

Policy solutions to recruiting and retaining minority children in research

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Despite substantial investments across research, policy, and legislation, inequities in child health persist and represent a formidable challenge to improving health outcomes for children. Disparities have been demonstrated in numerous health-care settings and across a vast number of chronic conditions (1–4). Root causes of disparities are complex and frequently intertwine multilevel factors such as race/ethnicity, socioeconomic status, discrimination, psychosocial stress, education, economic opportunity, and neighborhood environment (5,6). Although studies documenting disparities in child health have been plentiful, evidence-based interventions and policy solutions to address inequities are still in their infancy. In this issue, Gkouroggianni *et al.* (7) report on disparities in disease severity and outcomes among Hispanic and African-American children with Pediatric Cushing Disease (CD). The authors document disproportionately higher severity of CD in Hispanic and African-American children relative to white children both preoperatively and postoperatively. Both racial/ethnic minority groups also had higher proportions of diagnosis at an advanced stage. The authors postulate a number of mechanisms by which these disparities in CD severity scores occurred. They appropriately highlight variables at the level of the patient (e.g., genetics, social determinants of health), provider (e.g., fund of knowledge, quality of care), and health-care system (e.g., delays in referral, access to subspecialty care). Also important, the authors identify challenges in the conduct of research with respect to minorities being under-represented in pediatric oncology research protocols and clinical trials for rare diseases.

Randomized controlled trials (RCTs) are considered the gold standard in determining the effectiveness of health-care interventions (8). However, the reliability of results can be compromised with differential enrollment or retention among subsets of participants (9,10). This disparity constitutes a major obstacle in establishing the effectiveness of treatment modalities in diverse pediatric populations. The aim of this commentary is to review the literature on pediatric disparities in recruitment and retention, and to identify policies and evidence-based strategies with the potential to improve minority participation and completion in clinical trials.

The medical literature has extensively documented disparities among adults in recruitment and retention in clinical trials (11–13). Cumulatively, these studies demonstrate that individuals of racial/ethnic minority status, low socioeconomic status, or poor education are less likely to participate in research and consequently are under-represented (10). Factors driving lower participation among these populations include logistical and attitudinal barriers (14). Logistical barrier may consist of transportation difficulty, unavailable child care, time constraints, competing priorities, and changes in contact information. Attitudinal barriers may include historical mistrust of research with respect to minority populations and perceived discrimination. This body of work among adult populations provides a foundation for understanding disparities in recruitment and retention.

Decision-making on behalf of a child has been demonstrated to be a different process compared with adults making decisions for themselves (15). Parent, family, and child characteristics can be important determinants of whether a family chooses to participate. In pediatric studies in which children are old enough to provide consent, the combination of these characteristics adds further complexity. A recent systematic review found that predictors of recruitment and retention for children can be categorized into parent, child, family, and neighborhood characteristics (10). However, even with this complex set of drivers in pediatrics, disparities are still widely documented in the limited number of studies on recruitment and retention among children. Significant under-representation in cancer protocol participation has been documented for Hispanics and children of Spanish-speaking parents (16). For obesity studies, the mean retention rates were lower in trials solely targeting African-American and Hispanic children (17).

Efforts to increase minority participation in research have been addressed predominantly by policies and regulations of funding institutions, journals, and institutional review boards (IRBs). The 1993 National Institute of Health Revitalization Act mandated minority inclusion in RCTs, defining under-represented minorities as African Americans, Hispanics, and American Indians. Subsequently, NIH review criteria have formally required minority recruitment plans or scientifically justified exclusion. Although these policies address inclusion

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at grant submission and award, they may lack sufficient post-award procedures for monitoring compliance. The creation of the National Institute on Minority Health and Health Disparities in 2010 provided new opportunity to increase minority participation in research. However, a small budget relative to other institutes may limit its impact. The Patient-Centered Outcomes Research Institute, authorized by Congress in 2010, strongly encourages studies that include diverse populations and previously understudied groups so that outcomes can be examined according to different subgroups. However, even when clinical trials specifically focused on minorities have been planned and started, many have been terminated because of insufficient enrollment (9). In addition to funding institutions, IRBs also maintain policies to promote inclusion of minorities in research through documentation of inclusion, requirement of consents being available in multiple languages, and justification of homogeneous study populations. Last, journals have attempted to improve their scrutiny of racial/ethnic variables. Despite these policies and investments in new funding institutions, there is no clear evidence that these efforts have worked and recruitment and retention of minorities in clinical trials remain low.

Researchers and policymakers have increasingly advocated implementation of additional measures to promote inclusion and retention of minorities in research. Proposed policies at the level of funding institutions have included prioritization of clinical trials based on sampling of specific groups or increasing funding mechanisms targeting specific underrepresented groups. Journal editors have required appropriate representation of underserved populations and analyses of research by race/ethnicity. IRBs of academic centers have required that studies reflect the community of participants they serve. IRBs have also required researchers to document recruitment and retention strategies in proposal submissions. Although these policy strategies may heighten awareness among researchers, they only offer incremental modifications from previous measures. Consequently, they are unlikely to have a significant impact without corresponding evidence-based approaches to improve recruitment and minimize attrition.

A recent study by Flores *et al.* (18) evaluated a comprehensive approach to ensuring high RCT retention of minority children. The strategic framework consisted of the following components: optimize cultural and linguistic competency; build participants' relationship and trust; comprehensive contact information for participants and their relatives, friends, and neighbors; electronic tracking database; reminders for upcoming outcome-assessment appointments; frequent, sustained contact attempts for nonrespondents; incentives for every component completed; individualized rapid-cycle quality-improvement approach to nonrespondents; reinforce the importance of the study; and home visits as a last resort. In the study by Flores *et al.*, the authors compared attrition in their RCT with two previous RCTs in similar populations. Attrition in their trial was lower than that

in two similar RCTs, at 10.9% vs. 37% and 40%. Although many of these measures had been found to be effective in prior studies (14,19,20), two of the components had not been previously reported. One unique component was an electronic tracking database that was multifunctional in addressing monitoring of outcomes, adherence to outcome phone calls, and participants at risk for loss to follow-up or currently lost to follow-up. Another innovative component of the strategic framework was the individualized rapid-cycle quality-improvement approach to nonrespondents. This novel approach resulted in identification of root causes for nonresponse, creation, and implementation of an action plan, evaluation of response outcomes at team meetings, and continuous modification of the action plan. In addition to these strategies, collaboration with a community organization has also been shown to be effective in engaging low-socioeconomic status, racial/ethnic minority participants in research (20). Although resource- and time-intensive, these evidence-based strategies provide a systematic template to researchers.

Although mitigating root causes of disparities in child health should remain a paramount focus for clinicians, researchers, and policymakers, these efforts must be complemented by comprehensive policies and evidence-based strategies to improve recruitment and retention of underserved, minority children in research. The emerging evidence base on best practices to improve recruitment and minimize attrition should be collated and widely disseminated to researchers. Funding institutions and academic institutions should both educate and implement policies to require a standard level of competency in these strategies as they do with other fundamental components in the ethical conduct of research. Such requirements should exist both for researchers and grant reviewers. Funding institutions should also ensure that all awarded grants have adequate budgets for recruitment and retention of underserved children and systematically monitor enrollment post award. This blending of evidence-based approaches for recruitment and retention, active engagement and education with research teams and grant reviewers, and multipronged policies from diverse stakeholders (e.g., funding institutions, academic institutions, IRBs, and journal editorial boards) has the potential to transform how research is conducted and to ensure that findings are relevant to all populations.

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REFERENCES

1. Dimick J, Ruhter J, Sarrazin MV, Birkmeyer JD. Black patients more likely than whites to undergo surgery at low-quality hospitals in segregated regions. *Health Affairs* 2013;32:1046–53.
2. Lion KC, Rafton SA, Shafiq J, et al. Association between language, serious adverse events, and length of stay among hospitalized children. *Hosp Pediatr* 2013;3:219–5.
3. Chan T, Lion KC, Mangione-Smith R. Racial disparities in failure-to-rescue among children undergoing congenital heart surgery. *J Pediatr* 2015;166:e1–4.

- Raphael JL, Zhang Y, Liu H, Tapia CD, Giardino AP. Association of medical home care and disparities in emergency care utilization among children with special health care needs. *Acad Pediatr* 2009;9:242–8.
- Hasnain-Wynia R, Baker DW, Nerenz D, et al. Disparities in health care are driven by where minority patients seek care: examination of the hospital quality alliance measures. *Arch Intern Med* 2007;167:1233–9.
- Kimbro RT, Denney JT. Neighborhood context and racial/ethnic differences in young children's obesity: structural barriers to interventions. *Soc Sci Med* 2013;95:97–105.
- Gkourogiani A, Sinaii N, Jackson S, et al. Pediatric cusing disease: disparities in disease severity and outcomes in the hispanic and african american populations. *Pediatr Res* 2017.
- Akobeng AK. Understanding randomised controlled trials. *Arch Dis Childhood* 2005;90:840–4.
- Karolson CW, Rapoff MA. Attrition in randomized controlled trials for pediatric chronic conditions. *J Pediatr Psychol* 2009;34:782–93.
- Robinson L, Adair P, Coffey M, Harris R, Burnside G. Identifying the participant characteristics that predict recruitment and retention of participants to randomised controlled trials involving children: a systematic review. *Trials* 2016;17:294.
- Glickman SW, Anstrom KJ, Lin L, et al. Challenges in enrollment of minority, pediatric, and geriatric patients in emergency and acute care clinical research. *Ann Emerg Med* 2008;51:e3.
- Castillo-Mancilla JR, Cohn SE, Krishnan S, et al. Minorities remain underrepresented in HIV/AIDS research despite access to clinical trials. *HIV Clin Trials* 2014;15:14–26.
- Scalici J, Finan MA, Black J, et al. Minority participation in Gynecologic Oncology Group (GOG) Studies. *Gynecol Oncol* 2015;138:441–4.
- Kennedy BM, Kumanyika S, Ard JD, et al. Overall and minority-focused recruitment strategies in the PREMIER multicenter trial of lifestyle interventions for blood pressure control. *Contemp Clin Trials* 2010;31:49–54.
- Brooks-Gunn J, Duncan GJ, Aber JL. *Neighborhood Poverty: Context and Consequences for Children*. New York, NY, USA: Russell Sage Foundation, 2004.
- Aristizabal P, Singer J, Cooper R, et al. Participation in pediatric oncology research protocols: racial/ethnic, language and age-based disparities. *Pediatr Blood Cancer* 2015;62:1337–44.
- Cui Z, Seburg EM, Sherwood NE, Faith MS, Ward DS. Recruitment and retention in obesity prevention and treatment trials targeting minority or low-income children: a review of the clinical trials registration database. *Trials* 2015;16:564.
- Flores G, Portillo A, Lin H, et al. A successful approach to minimizing attrition in racial/ethnic minority, low-income populations. *Contemp Clin Trials Commun* 2017;5:168–74.
- Chang E, Bidewell J, Brownhill S, Farnsworth J, Ward J, Diehl H. Participant perceptions of a community-based lifestyle intervention: the CHIP. *Health Promot J Of Aust* 2012;23:177–82.
- Nicholson LM, Schwirian PM, Groner JA. Recruitment and retention strategies in clinical studies with low-income and minority populations: progress from 2004–2014. *Contemp Clin Trials* 2015;45:34–40.