frame was being developed, questions arose about the geographic scope of the investigation, with community partners calling attention to recent health-related research initiatives in specified areas within socioeconomically disadvantaged neighborhoods. Academic partners endorsed the idea of delimiting the geographic scope of the study and emphasized that the greater contextual knowledge of community partners was especially relevant to the decision. Following that clarification, the discussion flowed easily toward a consensus incorporating structure from other community-supported initiatives.

A reflection of how CPPR principles influenced communication within the research team grew out of a related exchange where an academic partner used the term "target population" more than once to refer to individuals within the scope of the study. While the term was understood as scientific jargon, its use led a community partner to comment bluntly that it is not desirable in the community to be regarded as a target. The academic partner expressed appreciation for the candid critique and subsequently used "study population" and other such terms to convey the underlying idea; the participants in the exchange later regarded the interaction as both a learning experience and a bonding experience.

Randomized Block Design

Given diversity in the size, scope, and substantive focus of programs, there was concern that assigning programs completely at random to CEP or RS would yield imbalances across intervention arms in agency characteristics that could be expected to translate into imbalances in client background characteristics. Accordingly, a randomized block design was instead used to assign interventions to programs.

Blocking was implemented by identifying groups (generally pairs) of programs that investigators regarded as plausibly exchangeable (ie, could be expected to yield interchangeable outcomes). A first set of provisional experimental blocks was developed by academic partners based primarily on geography (South Central or Hollywood/Metropolitan), the agency's main service focus (social services, substance abuse, primary care, mental health, faith-based, other community-trusted location), and the program's estimated number of clients served. If two similar-sized programs could not be found, the team considered aligning one larger program with two or more smaller programs to yield comparable numbers of clients in the respective intervention arms. Initially proposed groupings were then reviewed by community partners, whose familiarity with the community context led to several recommended changes.

During the meeting to reconfigure the blocking structure, confusion periodically arose about what it meant to "pair" programs. Regarding a statement such as "We should pair Program A and Program B," one intended meaning was, "Program A and Program B can be viewed as exchangeable, so we should assign CEP to one and RS to the other" (Meaning 1), but sometimes such a statement was used to mean, "Program A and Program B work closely together or share staff, risking a violation of SUTVA if they were to receive different interventions, so we should ensure they receive the same intervention" (Meaning 2). To avoid ambiguity, it was eventually agreed that "pairing" agencies would refer to Meaning 1 and that when Meaning 2 was intended, the programs would be described as "joined at the hip." In ad-

dition to yielding clarity, the distinction cultivated a sense of satisfaction and self-efficacy on the part of team members for creatively engineering successful communication in this way.

Matching can improve the precision of intervention effect estimates but can also have an adverse effect on statistical power if matching factors are included in the analysis without being meaningfully correlated with the outcome. In CPIC, the analysis did not attempt to reflect possible precision gains from matching in the design; rather, the randomized block design sought robustness by making intervention arms comparable, guarding against threats to validity from covariate imbalances. Implicitly, this approach anticipated that matching would be important, especially given plans to recruit clients from settings not typically included in studies of collaborative care for depression, but also that matching would be imperfect, thus recommending an analysis framework that avoided exaggerating precision.

Invoking CPPR Principles in CPIC Randomization Protocol

When treatments are to be assigned according to a randomized protocol, the implementation details are typically delegated to statistical programmers. A standard strategy is to use a random number generator incorporated in a statistical software package. It is understood that the numbers produced by these programs are not technically random but rather are derived from a deterministic sequence built on number theory insights, yielding digits that do not show evidence of systematic patterns.[20,21]

To start the sequence of numbers, such algorithms rely on a seed (typically a number with several digits chosen in some arbitrary manner) that would reproduce the exact same set of treatment assignments if there ever was a need to restart the process from the beginning. If a seed is not supplied, software packages typically refer to the computer's internal clock to obtain one. Even though intervention assignments are determined by the result, the choice of a seed is usually regarded as a routine task, commonly chosen without any discussion among research team members.

In CPIC, several reasons argued against delegating the determination of random number generator seeds entirely to a statistical programmer. First, such an approach seemed inconsistent with CPPR principles of openness and shared project oversight. Second, given the prospect that agencies might prefer the more active intervention (CEP) to the less-involved intervention (RS), it was thought that some sharing or diffusion of responsibility would be helpful if some participants were unhappy with their intervention assignments. Finally, given the level of sensitivity about randomization in the community, it seemed important for the sake of trust in the research effort to encourage community engagement in the process of assigning treatments.

With these considerations in mind, and building on the tradition of opening CPIC Council meetings with a community engagement activity that would bring team members closer together (eg, asking team members what they would do with the proceeds of winning a lottery jackpot, leading participants to reveal a mix of personal and societal goals), the CPIC Design Committee developed a proposal for a community engagement activity at a CPIC Council meeting that would yield random number generator seeds through a collaborative activity. The idea was simple: each CPIC Council member would write down a single digit on a piece of paper, a team member would draw 10 such numbers from a hat, and the resulting 10-digit number would serve as a seed. Related email correspondence included technical content in describing the algorithm, but the broader message was that the proposed plans were based on an accessible, transparent, and rigorous scientific foundation. After some deliberation, the CPIC Council endorsed the protocol. The approach was implemented at a subsequent meeting, and resulting seeds were entered into a randomization program to generate intervention assignments with both academic and community partners present.

Addressing Logistical Constraints in CPIC Field Operations

With clients regarded as having been accrued from a nested sampling design, analysis plans called for using multi-level models to account for clustering. Given variation in client volume across programs, it was additionally understood that power calculations should account for unequal program sample sizes. Simulation evaluations suggested that moderate departures from equality in program sample sizes did not substantially impact the power to detect significant differences on key outcome variables. In particular, satisfactory statistical power was found for the scenario that one-third of the programs had an aver-

age number of clients, one-third had 50% fewer than the average number of clients, and one-third had 50% more than the average number of clients. At the planning stage, these findings were translated into a provisional sampling plan where the number of clients enrolled in the study from an initial estimate of 108 programs might range from 4 to 12 after identifying 5 to 15 eligible clients from each program.

Different program contexts also presented challenges for field operations. In some settings, it was possible to screen all clients (eg, a program serving homeless individuals who were staying at the program site) while in others there was not enough time to enumerate and screen all potential clients (eg, when clients dispersed after standing in line to obtain a meal). Rules of thumb were developed based on familiarity with the flow of clients through programs during a typical day. For example, if field staff judged there to be meaningful distinctions among clients seen across broad time categories (eg, morning, afternoon, evening), then staff were guided to balance client recruitment across time, and within time frames; if the flow of clients exceeded the desired number to recruit, then a randomizing device (specifically a table of random digits to determine how many clients to skip) was used to accrue clients until a stopping criterion was satisfied. Field staff directed a few clarifying questions to the CPIC Design Committee during the screening process but generally reported feeling well-prepared to handle a diverse range of recruitment settings.

A simulation-based power calculation accounting for clustering in the design sought a six-month follow-up sample of 780 depressed clients after accounting for attrition.[22]

Results

A number of retrospective assessments reinforce the merit of CPIC design choices. In terms of recruitment, CPIC procedures yielded data on 1,018 clients from 90 programs (an average of roughly 11.3 per program), including 759 clients with six-month outcomes (an average of roughly 8.4 per program).[22] A reflection of the burden of depression in the communities studied is that 29.8% of the program clients successfully screened in CPIC met study eligibility criteria for referral to depression care.[22]

At the analysis stage, background characteristics on recruited clients proved to be well-balanced across the CPIC intervention arms. Across 17 characteristics of clients measured at baseline, none of the 17 showed an imbalance at the .05 significance level.[22] By chance, it would be somewhat more likely to have one or more significant imbalances at the .05 level across 17 characteristics (58.2%) than to have no imbalance across 17 characteristics (41.8%).

At the end of the six-month period when the CEP intervention was active, a smaller proportion of clients in the CEP arm than the RS arm had a score below a pre-determined threshold indicative of poor mental health quality of life, which was one of the study's pre-specified primary outcomes, and CEP-arm clients had significantly better scores on multiple secondary outcomes as well.[22] Longer-term effects were less evident, with estimates being more sensitive to analysis assumptions, but the profile of outcomes at 12 months was still modestly favorable to the community engagement intervention.[23] The study has yielded insights for a broader set of health services outcomes[24] and for relevant subpopulations[25] and has received favorable recognition from a number of sources of external review.[26-28]

Discussion

Successful experimental design relies on careful planning and anticipation of potential problems. Given the interpersonal dynamics involved, successful experimental design in community partnered participatory research requires a foundation of trust and anticipation of relationship concerns. We interpret CPPR principles as underscoring the importance of ensuring that all partners feel invested in design decisions, with effective communication being crucial.

CPPR principles influenced communication among CPIC investigators in a variety of ways. Although occasional adjustments were required, such adjustments were not regarded as being onerous. Communicating about concepts such as equipoise and balance did not require technical jargon, and as illustrated by the randomization seed strategy, non-technical engagement strategies helped reinforce trust.

Much of the strategic thinking in designing CPIC was oriented toward maintaining balance between intervention arms. Against the backdrop of historical distrust of research in the community, our shared sense is that open discussion of the mer-

its of randomization benefited the research effort beyond the eventual decision to carry out a randomized study. Appeals to universal common sense elements of scientific intuition led team members to feel invested in the design. The ensuing development of a randomized block design that helped balance background characteristics of programs and clients was correspondingly built on mutual respect for the technical knowledge of academic partners and the contextual knowledge of community partners.

Opportunities for strengthening a research partnership can emerge from a variety of sources. For example, the CPIC partnership was advanced through joint presentations at conferences featuring both an academic partner and a community partner as speakers. In particular, the first two authors of this paper gave a joint presentation on choosing random number generator seeds at the 2010 Joint Statistical Meetings in Vancouver, British Columbia, which led to an invitation to give a broader joint presentation on the CPIC design at the 2011 International Conference on Health Policy Statistics in Cleveland, Ohio.

CPIC also illustrates how creative application of experimental design ideas can enhance, rather than diminish, internal validity. For example, courses on research methods regularly consider randomized block designs, but the focus is often on how results should be analyzed as opposed to the importance of anticipating threats to internal validity (eg, potential covariate imbalances) and the importance of utilizing available information (eg, community knowledge of program content and context) to guard against such threats to the greatest extent possible. By avoiding sources of confounding that can undermine interpretations of outcome differences as intervention effects, the covariate balance achieved in CPIC greatly simplified the task of inference.

A novel feature of CPIC was the inclusion of community stakeholders in selecting seed numbers to generate randomized assignments. Even in partnered research, the implementation of randomization is typically delegated to technical staff and remains "out of sight" to community stakeholders. In the wake of two-way discussions of scientific equipoise, the scientific role of randomization, the merits of alternative forms of randomization, and historical research abuses such as Tuskegee, the idea of engaging the entire research team in selecting random number seeds was presented in the spirit of promoting two-way learning, motivated by the goal of further demystifying randomization. Consistent with CPPR-related research goals, participation in the randomization procedure enhanced the transparency of the process.

Communicating about concepts such as equipoise and balance did not require technical jargon, and as illustrated by the randomization seed strategy, non-technical engagement strategies helped reinforce trust.

Further, some aspects of shared decision making involved synthesizing the views of community and academic partners. For example, while acknowledging that continuously scaled measures are often preferred to binary variables in power calculations, community stakeholders favored a dichotomous mental-health-related quality-of-life outcome (an indicator of poor quality of life from the SF-12 mental health subscale) based on its clinical relevance and ease of interpretation. Fortunately, the research team had the technical capacity to perform the requisite simulation-based power calculations, and the estimated sample size proved feasible to accrue within the budget and sufficient to yield statistically and clinically significant findings. Beyond illustrating that flexibility did not require sacrificing scientific rigor at the design stage, this discussion underscores the value of CPPR principles for navigating complexity when both scientific considerations and partnership dynamics are involved for both community and academic partners.

Conclusion

In our view, the CPPR framework incorporated in CPIC was crucial to the success of the research effort. We do not believe that CPPR principles inherently conflict with scientific imperatives; rather, our shared sense is that creative and collaborative fulfillment of CPPR principles substantially reinforced the internal validity of CPIC,

strengthening the study's scientific rigor by engaging complementary areas of knowledge and expertise among members of the investigative team. We hope that experience from CPIC helps advance other related initiatives.

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Conflict of Interest

No conflicts of interest to report.

Author Contributions

Research concept and design: Belin, A Jones, Chung, Stockdale, F Jones, Wright, Sherbourne, Perlman, Pulido, Miranda, Dixon, L Jones, Wells; Acquisition of data: A Jones, Chung, Wright, Perlman, Gilmore, Miranda, Dixon, Wells; Data analysis and interpretation: Belin, Tang, Chung, Stockdale, F Jones, Sherbourne, Pulido, Ong, Gilmore, Miranda, Dixon, L Jones, Wells; Manuscript draft: Belin, Tang, Stockdale, F Jones, Pulido, Ong, Wells; Statistical expertise: Belin, Tang, Sherbourne; Acquisition of funding: Belin, Chung, Miranda, Wells; Administrative: Belin, A Jones, Tang, Chung, Stockdale, F Jones, Wright, Perlman, Pulido, Ong, Gilmore, Dixon, L Jones, Wells; Supervision: Chung, Stockdale, Perlman, L Jones

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