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Examining Barriers and Practices to Recruitment and Retention in Stroke Clinical Trials

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Abstract

Background and Purpose—The National Institutes of Health (NIH) policy calls for the inclusion of underrepresented groups, such as women and minorities, in clinical research. Poor minority recruitment and retention in stroke clinical trials remains a significant challenge limiting safety and efficacy in a general population. Previous research examines participant barriers to clinical trial involvement, but little is known about the investigator perspective. This study addresses this gap and examines researcher reported barriers and best practices of minority involvement in stroke clinical trials.

Methods—Quantitative and qualitative methods, including surveys, focus groups, and key informant interviews were used.

Results—In a survey of 93 prominent stroke researchers; n=43 (51.2%) (70% response rate) reported proactively setting recruitment goals for minority inclusion; n=29 (36.3 %) reported requiring cultural competency staff training and n=44 (51.2%) reported community consultation about trial design. Focus groups and key informant interviews highlighted structural and institutional challenges to recruitment of minorities, including mistrust of the research/medical enterprise, poor communication, and lack of understanding of clinical trials. Researcher-identified best practices included using standardized project management procedures and protocols (e.g., realistic budgeting to support challenges in recruitment, such as travel/parking reimbursement for participants), training research staff on cultural competency and communication strategies, and developing and fostering community partnerships that guide the research process.

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Conclusion—This study's formative evaluation contributes a new dimension to the literature as it highlights researcher-reported barriers and best practices for enhancing participation of minority populations into stroke clinical trials.

Keywords

clinical trial; race and ethnicity; health policy

Introduction

Inadequate involvement of underrepresented groups, such as women and racial-ethnic minorities, can negatively impact the scientific, economic, and ethical value of a clinical trial.[1] Specifically, non-representative samples limit a trial's safety and efficacy to the general U.S. population.[2–4] Accordingly, the National Institutes of Health (NIH) Revitalization Act of 1993, PL 103-43 established guidelines for "appropriate representation"[3] of women and minorities in NIH-funded clinical research. Despite this legislative intervention, minority participation rates remain suboptimal, especially in neurological clinical trials.[2, 4, 5] In an analysis of National Institute of Neurological Disorders and Stroke (NINDS)-funded clinical trials, Burke and colleagues found that African American participation rates are above population levels while Hispanics and other racial-ethnic groups remain underrepresented.[4] Given the documented racial-ethnic disparities in the incidence of neurological conditions, particularly stroke,[6] representative clinical trial study samples are critical.

Previous research has explored lay/patient-level recruitment and retention barriers in stroke clinical trials.[1, 7] Identified lay-barriers include, inadequate information on research opportunities and trial requirements, burdensome time commitment (employment, lack of child care), reluctance to adhere to prescribed behavior change, medication-related difficulties, transportation, and a general sense of "mistrust" toward the healthcare system.[1, 7–9] In particular, minorities noted fears of mistreatment, exploitation, and being treated as a "guinea pig" (e.g., Tuskegee Syphilis Study[9]) as prominent factors when considering clinical trial participation. Despite these barriers, research suggests that Hispanic and Black populations report being positively interested in trial participation; however, they were neither asked nor eligible.[6] Researchers' attitudes and behaviors, as well as trial procedures may be directly related to the success or failure to recruit representative populations.[10, 11] Indeed researchers stand at the forefront of enrollment procedures and act as the intermediary between patients and therapeutic options. Yet literature is sparse eliciting investigator-level barriers to minority trial involvement in stroke clinical trials.

The National Initiative for Minority Involvement in Neurological Clinical Trials (NIMICT) (NIH NINDS/NIMHD:5U24MD006961) seeks to identify the constellation of investigator-level barriers to create and test a series of evidence-based toolkits that address minority recruitment and retention challenges in neurological clinical trials. Our initial work focuses on stroke as it is the leading cause of disability and death[12] and carries a large portfolio of clinical trials with low rates of minority participation.[4] The aim of this manuscript is to

report on NIMICT's formative research identifying investigator-level barriers to minority involvement in stroke clinical trials.

Methods

We used a mixed methods approach (survey, focus groups, and key informant interviews) to identify investigator-level barriers. Our guiding research questions include: 1) What are the most cited challenges in racial-ethnic minority recruitment and retention in clinical research articles across different diseases and disciplines? and 2) What are the distinctive barriers in neurological (e.g., stroke) clinical research? We engaged in an iterative, progressive process of data collection. First, a traditional/narrative literature review identified recruitment and retention challenges and successes. We modeled our search on the work conducted in cancer therapeutic clinical trials, as they lead the field with evaluating barriers and facilitators to minority involvement in clinical trials[10] (http://stroke.ahajournals.org for Online Supplement, Appendix A: Traditional Literature Review methods and results). The literature review findings guided the creation of the survey instrument. Knowledge gained from the survey was used to formulate the focus group guide, and preliminary analysis of the focus groups' data was instrumental in advancing the key informant guide. At each step, findings were discussed and then additional questions were queried (http://stroke.ahajournals.org for Online Supplement, Appendix A for the iterative data collection schematic).

Survey

A 43-item online survey was developed to collect data on stroke investigators' perspectives on minority recruitment and retention practices. The instrument included open- and closed-ended questions on: researcher training, recruitment planning, knowledge of NIH Inclusion Policy, informed consent processes, and barriers to minority involvement. "Best practices" were captured when available (http://stroke.ahajournals.org for Online Supplement, Appendix B for Survey Questionnaire). Participants were recruited from the 2012 Princeton Conference on Cerebrovascular Disease,[13] providing access to a network of prominent clinical stroke investigators. In fall 2012, the survey was electronically distributed via Survey Monkey, an online survey tool, with two follow-up reminder emails within a six-week period. The survey items were not randomized, and participation was voluntary and anonymous. Completion of the survey was deemed as implied consent, and thus, the Institutional Review Board did not require informed consent.

Focus Groups

A semi-structured focus group was conducted with a purposive sample of 18 stroke investigators at the 2013 International Stroke Conference. Two NIMICT researchers facilitated the 90 minute session. Discussion topics included: 1) Challenges to integrating NIH Inclusion Policy into trial design and recruitment strategies; 2) Distinctive barriers to minority recruitment in stroke/neurological trials; and 3) Identification of best practices to enhance minority involvement (http://stroke.ahajournals.org for Online Supplement, Appendix C, Focus Group Guide).

Key Informant Interviews

We conducted a series of key informant interviews (n=6) were conducted at the 2013 American Academy of Neurology conference. Participants were: 1) senior research members (Principal Investigator/Co-Investigator); 2) involved in large multi-center trials; 3) identified for successful inclusion of minority participants; and/or 4) recommended by NIH peer. We focused on identification of key “best practices” perceived to increase minority involvement.

Analysis

We present survey findings using descriptive statistics. For the qualitative data, all focus group sessions and key informant interviews were audio-taped and transcribed. The transcripts were analyzed by four investigators (BBA, DFE, HC, LS) to determine thematic codes, following procedures outlined by Patton.[14] Using the COREQ checklist,[15] our approach and additional details are described in Supplemental Table I, Online Supplement, Appendix D (http://stroke.ahajournals.org).

Results

Survey

Ninety-three clinical stroke investigators out of 123 invited to the Princeton Conference responded to our survey (response rate: 75%). Twenty-eight respondents (32.2%) self-identified as non-white and n=19 (22.6%) noted fluency in a language(s) other than English. Thirty-eight (44.7%) participants have been involved in over 10 stroke trials. The majority (n=71, 84.5%) of respondents reported working with several different racial-ethnic groups (Caucasian: n=68; Asian American: n=13; Black/African American: n=63; Hispanic/Latino: n=40; Native Hawaiian/other Pacific Islander: n=2; American Indian/Alaska Native: n=3). Twenty-three (27.1%) respondents indicated working exclusively in minority communities. Researchers reported actively recruiting from patient populations unable to consent (n=49, 81.7%).

We asked a series of questions to capture researcher strategies to incorporate the NIH Inclusion Policy (Table 1). Half (n= 43, 51.2%) reported proactively setting recruitment goals for minority inclusion. Twenty-nine respondents (36.3%) reported requiring cultural competency for staff training and forty-four (51.2%) reported using community consultation about trial design. Thirty-one (36.9%) chose “strongly agreed” to being “successful” in minority recruitment. We examined whether patterns in the above strategies for improving minority involvement differed by the researcher’s race-ethnicity, but did not find significant differences. In a ranked question, we queried investigators’ perspectives on minority recruitment difficulties (http://stroke.ahajournals.org for Online Supplement, Appendix C, Survey Questionnaire, Question 36). The three leading obstacles were mistrust of research and medical system (n=43), lack of awareness about trials (n=38), and communication issues (n=29).

In a series of questions about trial mechanics, over one-third of respondents (n=24, 34.8%) reported enrollment hours as 24 hours/7 days a week. The top three “best” people to obtain

consent were study coordinators (n=28, 37.3%), PIs (n=15, 20.0%), and attending physicians (n= 11, 14.7%). Almost 75% of respondents reported providing some form of compensation: money (n=35, 64.8%), travel (n=36, 66.7%), and food (n=13, 24.1%); however, no site reported providing childcare. When presenting participant trial information, print materials (n=57, 87.7%) were the overwhelming choice for information dissemination while thirty researchers (40%) supplemented it with visual aids. In open-ended questions to further explore recruitment challenges, researchers expressed vulnerability and concern about general trial recruitment in time-sensitive settings (e.g., ED, NICU). They expressed difficulty about relaying the concept of prognostic uncertainty, explaining research concepts in lay terminology (e.g., therapeutic misconception), and poor communication due to language, education and culture.

Focus Group and Key Informant Interviews

Focus group discussion and key informant interviews highlight 1) structural/institutional constraints, 2) recruitment communication, and 3) difficulties unique to the recruitment of stroke patients. Table 2 outlines best practices/recommendations and illustrative quotes underscoring the aforementioned themes.

Researchers expressed frustration regarding the practical application of the NIH Inclusion Policy for “adequate representation” for valid analysis. In a discussion of adequate power for multiple race-ethnic group comparisons, several questioned operational parameters and denominator definitions for adequate representation. Investigators also articulated inter- and intra-institutional challenges to minority recruitment. They noted examples of “geographical disconnect” between research institutions and organizations serving minority populations. To bridge this gap, a suggested best practice described how providing salary coverage for remote clinic staff improved the patient experience and thus increased enrollment. The inclusion of a community advisory board and culturally tailored projects were successful strategies for study protocol appropriateness.

> We have [a]community advisory board and … have protocol review. We give them a protocol and they comment on it and tell us what they like and don’t like about it… Our trial had slow enrollment rates and our community told us that over 30% of the population couldn’t [or would not use the treatment …] because they had a previous [negative] history.

Engaging the larger non-research community (i.e., primary care physicians) was also a best practice; however, some expressed concern that non-research clinicians often worry patients will be taken away from them if they enter a trial.

Recruitment communication, especially establishing trust, was a prominent theme for general recruitment practices, especially among minority participants. A respondent elaborated, “*The bottom line is trust. If you cannot establish trust with your patients, forget it.”* Investigators agreed that successful recruiters create trust by treating participants with compassion. Another participant described how lay/patient mistrust may be related to a lack of clinical trial awareness stating, “…*when you come to someone and start talking about a trial, and they don’t even know the basics of research, of course they may say ‘no, I don’t want to participate’ because they already don’t understand exactly what [being part of a*

trial] will consist of." Throughout the discussion, respondents noted several ways to establish trust and clearly communicate clinical concepts (Table 2). One researcher noted the value of treating patients as "*humans*" rather than "*research subjects*," and suggested motivational interviewing as a best practice.

Researchers described two distinct qualities of the neurological clinical environment and patient population that present unique recruitment and retention challenges. First, eligible patients may experience multiple cognitive and physical sequelae. Respondents indicated that ED arrival time may deter patients from receiving a timely diagnosis, which excludes them from a trial. Many neurological trials, especially acute stroke, rely on proxy consent. Proxy consent and communicating with family along with or instead of the patient adds another level of complication. Researchers noted how families express fear about making the "*right decision*" because they now are "*in charge of someone's life*." Second, trial retention and attrition are hampered by patient denial and stigma of neurological conditions. One researcher elaborated that, *"the [patients] don't want other people to know… It's about stigma."* Stigma towards neurologic injuries may play a role while trial participation can be an unwelcomed reminder of one's condition. Stroke trials present unique recruitment and retention challenges that must be addressed at the patient, caregiver, and health professional level.

Discussion

Historically, minority clinical trial participation rates remain below U.S. population representation levels.[4] The U.S. demographic landscape is becoming more multi-ethnic, and the lack of balanced clinical trial participation by diverse racial-ethnic groups hinders our ability to generalize scientific findings at the population level. Since the NIH Inclusion Policy was signed into law, overall participation rates in NINDS-funded trials has grown; [4] African-American enrollment increased while participation among Hispanics decreased,[4] American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, and Two or More Races groups remain largely underreported, which raises concern with regard to subgroup generalizability.[2,4] Across major diseases (e.g., oncology, cardiology)[2], minority trial participation rates remain low; for example the National Cancer Institute noted similar rates: 0.3 % American Indian/Alaska Native, 1.8% Asian/Pacific Islander, 8.2% Black, 4.5% Hispanic, 82.6% White, and 2.7% Other.[16]

NIMICT's mixed method approach explored the multifaceted challenges of minority recruitment and retention in stroke clinical trials. NIMICT captured researcher challenges and identified the complexities embedded in stroke clinical trials, all of which are further compounded with minorities. We highlight challenges at the structural/institutional level as well as outline two additional thematic areas - recruitment communication and challenges unique to enrollment in stroke trials. Despite that the NIH Inclusion Policy is mandated by law, minority participation is inconsistent and varied. We report nearly half of researchers do not incorporate active planning for and recruitment of minority population. Focus group members expressed open concern about the lack of clarification regarding the inclusion of minority populations and what constitutes appropriate and sufficient minority representation in trials. The NIH Inclusion Policy's intent suggests that Phase III trials ensure the

distribution of benefits by allowing for meaningful analysis; yet meaningful analysis requires appropriately powered studies that allow for valid sub-group analyses. The focus of the policy lies in understanding that both race and sex/gender have biological and social implications for trial design. For example, if a comorbidity has a differential distribution by race-ethnicity, then, analyses should be centered on relevant comorbidities (as effect modifiers or confounders) rather than race-ethnicity. Additional guidance, training, and resources from government and funding agencies are a necessity to better inform researchers on design and analysis.[1]

Institutional infrastructure plays an important role. Our work illustrates the lack of support to accommodate additional challenges accompanying minority recruitment. Although it might be expected that a “good researcher” would recognize the challenges, there is value in outlining recommendations from our focus groups. They include travel and parking reimbursements, additional research staff at remote sites, and flexible enrollment hours, all of which require additional monies. Realistic budgeting coupled with enhanced training on communication strategies are two key practices NIMICT plans to implement into the toolkit.

Our survey results also demonstrate general recruitment challenges while underscoring the investigators’ primary concerns about communicating research terminology. The complex nature of trials demands accessible materials to help communicate unclear terminology to subjects and their families and training research personnel through a culturally competent lens is critical. In addition, addressing perceptions about race-ethnicity, culture, and socioeconomic status,[17] as well as engendering trust is important to improve minority recruitment. This includes addressing biases and stereotypes about patients and communities.[18, 19] Finally, creating meaningful community partnerships that guide enrollment of participants should be recognized as an important first step.[1, 17] Given the arduous nature of clinical trials, increasing accessibility and providing support (e.g., additional training/education and budgetary) for stroke trial enrollment will benefit all populations.

Conducting stroke research raises unique challenges including, the acute nature of conditions, lack of decisional capacity, and limited knowledge or misunderstanding of neurological conditions,[18, 20] requiring an added level of sensitivity on the part of recruiters. Noted in cancer research,[21, 22] as well as in stroke trials, many patients do not receive a timely diagnosis due to limited access to healthcare[23] that often excludes the individual from trial participation. The inclusion/exclusion criteria are also equally pertinent. Often, patients are ineligible due to comorbid conditions or struggle with communication issues (e.g., dementia and aphasia), but also age restrictions often exclude many stroke patients. Tools and resources that are developed need to take into account these unique challenges, and address broader barriers to access.

Our approach has possible limitations including purposive sampling, which was used to select stroke investigators for the focus group sessions and key informant interviews. We believe that the cross-section of researchers sampled provided a varied perspective, but it is possible not all viewpoints are represented. In addition the survey provided only researchers’ perception of their recruitment and retention best practices while true rates and practices

may differ. Despite our possible limitations, NIMICT's mixed method approach identified several best practices that we plan to develop and test as a series of tailored recruitment and retention "toolkits." Given the limited number of best practices that are rigorously evaluated, there is a need to test and report successful recruitment and retention strategies. For example, Beach and colleagues (2005) show that cultural competency training improves healthcare providers' attitudes, beliefs and knowledge about patient populations,[17] but few studies examine the role of cultural competence in the recruitment and retention of minority populations in clinical trials and even fewer evaluate patient outcomes. Therefore, in developing our toolkit, NIMICT will synthesis, review and test innovative strategies to improve minority recruitment in neurological and stroke clinical trials. Our first priority is to adapt and test a motivational interviewing (MI) training aimed at clinical trial investigators and personnel. Respondents in our study reported that mistrust of the medical establishment was a critical barrier. We will leverage MI as a tool to improve communication between the clinical research team and patients and their families by engendering trust, practicing cultural competency, and adapting accessible techniques (e.g., visual explanations of research terminology) to address participants' concerns.

Conclusion

NIMICT's formative research identified several critical issues that require further investigation. We will provide validated recruitment and retention strategies and resources to stroke researchers. Yet, solutions are not one-dimensional and must be implemented on all levels. Policy changes and enforcement must come from the government at early stages in the grant review process and continue throughout study set-up, implementation and community dissemination. NIMICT's research contributes a new dimension to the literature as it highlights researcher-reported barriers, challenges, and identifies future directions for creating evidence-based tools and solutions.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Investigators' strategies to incorporate NIH Inclusion Policy.

	n=93*	Percent (%)
Study Procedures		
Adjusted research to include minority populations	45	53.6
Actively set minority recruitment goals	43	51.2
Requested extra time/money to achieve minority recruitment goals	8	9.5
Education and working with community members		
Required all staff to complete cultural competency training	29	36.3
Collaborated with minority community members in study design and planning	44	51.2
Research procedures		
Clinicaltrials.gov to advertise trial	45	91.8
Visual aids to obtain consent	30	40.0
Language translation services	58	80.6

*Due to missing values, the totals may be less than 93.

Table 2

Investigator identified best practices and recommendations.

Barrier	Theme	Illustrative Quote(s)	Best Practice, Recommendation(s)
Structural and Institutional	NIH Inclusion Policy Clarification	If the African American community makes up 12% of the population and you have 12% of your study patients who are African American, is that adequate? Will you be able to anything with that analysis?	• Guidance on criteria for optimal inclusion rates; • A priori minority recruitment and retention budget parameter.
	Trial design and site selection	What is the prevalence of the disease? Are you mimicking the prevalence or the racial breakdown of wherever you are conducting the trial?	• Best practices on clinical trial design/analysis.
	Value of community engagement and partnerships	You have to go to the community to develop those relationships. That's the only way you're going to get those participants. [An academic institution] is two miles from the clinic, and the patients are there, the diversity is there but the patients are not traveling to [the institution] and vice versa. I think that is one of the biggest challenges…bridg[ing] trials to communities.	• Tips/tools on fostering and maintaining equitable community partnerships.
	Physician relationships	If the physician believes it's a good choice for [the patient then] he/she are usually more onboard.	• Primary Physician toolkit with active trial information.
Recruitment Communication	Effective training	I would support training to recruit minorities or recruit anyone, recruitment is training people about what are these peoples' concerns, how do I establish trust, what are the patients' needs. Recruitment is not based on the recruiter but it is really the psychologies, motivational interviewing, the 'human factor.'	• Communication education; • Cultural Competency training; • Motivational Interviewing.
Unique challenges	Clinical environment and patient population	Because neurologic injury occurs, a proxy now has to make a decision about a loved one to enroll in a clinical trial… It's not your own risk; it's the risk for a loved one.	• Navigating acute clinical trials; • Guidance on patient denial/ stigma.