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

Bernadette Boden-Albala, DrPH; Heather Carman, MPH; Lauren Southwick, BA; Nina S. Parikh, PhD, MPH; Eric Roberts, MPH; Salina Waddy, MD; Dorothy Edwards, PhD

Background and Purpose—The National Institutes of Health policy calls for the inclusion of under-represented groups, such as women and minorities, in clinical research. Poor minority recruitment and retention in stroke clinical trials remain 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, 43 (51.2%; 70% response rate) respondents reported proactively setting recruitment goals for minority inclusion, 29 respondents (36.3%) reported requiring cultural competency staff training, and 44 respondents (51.2%) reported using 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 (eg, realistic budgeting to support challenges in recruitment, such as travel/parking reimbursement for participants), research staff cultural competency and communication training, and developing and fostering community partnerships that guide the research process.

Conclusions—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. (Stroke. 2015;46:00:00. DOI: 10.1161/STROKEAHA.114.008564.)

Key Words: clinical trial ■ ethnic groups ■ health policy ■ National Institutes of Health (US) ■ stroke

Inadequate involvement of under-represented groups, such as women and racial-ethnic minorities, can negatively affect the scientific, economic, and ethical value of a clinical trial. Specifically, nonrepresentative samples limit a trial’s safety and efficacy to the general US population. Accordingly, the National Institutes of Health (NIH) Revitalization Act of 1993, PL 103–43, established guidelines for appropriate representation of women and minorities in NIH-funded clinical research. Despite this legislative intervention, minority participation rates remain suboptimal, especially in neurological clinical trials. In an analysis of National Institute of Neurological Disorders and Stroke funded clinical trials, Burke et al found that black participation rates are above population levels, whereas Hispanics and other racial-ethnic groups remain under-represented. Given the documented racial-ethnic disparities in the incidence of neurological conditions, particularly stroke, representative clinical trial study samples are critical.

Previous research has explored lay/patient-level recruitment and retention barriers in stroke clinical trials. Identified lay-barriers include inadequate information on research opportunities and trial requirements, burdensome time commitment (eg, 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. In particular, minorities noted fears of mistreatment, exploitation, and being treated as a guinea pig (eg, Tuskegee Syphilis Study) 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 National Institute of Neurological Disorders and Stroke/National Institute on Minority Health and Health Disparities:5U24MD006961) seeks to identify the constellation of investigator-level barriers, and 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 death12 and carries a large portfolio of clinical trials. The aim of this article 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 (eg, 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 trials10 (Methods and Results in Appendix I in the online-only Data Supplement). 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 (Iterative data collection schematic is provided in Appendix I in the online-only Data Supplement).

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 (Survey questionnaire is provided in Appendix II in the online-only Data Supplement). 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 2 follow-up reminder emails within a 6-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 semistructured 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 (Focus Group Guide in Appendix III in the online-only Data Supplement).

Key Informant Interviews

We conducted a series of key informant interviews (n=6) at the 2013 American Academy of Neurology conference. Participants were (1) senior research members (Principal Investigator/Coinvestigator); (2) involved in large multicenter trials; (3) identified for successful inclusion of minority participants; and (4) recommended by NIH peers. 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 4 investigators (BBA, DFE, HC, and LS) to determine thematic codes, following procedures outlined by Patton.14 Using the consolidated criteria for reporting qualitative research checklist,15 our approach and additional details are described in Appendix IV in the online-only Data Supplement.

Results

Survey

Ninety-three clinical stroke investigators of 123 invited to the Princeton Conference responded to our survey (response rate, 75%). Twenty-eight respondents (32.2%) self-identified as nonwhite and n=19 (22.6%) noted fluency in language other than English. Thirty-eight (44.7%) participants have been involved in >10 stroke trials. The majority (n=71; 84.5%) of respondents reported working with several different racial-ethnic groups (white, n=68; Asian American, n=13; black, n=63; Hispanic, n=40; Native Hawaiian/other Pacific Islander, n=2; American Indian/Alaska Native, n=3). Twenty-three respondents (27.1%) 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 reported (n=43; 51.2%) proactively setting recruitment goals for minority inclusion. Twenty-nine respondents (36.3%) reported requiring cultural competency for staff training and forty-four reported (51.2%) using community consultation about trial design. Thirty-one (36.9%) 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 (Survey questionnaire Question 36) is provided in Appendix II in the online-only Data Supplement). The 3 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 3 best people to obtain...
Table 1. Investigators’ Strategies to Incorporate National Institutes of Health Inclusion Policy

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

*Because of missing values, the totals may be <93.

cost were study coordinators (n=28; 37.3%), principal investigators (n=15; 20.0%), and attending physicians (n=11; 14.7%). Approximately 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, whereas 30 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 (eg, Emergency Department, Intensive Care Unit [ICU]). They expressed difficulty about relaying the concept of prognostic uncertainty, explaining research concepts in lay terminology (eg, therapeutic misconception), and poor communication because of language, education, and culture.

**Focus Group and Key Informant Interviews**

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

Researchers expressed frustration on the practical application of the NIH Inclusion Policy for adequate representation for valid analysis. In a discussion of adequate power for multiple racial-ethnic group comparisons, several questioned operational parameters and denominator definitions for adequate representation. Investigators also articulated inter- and intrainstitutional 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 materials 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 nonresearch community (ie, primary care physicians) was also a best practice; however, some expressed concern that nonresearch 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 2 distinct qualitative approaches to 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 add 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 toward neurological injuries may play a role, whereas 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 US population representation levels. The US demographic landscape is becoming more multiethnic, and the lack of balanced clinical trial participation by diverse racial-ethnic...
groups hinders our ability to generalize scientific findings at the population level. Because the NIH Inclusion Policy was signed into law, overall participation rates in the National Institute of Neurological Disorders and Stroke funded trials has grown,4 Black enrollment increased, whereas participation among Hispanics decreased,4 American Indian/Alaska Native, Asian, Native Hawaiian/Other Pacific Islander, and ≥2 race groups remain largely under-reported, which raises concern with regard to subgroup generalizability.2,4 Across major diseases (eg, 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. We highlight challenges at the structural/institutional level as well as outline 2 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 that 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 on 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 subgroup analyses. The focus of the policy lies in understanding that both race and sex 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 2 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

Table 2. Investigator Identified Best Practices and Recommendations

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Theme</th>
<th>Illustrative Quote(s)</th>
<th>Best Practice, Recommendation(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Structural and institutional</td>
<td>NIH inclusion policy clarification</td>
<td>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?</td>
<td>Guidance on criteria for optimal inclusion rates</td>
</tr>
<tr>
<td></td>
<td></td>
<td>What is the prevalence of the disease? Are you mimicking the prevalence or the racial breakdown of wherever you are conducting the trial?</td>
<td>Best practices on clinical trial design/analysis</td>
</tr>
<tr>
<td></td>
<td>Value of community engagement and partnerships</td>
<td>You have to go to the community to develop those relationships [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… bridging trials to communities</td>
<td>Tips/tools on fostering and maintaining equitable community partnerships</td>
</tr>
<tr>
<td>Physician relationships</td>
<td>Effective training</td>
<td>If the physician believes it’s a good choice for [the patient then] he/she is usually more onboard</td>
<td>Primary physician toolkit with active trial information</td>
</tr>
<tr>
<td>Recruitment communication</td>
<td></td>
<td>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</td>
<td>Communication education Cultural competency training Motivational interviewing</td>
</tr>
<tr>
<td>Unique challenges</td>
<td>Clinical environment and patient population</td>
<td>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</td>
<td>Navigating acute clinical trials Guidance on patient denial/stigma</td>
</tr>
</tbody>
</table>

NIH indicates National Institutes of Health.
Competent lens is critical. In addition, addressing perceptions about race-ethnicity, culture, and socioeconomic status, as well as engendering trust, is important to improve minority recruitment. This includes addressing biases and stereotypes about patients and communities. Finally, creating meaningful community partnerships that guide enrollment of participants should be recognized as an important first step. 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, requiring an added level of sensitivity on the part of recruiters. Noted in cancer research, as well as in stroke trials, many patients do not receive a timely diagnosis because of limited access to health care that often excludes the individual from trial participation. The inclusion/exclusion criteria are also equally pertinent. Often, patients are ineligible because of comorbid conditions or struggle with communication issues (e.g., dementia and aphasia), but also age restrictions often exclude many patients with stroke. 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 think 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 et al show that cultural competency training improves healthcare providers’ attitudes, beliefs, and knowledge about patient populations, 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 develop and test a motivational interviewing 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 motivational interviewing 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.

Conclusions
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 1-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.

Sources of Funding
This work was supported by the National Institutes of Health (U24MD006961).

Disclosures
None.

References
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Stroke. published online July 16, 2015;
Stroke is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0039-2499. Online ISSN: 1524-4628

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://stroke.ahajournals.org/content/early/2015/07/16/STROKEAHA.114.008564

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SUPPLEMENTAL MATERIAL
Supplemental Methods: Appendix A

Phase I: Traditional Literature Review

Methods:
- A PubMed search was performed in Summer 2012 covering the period January 2001 to August 2012.
- To identify all relevant articles, the following Medical Subject Heading (MeSH) terms and keywords were used: Barriers, Best practices, Challenges, Clinical trial, Ethics, Informed consent, Neurological/stroke clinical trials, Racial-ethnic minority, Recruitment, and Retention.
- To minimize bias, two reviewers conducted the traditional/narrative literature review to compile a database. A third reviewer adjudicated unresolved disagreements between reviewers.
- Once the database was compiled, manuscripts were alphabetically and systematically screened for inclusion/exclusion criteria by two reviewers. The systematic screening procedure involved abstract screening and full-text manuscript review in Endnote X6.
- Articles were included if they:
  - contained at least one MeSH term; discussed racial-ethnic minority, women, or other underserved populations involvement in any type of clinical research, noted the NIH Revitalization Act and/or NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.
- Qualitative analysis consisted of categorizing articles by theme(s) and subtheme(s). Article reviewers found a total of four themes and twelve subthemes. Themes and subthemes were selected by using MeSH terms and PubMed keywords. The theme and sub-theme categorization was not mutually exclusive.
- Each article was categorized under at least one theme and at least one subtheme. Articles were organized with EndNote X6 and data were extracted using Microsoft Excel to create a two-mode matrix to graph the article and theme classifications.

Results:
- A total of 300 articles serve as the basis for analysis. The majority of the articles (n=155) were published within 2008-2013 while a third of the articles (n=103) were published in 2010-2013. Despite the original 2001 start date; the reference list examination yielded additional pertinent articles published prior to 2001 (n=19).
- Most articles were classified as clinical trial/research (n=154), including manuscripts reporting findings of clinical trials, retrospective analysis, and comparative research.
- Of the clinical trial/research articles’ (n=154), the majority included demographic information of race-ethnicity (n=123) and gender (n=121) of participants in results or findings section.
- More than half of clinical trial/research articles conducted quantitative studies (n=79).
- Of the qualitative research articles (n=75), the majority reported on the patient perspective (n=55).
- Review, commentary, and editorial articles (n=115) identified critical barriers in clinical trial research and helped to inform sub-theme categories (see below).

### Challenges and barriers
- Ethical considerations
- Emergency/acute care
- Informed consent
- Mistrust
- Community-based participatory research
- Lay populations’ willingness to participate in clinical research
- Values, attitudes, and experiences

### Research planning
- Recruitment, enrollment
- Retention/attrition
- Study/trial design
- Network and cost

Phase II: Survey Creation

Using the literature review results as a guide, a 43-item survey instrument was created. Domain question included:
SUPPLEMENTAL MATERIAL

Phase III: Focus Group Guide
Using the survey results, we focused on the following questions in the focus group discussion:
- U.S. government policy on minority recruitment/retention
  - NIH has a mandate/policy on minority recruitment into clinical trials
- Successful recruitment/retention strategies
- Unique nature of neurological clinical research
- Best practices and resources (requested)

Phase IV: Key Informant Interview Guide
Using results from the survey and focus group discussion, we queried on the following topics:
- Unique nature of neurological/stroke clinical research
  - Ethical considerations
  - Issues with inclusion/exclusion criteria
- Community and institutional collaborations
- Patient engagement education and outreach strategies
Supplemental Methods: Appendix B
Survey questionnaire

MSSM IRB HSM# 12-00366

Dear Investigator,
You have been identified as an investigator or research coordinator for neurological clinical trials and
your feedback will help us to better understand barriers to recruitment and retention of racial and ethnic
minorities while also providing insight into best practices. We hope to receive completed questionnaires
from about 150 investigators and coordinators, so your answers are important to us. Should you choose to
participate, you are free to skip any questions or discontinue at any time. Your responses are anonymous.
The research team will not know that any information you provided came from you, nor even whether
you participated. By taking part in this survey, you are agreeing to be a participant in this research study.
If you have any questions or comments about this survey, please contact the PI: Bernadette Boden-Albala,
DrPH.

DEMOGRAPHICS
1. What is your age? _____

2. Which race/ethnicity best describes you? (Please choose only one.)
   o American Indian or Alaskan Native
   o Asian / Pacific Islander
   o Black or African American
   o Hispanic American
   o White / Caucasian

3. What language(s) do you speak fluently? (Check all that apply)
   - Arabic
   - Armenian
   - Chinese
   - English
   - French
   - French Creole
   - German
   - Greek
   - Gujarati
   - Hindi
   - Italian
   - Japanese
   - Korean
   - Persian
   - Polish
   - Portuguese
   - Russian
   - Spanish
   - Tagalog
   - Urdu
   - Vietnamese

4. Do you consider yourself to be:
   o a basic science researcher
   o a clinical researcher
   o both basic and clinical researcher
   o Other (please specify)

5. How many clinical trials have you participated in as a researcher?
   o 1-3
   o 4-6
   o 7-9
   o 10+
6. Are any of the following positions on your research team held by individuals with minority status? (Minority Populations defined as: Asian American; Black or African American; Hispanic or Latino; Native Hawaiian and other Pacific Islander; American Indian and Alaska Native).
   - Recruiters? Yes No
   - Co-investigators? Yes No
   - Project managers/coordinators? Yes No
   - Research Assistants? Yes No
   - Community Health Workers? Yes No
   - Nurses? Yes No

7. Are staff members who will be working on projects with minority populations required to go through cultural sensitivity training?
   - Yes
   - No

CLINICAL TRIAL PARTICIPANT DEMOGRAPHICS:
8. Would you consider the areas in which you practice/conduct research to be?
   - Rural
   - Urban
   - Both Rural and Urban
   - Other (please specify)

9. What are the demographics of the subjects you most commonly work with in your research? (Minority Populations defined as: Asian American; Black or African American; Hispanic or Latino; Native Hawaiian and other Pacific Islander; American Indian and Alaska Native)
   - Minority Populations
   - Majority Populations
   - Both Minority and Majority Populations Equally

10. What are the race/ethnicities that make up more than 10% of the participants in your clinical trials? (Check all that apply)
    - Caucasian
    - Asian American
    - Black or African American
    - Hispanic or Latino
    - Native Hawaiian and other Pacific Islander
    - American Indian and Alaska Native
    - Other (please list)

11. What is the sex of the majority of the subjects in your clinical trials?
    - Male
    - Female
    - Evenly Distributed

12. Check all age brackets that represent more than 10% of the subjects in your clinical trials:
    - 0-18
    - 19-40
    - 41-55
    - 56-65
    - 65+
13. Do you work with any vulnerable populations? (Check all that apply)
- Adults unable to consent
- Individuals who are not yet adults (e.g. infants, children, teenagers)
- Wards of the State (e.g. foster children)
- Pregnant women
- Prisoners

RECRUITMENT PRACTICES:
14. Do you actively set specific goals for recruitment of minority populations? (i.e. NIH targeted enrollment forms reflect minority population enrollment)
   - Yes
   - No

15. Have you adjusted your research to be more inclusive of minority participants, in line with the NIH criteria for clinical trial participant eligibility?
   - Yes
   - No
   - I Don't Know

16. Have you had to ask for extra time or money based on achieving your minority recruitment goals?
   - Yes
   - No

17. How much do you agree with the following statement: I feel that I have been very successful in recruiting minority participants?
   - Strongly Disagree
   - Disagree
   - Neutral
   - Agree
   - Strongly Agree

18. Have you collaborated with or sought out advice from minority community groups/members in the planning stages of your neurological studies?
   - Yes
   - No

19. If so, was this a helpful strategy?
   - Yes
   - No

20. Any other comments regarding useful strategies? ________________________________

21. Have you used any of the following online venues to advertise your trial? (please check all that apply)
   - clinicaltrials.gov
   - trialx
   - research match
   - Other (please specify): ________________________________

22. Which of the following materials have you used in previous studies in order to provide information to prospective participants? (check all that apply)
   - Educational Brochures
   - Newsletters
   - Educational Sessions
   - Other (please specify) : ________________________________
23. In your opinion, which of the following play a role in participants’ decisions regarding taking part in neurological studies/trials? (check your top 5)

- Mistrust of science/med establishment
- Lack of understanding of research
- Health literacy level
- Age
- Education level
- Religion
- Ethnicity
- Time commitment
- Privacy concerns
- Invasion of body
- Transportation
- Compensation
- Support
- Stigma
- Cultural understanding
- Family

24. In your experience, what is the most difficult type of neurological study to recruit for?

- Behavioral
- Phase 1
- Phase 2
- Phase 3
- Observational
- Other (please specify):

25. In your experience, what are the most difficult neurological concepts to communicate to patients and their families? (list up to three)

1. _________________________________________________________________________
2. _________________________________________________________________________
3. _________________________________________________________________________

26. My sense is that ___% of my study participants have a comprehensive understanding of the clinical trial they are participating in

- Less than 15%
- 16% - 25%
- 25% - 49%
- About 50%
- 51% - 74%
- 75% - 99%
- About 100%
- Never inquired

27. At what reading level do you write your consent forms at?

____________________________________________________________________________

28. Have you used visual aids in obtaining consent?

- Yes
- No

29. Are language translation services typically available to your participants?

- Yes
- No

30. What do you think are the most important concepts participants need to be fully informed about in a clinical trial? (list up to three)

1. ____________________________________________________________________________
2. ____________________________________________________________________________
3. ____________________________________________________________________________

ENROLLMENT PRACTICES:

31. What percentage of participants in your clinical trials have participated in previous clinical trials?

- Less than 15%
- 16% - 25%
- 25% - 49%
- About 50%
SUPPLEMENTAL MATERIAL

- 51% - 74%
- 75% - 99%
- About 100%
- Never inquired

32. In your experience, is it usual for your enrolled research population to mirror the demographics surrounding your research facility?
   - Yes
   - No

33. In your opinion, who is best suited to recruit and enroll participants?
   - Study Coordinator
   - PI
   - Attending Physician
   - Fellows
   - Clinic/Floor Nurse
   - RA (Research Assistant)
   - Other (please specify):

34. In your opinion, are neurological clinical trials more difficult to enroll participants in than other types of clinical trials?
   - Yes
   - No

35. If yes, why do you believe this to be true?

36. In your opinion, what are the 3 largest obstacles to enrolling minorities in neurological clinical trials?
   - Lack of awareness about trials
   - Economic factors for participants/patients
   - Economic factors for study team (e.g. not enough money for incentives; etc.)
   - Communication issues
   - Mistrust of research and medical system
   - Lack of evidence based recruitment technology
   - Patient population not available
   - Time commitment
   - Time of recruitment
   - Minority populations are less likely to meet inclusion criteria
   - Other (please specify):

37. What are your most successful strategies for enrolling participants in neurological studies? (list up to 3)
1.
2.
3.

38. What are your typical enrollment hours for your clinical trials?
   - Monday-Friday (Normal business hours)
   - Monday-Friday (Flexible)
   - Monday-Friday (24 hours)
   - Monday-Sunday (Normal business hours)
   - Monday-Sunday (Flexible)
   - Monday-Sunday (24 hours)
   - Other (please specify):

COMPENSATION:
39. Do you offer compensation in your clinical trials?
   - Yes
   - No

40. What type(s) of compensation do you offer?
SUPPLEMENTAL MATERIAL

- Monetary compensation
- Reimbursement for travel
- Reimbursement for parking
- Reimbursement for food expenses
- Childcare
- Food
- Other (please specify): ____________________________

RETENTION PRACTICES:
41. What strategies do you employ to better ensure participant retention? Please check all that apply:
- Consistent mail and/or e-mails of important information about the trial
- Phone call reminders
- Working with participants schedules
- Materials (ie. magnets, pens, etc.) with the name and contact of the study
- Transportation reimbursement
- Cash incentive
- Other (please specify): ____________________________

42. In your opinion, which of the following play a role in hindering minority participant retention in neurological studies/trials? (check your top 5)
- Mistrust of science/med establishment
- Lack of understanding of research
- Health literacy level
- Age
- Education level
- Religion
- Ethnicity
- Time commitment
- Privacy concerns
- Invasion of body
- Transportation
- Compensation
- Support
- Stigma
- Cultural understanding

43. In your opinion, should the government have a role in providing support for minority recruitment and retention in neurological clinical trials?
- Yes
- No

MSSM IRB HSM# 12-00366
Thank you for taking the time to complete this survey. As previously mentioned, we will also be conducting focus groups and key informant interviews to gain a more in depth understanding of the barriers to minority recruitment and retention in neurological clinical trials with a particular focus on the issues identified after analysis of this survey. Should you wish to participate in either or both, would like to nominate someone as a key informant, or have general feedback, please contact the PI. Your participation is crucial in gaining a better understanding and addressing barriers to recruitment and retention of minority populations in neurological clinical trials. Thank you for your support!
Focus Group Guide

**Topic 1: GOVERNMENT POLICY ON MINORITY RECRUITMENT/RETENTION?**
- NIH has a mandate/policy on minority recruitment into clinical trials. It says: show slide
- In thinking about the work that you do, focusing particularly on clinical trials and studies, what role does this mandate play in how you approach minority recruitment and what you do?
  - PROBES: Knowing that this exists, does this change the way you think about enrollment? What are the things you are doing now to address this?
- What is your role in ensuring minority recruitment?
  - PROBE: is this a role you assumed? Tasked to you by the PI? Do you feel that you have been adequately prepared?

**Topic 2: SUCCESSFUL RECRUITMENT/RETENTION STRATEGIES**
- What strategies have you used to successfully recruit minority populations into neurological clinical trials?
  - PROBES: What do you think made them successful? What steps were critical in the process? Who needs to be part of this?

**Topic 3: UNIQUENESS OF NEUROLOGICAL CLINICAL RESEARCH**
- We know that there are unique aspects to neurological clinical trials and recruitment, which is why we have been, tasked with this project and we think that the nature of these differences probably are barriers to recruitment of minorities. Let’s talk about what you all feel are differences in neurological/stroke clinical trials
- These require strategies that are very different from other disease areas, i.e. cancer, what are people’s experiences with these areas and do you have any success stories in dealing with these?
  - PROBE: if no success stories, what are some frustrations?
- What can we do to help overcome the “uniqueness” of stroke clinical trials?

**Topic 4 : RESOURCES AVAILABLE**
- Now let’s talk about what is already been done in other disease areas. We are going to show you some sections from Enhancing Minority Participation in Clinical Trials (EMPACT)’s online resource center/toolkit. They came up with several things:
  - Needed cultural competency as part of training
  - Tracking minority recruitment
  - Training on raising awareness about clinical trials
  - Self-assessment of recruitment effectiveness

This is what NIMHD has developed. The mission of EMPaCT is to increase recruitment and retention of racial/ethnic minorities into therapeutic clinical trials with the ultimate goal of reducing cancer-related health disparities. What is your reaction to this kind of toolkit? Are there elements or topic areas that would be helpful for your team/institution? Would people use this? What would you add for neurological diseases?
- Are there resources currently available that have been helpful to you and your team in recruiting and retaining minority participants in neurological clinical trials? What is missing? Are there other kinds of resources that could be in here; business modeling (can we budget for adequate recruitment), how do we market and communicate our trials successfully? How does this interplay with the IRB? Would it be useful to have training on how to disseminate to communities?
- Let’s think bigger. Is a web-based portal enough or are there roles and responsibilities that other partners, team members, institution government, community can play? What would they be and how can we think about integrating them into our focus for this project?

**Conclusion:** Is there anything else that we haven’t touched upon, that you feel we need to know?
## SUPPLEMENTAL MATERIAL

Appendix D.

Focus Group and Key Informant Interviews characteristics: adapted from the consolidated criteria for reporting qualitative research (COREQ) checklist for interviews and focus groups (Tong, Sainsbury, and Craig, 2007).

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<tr>
<th>No Item Guide questions/description</th>
<th>Item</th>
<th>Description</th>
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</table>
| **Domain 1: Research team and reflexivity** | 1. Interviewer/facilitator | Bernadette Boden-Albala, DrPH - NIMICT Principal Investigator  
Heather Carman, MPH - NIMICT Program Manager  
Salina Waddy, MD - NIMICT Scientific Director  
Dorothy Edwards, PhD - NIMICT Co-Investigator |
| 2. Credentials | Boden-Albala is a Social Epidemiologist, Associate Dean, Professor of Public Health, Neurology and Dentistry. Carman specializes in health communication and is a Program Manager. Waddy is an MD and the Program Director of Health Disparities at NINDS NIH. Edwards is a Professor and Chair Department of Kinesiology. |
| 3. Occupation | | |
| 4. Gender | All four researchers are female |
| 5. Experience and training | Boden-Albala and Edwards have extensive experience in neurological clinical trials and mixed methods research. Waddy specializes in health disparities research and minority health while Carman specialized in health communication and health promotion. |
| 6. Relationship established | Due to the convenient sampling, there was a relationship to the interviewees and focus group members prior to participation. |
| 7. Participant knowledge of the interviewer | All participants conduct research and described their experience in the interviews and focus groups. The participants knew that the intent of the conversation was to identify challenges or barriers and best practices with regard to minority recruitment in neurological/stroke clinical trials. Participants were also made aware that the researchers were conducting this study as part of a NIH funded grant with the goal of creating a researcher toolkit. |
| 8. Interviewer characteristics | Due to the purposive sampling, most participants knew the interviewers credentials, background, and occupation. For the participants that did not have a personal connection to one of the NIMICT researchers, the team gave a brief description of their credentials, background, and occupation. |
| **Domain 2: Study design** | 9. Methodological orientation and Theory | Grounded Theory |
| Theoretical framework | | |
| 10. Sampling | Participants were recruited through purposive and snowball sampling. |
| 11. Method of approach | Participants were invited via email to participate in the focus group discussion and an interview by Boden-Albala and followed up by a NIMICT researcher via email. |
| 12. Sample size | Principal Investigator focus group 2013: 18  
Key Informant Interviews 2014: 6 |
| 13. Non-participation | N/A |
## SUPPLEMENTAL MATERIAL

<table>
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<tr>
<th>Domain 3: Analysis and findings</th>
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<td>24. Number of data coders</td>
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<td>Reporting</td>
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<td>29. Quotations presented</td>
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<td>30. Data and findings consistent</td>
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