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VIEWPOINT

Integrating Community-Based Participatory Research Into Cardiac Clinical Trials

Lessons From REVASCHOICE

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Despite advances in cardiovascular care, racial, ethnic, and socioeconomic disparities persist among patients with coronary artery disease (CAD).[1] Inequities are particularly evident among women and minorities undergoing coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI). They experience worse access, lower rates of guideline-concordant care, and poorer outcomes.[2] Their underrepresentation in the randomized clinical trials that inform practice likely contributes to these disparities.[3]

Historical and ongoing mistrust of health care and the research enterprise exacerbates this problem, limiting both the generalizability and equitable impact of clinical trials. Incorporating community-based participatory research (CBPR) approaches to trial development and implementation can enhance trust, improve recruitment, and ultimately produce more generalizable evidence.[4] By emphasizing shared power, cocreation, and respect for community expertise, CBPR offers a potential path forward for clinical trials seeking to redress long-standing inequities.

Accordingly, CBPR principles were applied in Revascularization Choices (REVASCHOICE), a prospective study designed to explore how women and underrepresented minorities make decisions between PCI and CABG, as well as their willingness to participate in randomization between the 2 strategies. REVASCHOICE was a critical step in developing recruitment strategies for the RECHARGE (Revascularization Choices Among Underrepresented Groups Evaluation; NCT06399705) study,[5] a multisite randomized clinical trial comparing PCI vs CABG in women and underrepresented minorities to inform treatment decisions in these populations. Lessons learned from REVASCHOICE offer a practical blueprint for integrating CBPR into cardiac clinical trials.

To start, we focused on early and meaningful involvement of community members as co-investigators who helped to shape the research agenda prior to patient recruitment through the establishment of a Stakeholder Advisory Board (SAB). The SAB consisted of 15 members, including patients with lived experience of CAD, physicians, nurses, community leaders, and a health educator. The SAB was coled by 2 patients and community organizers with a history of CAD and deep ties to local underrepresented populations.

The SAB reviewed the study design, outreach strategies, recruitment progress, and the findings of the REVASCHOICE study. Feedback from the SAB shaped the subsequent strategies for patient recruitment and engagement, including the design of participant-facing materials for RECHARGE.

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ABBREVIATIONS AND ACRONYMS

CPBR = community-based participatory research

CAD = coronary artery disease

PCI = percutaneous coronary intervention

CABG = coronary artery bypass grafting

SAB = Stakeholder Advisory Board

REVASCHOICE = Revascularization Choices

RECHARGE = Revascularization Choices Among Underrepresented Groups Evaluation

Continuous engagement with the SAB ensured that CBPR principles were not episodic but embedded into the core of the research infrastructure.

Throughout REVASCHOICE, one of the most consistent lessons we learned was that trust cannot be parachuted in for trial recruitment—it must be cultivated, often over years, through authentic community engagement. The REVASCHOICE study benefitted from the CBPR infrastructure of the Washington Heights/Inwood Infrastructure for Comparative Effectiveness Research (WICER) project, a long-standing network of over 6,000 Hispanic and African American individuals in Upper Manhattan interested in health research.[6] Engaging with WICER strengthened the credibility of REVASCHOICE, allowing us to embed the study into a broader narrative of community empowerment and research partnership.

Key to this trust building was the leadership of a project leader (N.S.T.), who has spent years building rapport with community members both through the WICER network and other projects. Participants consistently cited their trust in the project leader as the basis for their trust in the research team. This illustrates a core tenet of successful CBPR: the credibility and social capital of individual research team members can facilitate trust in the research institution itself.

Indeed, effective CBPR requires researchers to move beyond transactional relationships with participants and engage with the broader social determinants affecting their health and well-being. REVASCHOICE benefitted from historical efforts made by the research staff as part of other research projects done in partnership with the community to intentionally address both clinical and nonclinical needs. These efforts strengthened participants' willingness to engage with the study.

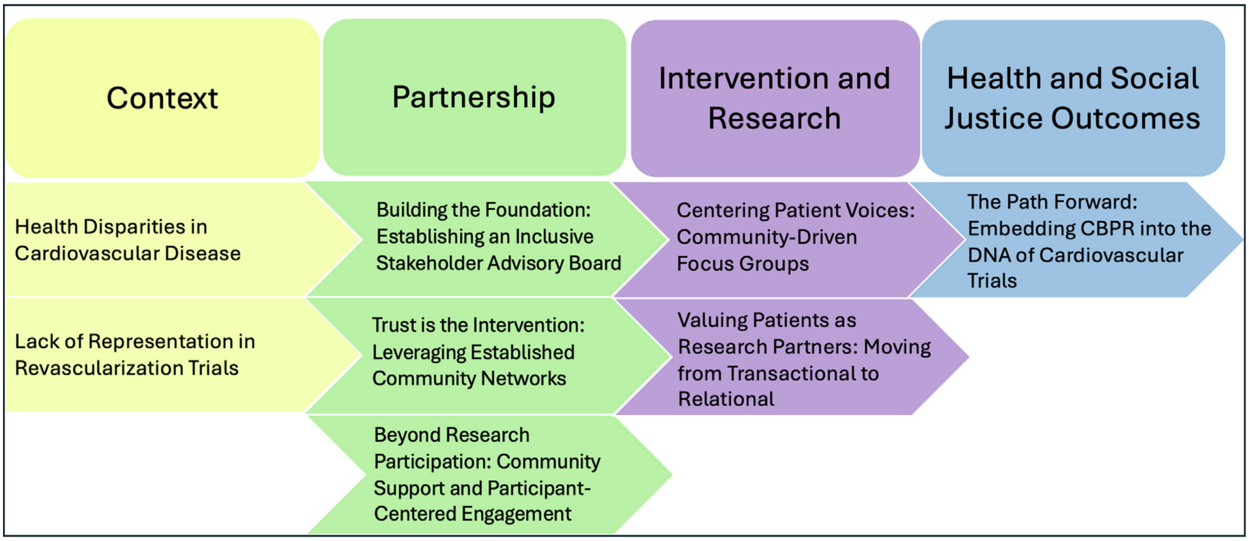
An example of these efforts is the development of a community resource guide that is distributed regardless of study participation and is continuously adapted. It includes referrals for health care services, for immigration assistance, job training, domestic violence counseling, and food insecurity resources. Another example was the practice of sending personalized birthday cards to participants, even after completion of study participation. These small, humanizing acts reinforced the message that the research team was invested in long-term relationships with the community and not just short-term data collection. The effect has been a shift in the perceived role of the research team from outsiders extracting data to community allies working toward shared goals.

CBPR principles further informed study design, implementation, and analysis. As part of REVASCHOICE, we conducted 42 focus groups in English and Spanish with women and racial and ethnic minority patients, who either had a diagnosis of cardiovascular disease or had undergone PCI or CABG, to explore their experiences, values, and preferences around revascularization. These results directly shaped the design and recruitment/retention strategies of RECHARGE by ensuring the trial was responsive to the experiences and decision-making frameworks of the populations it wanted to enroll.

A particularly impactful product of these conversations was the development of visual decision aids, designed to demystify the randomization process and replace dense medical jargon with clear and culturally relevant language and imagery. The patient-driven development of study materials exemplifies the core of CBPR: research designed with communities, not just for communities.

Ultimately, the lessons from REVASCHOICE are broadly applicable to cardiovascular research seeking to improve the representation and outcomes of historically excluded populations. We have learned that CBPR is not a checklist of isolated activities but rather a fundamental reorientation of the research process toward shared power, reciprocal trust, and co-ownership of knowledge production. To generate evidence that addresses prevalent racial and socioeconomic disparities in the management of cardiovascular disease, we must reimagine clinical trials as collaborative projects between academic institutions and the communities they seek to serve. Our experiences with REVASCHOICE offered a pragmatic model for how best to do this with RECHARGE (Figure 1). The time has come to embrace a new paradigm where community engagement is not a recruitment strategy, but the foundation of rigorous and equitable science.

FIGURE 1 **Integrating Community-Based Participatory Research Into RECHARGE**



This figure outlines the application of CBPR principles in the design and implementation of RECHARGE. Community engagement, trust-building, and patient-centered practices informed every stage of the research process to promote equity and inclusion in cardiovascular trials. CBPR = community-based participatory research.

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