

Developing a Randomization Protocol in a Community-Partnered Participatory Research Project to Reduce the Burden of Depression

Thomas R. Belin, UCLA

Andrea Jones, Healthy African American Families II

Susan E. Stockdale, West LA VA Medical Center

Lingqi Tang, UCLA

Felica Jones, Healthy African American Families II

Esmeralda Ramos, UCLA

Aziza Wright, Healthy African American Families II

Judy Perlman, RAND Corporation

Elizabeth Dixon, Queenscare

Loretta Jones, Healthy African American Families II

Kenneth B. Wells, UCLA

Applied context

- Research on collaborative care for depression (Partners in Care, PIC, and successor studies) shows:
 - Staffing primary-care clinic with “depression care specialist” and screening for depression results in improved health outcomes as well as economic outcomes, such as fewer days lost from work
 - Success of collaborative-care framework extends to settings with elderly subjects, youth struggling with depression
 - Effect sizes in PIC were observed to be larger than average for minority individuals, who might also be less likely than non-minorities to obtain health services

Applied context (cont'd)

- Question: Can evidence-based depression treatments be disseminated by adapting collaborative-care framework to
 - Social service agencies
 - Substance-abuse treatment settings
 - Community-based primary-care clinics
 - Community-based mental-health treatment settings
 - Faith-based entities
 - Other community-trusted locations (e.g., parks and recreation programs, salons/barber shops, fitness centers)

Community Partners in Care (CPIC) Study

- Two-arm randomized study of alternative approaches to disseminate information on evidence-based depression care
 - Community Engagement and Planning (CEP): groups of agencies work together on implementation plans
 - Resources for Services (RS): agencies receive technical assistance, access to depression training materials, online training
- Built on previous community-based efforts:
 - Witness for Wellness (W4W), bridging academic partners and Healthy African American Families II (HAAF), a non-profit organization aiming to improve health outcomes for underserved
 - Queenscare Health and Faith Partnership Depression Project, bridging academic partners and Queenscare, a public charity with a mission to provide accessible health care

CPIC design features

- Enrollment of agencies (based on consent of agency decision-makers)
- Randomization of sites/programs/agencies
- Data collection from agency administrators
- Enrollment of and data collection from agency providers
- Field interviews where staff approach agency clients, administer informed-consent procedures, and perform initial eligibility screening (based on signs of depression)
- Telephone surveys to collect client outcomes at baseline, 6 months, 12 months

Community-Partnered Participatory Research (CPPR) Framework

- Community/academic partnership to fulfill research aims
- Key principles
 - “Engagement” requires more than just “Involvement”
 - Project goals should include building problem-solving capacity, not just solving immediate problem
- Core values
 - Respect for diversity
 - Openness
 - Equality
 - “Redirected Power” (Empowerment/Power-Sharing)
 - Asset-based approach

Challenges

- Traditional statistical framework for experimental design, causal inference (e.g., Rubin 1978 *Annals of Statistics*) conceives of:
 - exchangeable units with no interference between units (i.e., “Stable Unit Treatment Value Assumption”: outcome for a given unit depends on treatment assigned to that unit, not on treatments assigned to other units)
 - well-defined “treatment” as a replicable set of actions

Incorporating experimental-design principles

- Can strengthen ability to answer research questions through strategies such as:
 - Blocking in design (identifying subgroups, often pairs, of sites/programs/agencies that seem exchangeable, randomizing within subgroups)
 - Balancing sample sizes across intervention arms

Organizational structure for study

- CPIC led by “CPIC Council” (a few dozen investigators from participating entities, evolving membership)
- Committee structure (Design, Operations/Recruitment, Measures, Intervention Development)
- Importance of two-way capacity building, clear communication, active listening
 - Concepts with technical overtones such as “exchangeability of units” and “balance in background characteristics” can be appreciated by study partners who do not have technical training
- CPIC Council meetings typically include a “community engagement activity” (aimed at building trust, shared understanding)

Role of CPIC Design Committee

- Developing protocols aimed at preserving ability to draw inference regarding hypothetical future implementation of CEP versus RS dissemination of evidence-based depression care
- Clarifying whether protocol alternatives involve scientific imperatives, with an eye toward fostering CPPR goals, e.g.,
 - Q: Do statistical considerations dictate constraints on the geographical area under study?
 - A: It is important to be able to view enrolled agencies as exchangeable, but subject-matter knowledge and community perspective on neighborhood structure would be helpful to characterize geographic boundaries of areas under study

CPPR approach to randomization protocol

- Idea: Generate random-number-generation seeds for intervention assignment through community engagement activity
- Typically left to a statistical programmer, not regarded as subject to strict protocol
- Rationale for avoiding reliance on statistical programmer:
 - Inconsistent with principles such as openness, equality?
 - Better to decentralize responsibility for intervention assignments given prospect that agencies might prefer CEP to RS?
 - Sensitivity about randomization in study population, notably among African Americans with reference to Tuskegee Syphilis Experiment—better for cultivating trust to ensure community engagement in process?

Approach: Randomization protocol

Excerpt from memo to CPIC Council: “[T]here was a Design Committee report on a proposed community-based participatory approach to randomization in the CPIC study. Specifically, the idea called for obtaining input for a computer program with a ‘random number generator’ that can be used to randomize agencies to either the community engagement arm of the CPIC study or the technical assistance arm of the CPIC study. There are a number of mathematical details involved in explaining how computer programs are used to produce a sequence of ‘random’ numbers, but in the end, it is sufficient for a statistical programmer to supply a 10-digit number as input to a program, and then the output would be a sequence of ‘random’ digits that could be used to randomize agencies.”

Approach: Randomization protocol (cont'd)

“A community-based participatory approach that would accomplish this would be for everyone to write down a digit—0, 1, 2, 3, 4, 5, 6, 7, 8, or 9—on a piece of paper, and then one of our team members [Andrea?] will pick them up in an order that s/he determines. The resulting first 10 digits will be supplied as a 10-digit number to a statistical software program to determine which agencies get the community-engagement intervention and which agencies get the technical-assistance intervention.”

Approach: Randomization protocol (cont'd)

”It might seem maddeningly simple, just writing down a single-digit number, but an appealing feature of such a community-based participatory approach is that no one person has control over which agencies get which intervention. Rather, the determination of intervention assignments would reflect shared involvement of the broader CPIC Council.”

Approach: Randomization protocol (cont'd)

Memo included:

- Description of random-number generation algorithm:
“[T]he usual such procedure involves taking a ‘seed’, which is a whole number between 1 and 2,147,483,647 (the latter equals 2 to the 31st power minus 1), multiplying it by another large number (e.g., 397204094, per Fishman and Moore 1982, cited below), dividing by a large prime number (2,147,483,647), and viewing the digits of the remainder as moreorless random.”
- Excerpt from SAS online help and documentation for “random numbers, uniform distribution”

Implementation of randomization

- Identifying blocks of agencies relied on expertise of community partners
 - Typically identified pairs of agencies that were deemed roughly comparable
 - Sometimes identified triples where a degree of balance would be achieved by assigning one intervention to one of the agencies and the other intervention to the other two agencies

“Rolling randomization” perspective

- Ken Wells characterization of “rolling” randomization and recruitment: Randomization at the program level involved efforts both to build trust in randomization and to recruit committed programs that were able to carry out study
- “[I]n a large community with historical distrust in research, the idea of somehow lining up all the agencies that were willing to do the study, while at the same time really trying to get a large, representative (or reasonable) set of agencies across multiple sectors – was very difficult to do and perhaps impossible. That is, we would have to have all 100 agencies lined up, selected, committed, and then we say ‘here we go, we randomize.’ Then, meanwhile, we do that and it all falls apart because of changes in the environment and the economy.”

“Rolling randomization” perspective (cont’d)

Email within study team: “[I]n a large community with historical distrust in research, the idea of somehow lining up all the agencies that were willing to do the study, while at the same time really trying to get a large, representative (or reasonable) set of agencies across multiple sectors – was very difficult to do and perhaps impossible. That is, we would have to have all 100 agencies lined up, selected, committed, and then we say ‘here we go, we randomize.’ Then, meanwhile, we do that and it all falls apart because of changes in the environment and the economy.”

“Rolling randomization” perspective (cont’d)

“What happened as a slight adaptation, is that we randomized somewhat early in the process –when we had agencies signing letters and an administrator on board – but probably not really fully realizing either what commitment to such a study meant, or what their situation was as things rolled out; as an example, funding for some Medicaid programs became very unstable. Further, we weren’t doing survey group site visits until after we were sure the site was on board – however, in fact, my impression is that the survey group site visit was in fact a kind of commitment test, retooling of awareness of what commitment meant, and check on whether the programs that we thought were there, were there, had providers, and that kind of thing.”

“Rolling randomization” perspective (cont’d)

“Also, in the course of enrolling such a large number of sites and setting them up – changes occurred in the community, and in addition, our own resources to take on such diversity or not, became clarified. As an example, some programs closed or became in a financial situation where the risks for them of participation were too great; and on our side, it became clear that we could not take on sites having only home-based services or have too many homeless-serving sites, because of the costs of either screening outside of clinics, or the costs of tracking subjects, respectively; but meanwhile in case we were going to decide we could take that on, we had prepared to match and randomize such sites.”

“Rolling randomization” perspective (cont’d)

“Because of the costs of implementing such a large and diverse group-level randomized trial, we couldn’t really have done all of this cross-checking prior to any randomization ..., much less anticipate changes due to external factors over several months of roll out. Thus it was inevitable that at some reasonable time point, we assembled the most likely committed candidates, matched them, and randomized them; we then went through the process of preparing to screen them – which with changes over time, weeding out unstable or infeasible programs, and the checking on eligibility and commitment that the site visits afforded by the survey group – led to some shifting in remaining programs; which ultimately however, maintained a balance of program numbers and reasonable matches within clusters by intervention status.”

“Rolling randomization” perspective (cont’d)

“I believe that this led to a highly successful end result, of reasonably balanced sites by intervention status AND an engaged set of sites with highly successful client screening; AND maintaining almost all of the principles and details of randomization – and probably as much or more so than is feasible, given what it means to engage a large and diverse number of community agencies in such a randomized comparative effectiveness study – while maintaining engagement and attending to the realities of the external world.”

Screening results: Clients within agencies

Agency type	n	% eligible (> threshold on depression scale)
Community trusted locations	167	10.2%
Homeless services	654	32.6%
Mental health services	520	46.9%
Primary care services	1399	28.9%
Public health services	85	31.8%
Religious/spiritual services	104	13.5%
Social services	740	18.2%
Substance abuse services	767	34.8%
Total	4436	29.8%

Discussion

- Partnered research builds on a foundation of trust
- Seemingly minor technical issues (e.g., choice of seed for randomization) can have broader implications:
 - For the worse if partnership is ignored (e.g., leading to perceptions of cutting corners, leaving academic partners in control)
 - For the better if partnership is embraced (sharing control, diffusing responsibility for intervention assignment if participants unhappy)
- Flexibility crucial
 - Can solid inferential foundation be maintained?
- Innovative strategies for cultivating trust in community-partnered research need not be technically difficult