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A Qualitative Study of Motivations for Minority Recruitment in Cancer Clinical Trials Across Five NCI-Designated Cancer Centers

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Abstract

Background—Minority enrollment in cancer clinical trials is traditionally low. In light of this fact, numerous studies have investigated barriers to recruitment and retention within minority populations. However, very little research has investigated the importance of clinicians' and researchers' motivations for minority recruitment in cancer clinical trials. Therefore, we sought to examine motivations for minority recruitment across four professional stakeholder groups (principal investigators, clinicians, research staff, and Cancer Center leaders) at five National Cancer Institute (NCI)-designated Comprehensive Cancer Centers.

Methods—This study is based on the data from 91 qualitative interviews conducted across the five NCI-designated Comprehensive Cancer Centers to investigate stakeholders' motivations for minority recruitment in cancer clinical trials.

Results—Emergent themes include (a) minority recruitment increases generalizability of cancer clinical trials, (b) minority recruitment is motivated by social justice, (c) some institutions promote minority recruitment through the use of supplemental financial support, (d) federal funding requirements for minority inclusion in clinical research motivate investigators to focus on minority recruitment, and (e) some stakeholders favor a more race-neutral approach to participant recruitment rather than an emphasis on targeted minority recruitment.

Conclusion—The perspectives of clinical and research stakeholders potentially inform the assessment of existing strategies and the development of new strategies to increase motivation for minority recruitment in cancer clinical trials.

Keywords

Cancer clinical trials; Minority recruitment; Stakeholders; Motivations for minority recruitment

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Compliance with Ethical Standards

Informed Consent All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000 (5). Informed consent was obtained from all the patients for being included in the study.

Animal Studies No animal or human studies were carried out by the authors for this article.

Conflict of Interest The authors declare that they have no conflict of interest.

Introduction

Minority populations are consistently underrepresented in cancer clinical trials [1–4]. In light of this disparity, researchers have investigated factors that may serve as either barriers or facilitators and decreasing or increasing, respectively, the likelihood of minority recruitment in cancer clinical trials [1–8]. However, most researches focus solely on actual or potential minority participants and overlook the clinical and research professionals who recruit participants to clinical trials [5–11]. Consequently, we know very little about what motivates those persons involved in a trial recruitment to engage in efforts specifically aimed at the enrollment of racial and ethnic minorities into cancer clinical trials. Clinical trial recruitment often requires the joint efforts of multiple groups of clinical and research professionals, and their specific perspectives on minority recruitment may collectively inform ways to improve minority recruitment in cancer clinical trials. Utilizing the data from 91 qualitative interviews with clinical and research stakeholders (principal investigators, clinicians, research staff, and Cancer Center leaders) at five NIH-designated Cancer Centers, we identify motivations for minority recruitment in cancer clinical trials.

Methods

Study Design

The Consortium for Enhancing Minority Participation in Clinical Trials (EMPaCT) was established in 2009 among the NCI-designated Comprehensive Cancer Centers at five institutions: University of Minnesota; University of Alabama at Birmingham; Johns Hopkins University; the University of Texas MD Anderson Cancer Center; and the University of California, Davis. The goal of the consortium was to systematically address limited enrollment of minorities in cancer clinical trials. In the current manuscript, we present the qualitative research findings from interviews across the five sites to identify motivations for minority trial participation among stakeholders at various levels.

Study Population

Qualitative interviews were conducted, in November and December 2010, at each site among the four key stakeholder groups: (1) principal investigators, (2) research staff, (3) referring clinicians, and (4) Cancer Center leaders. Investigators at EMPaCT sites used administrative data on existing oncology studies and personal contacts to identify eligible participants. Potential participants in each stakeholder group were first identified based on group-specific inclusion criteria (Table 1) and the interviewees recruited and enrolled based on personal contacts of investigators at each site.

Data Collection

An interview guide for each of the four key stakeholder groups was drafted and reviewed by the collaborators at each EMPaCT site for content, item clarity, and relevance to minority recruitment in cancer studies. Guides for each stakeholder group included the same content with slight modifications in the wording to fit the corresponding stakeholder group. The interview guide was based on preliminary work and existing literature on the perspectives of research and healthcare professionals on minority recruitment in clinical trials. The

interview guide covered (1) barriers and facilitators to minority recruitment, (2) motivation for minority recruitment for clinical trials (What motivates you to recruit racial/ethnic minorities to trials? What sorts of rewards or incentives are used to motivate you to recruit racial/ethnic minorities to clinical trials?), and (3) resources and support for minority recruitment for clinical trials (Please describe any training you may have had that provided any information about recruitment of racial/ethnic minorities in clinical trials? What sort of support do you receive in the recruitment of racial/ethnic minorities to clinical trials?). In addition, each guide was pilot tested with a member of each corresponding stakeholder group at the University of Alabama at Birmingham Comprehensive Cancer Center; subsequent revisions based on pilot interviewee feedback were incorporated into the final guide. Final interview guides received approval from the respective institutional review boards at all the sites.

The interviewers were comprised of research staff and faculty investigators. All interviewers participated in a 2-day centralized training session, which included the fundamentals of qualitative interviewing and mock interviews using the interview guides. Interviewers (n = 15) were assigned in a manner to avoid any interviewer collecting data at his or her own institution or from a known acquaintance.

All interviews were recorded and the resultant transcripts were coded by 11 coders. Once the final codebook was created, all the 91 transcripts were assigned to pairs of coders. Paired coders reviewed assigned transcripts independently and were blinded to their partners' coding decisions. Coding agreement (Kappa analysis) among all pairs of coders was assessed to ensure quality control, and the average level of agreement on coded transcript excerpts was 99.7% between pairs of coders. Codes were consolidated in instances of coder disagreement. For a further elucidation of the coding strategy, see Durant et al. (2014).

We report only the analysis of those codes that were categorized as motivation and prioritization of minority recruitment according to the organizational scheme of the codebook. The interview excerpts associated with the motivation and prioritization codes for each stakeholder group were reviewed by the investigators to identify unifying themes.

Results

As demonstrated in Table 2, of the 91 interviewees, principal investigators comprised the largest stakeholder group; Cancer Center Leaders comprised the smallest. Men and women were represented almost equally and the majority (>70 %) of interviewees were white. Six themes emerged from the data. Emergent themes are displayed (Table 3).

Theme 1: Minority recruitment increases generalizability of cancer clinical trials

Interviewees across the four stakeholder groups mentioned the importance of generalizability. The concern among many interviewees was that the lower representation of minorities from cancer clinical trials reduces the ability of researchers to extrapolate findings to the larger, more diverse populations. One interviewee expressed this theme in the passage below.

"We know from other data that Asians have different characteristics of certain types of tumors and penetration of those tumors. Okay, well—but if we don't have that data, how do we know how to address it? So I think that's my primary motivation if you were to ask me...." (Referring clinician)

Furthermore, interviewees noted limited generalizability to minority populations was an even bigger concern in the study of some cancers (e.g., prostate cancer) that are more prevalent and aggressive in minority ethnic and racial groups. Interviewees expressed concern that if study populations are not recruited in a way to identify racial and ethnic differences, these disease nuances according to race and ethnicity may be overlooked.

Theme 2: Minority recruitment is motivated by social justice

Interviewees noted social justice as a motivation for minority recruitment in cancer clinical trials. In particular, the interviewees mentioned that some ethnic and racial groups in the USA have suffered disproportionately from social problems including discrimination, poverty, and limited access to healthcare. Interviewees also noted that cancer clinical trials are viewed as cutting edge and potentially very beneficial to the actual participants. Additionally, interviewees believed the inclusion of minorities would potentially lead to a better understanding of health disparities and, thus, a potential reduction in health disparities. While discussing minority recruitment, one interviewee explicitly stated that minority recruitment is a "justice issue" for him:

"You know, because I've been teaching enough that, I think it's a justice issue." (Cancer Center leader)

Also, interviewees were motivated by personal experience in terms of cancer and racial health disparities. The passage below helps to demonstrate how the interviewee's attitudes and experiences dealing with race relations in contemporary American society helped to motivate her to recruit minorities onto cancer clinical trials.

"... a large part of my work, both within cancer and outside of cancer, has focused on those areas, on those target (minority) populations, who are most vulnerable, and so, talking with them, meeting with them, figuring out what the issues are, and then helping to use that information to form interventions is primarily what I do, so I think, on a personal level, in my own family history of disparities and, and particularly around cancer, with significant family members having died from cancers that really shouldn't have, things that were, that are typically thought of as preventable, so that, I think there's a motivation to be able to reach more people to help them to prevent, and in the cases where they do have cancer, become, have better success with their survivorship." (Principal investigator)

In the passage above, the interviewee stated that she had personal experience with someone who the interviewee believe should not have died from cancer due to racial disparities in access to treatment. The respondent recognized the role of health disparities in the demise of minority family members stricken with cancer and suggests that increased access to clinical trials may lead to better outcomes among minority cancer patients in the future.

Theme 3: Minority recruitment is motivated by supplemental financial support

Stakeholders discussed the use of supplemental financial support for researchers to motivate them for minority recruitment. Supplemental support is offered internally by the institution and once the researcher has fallen short of meeting mandated minority recruitment specifications. Supplemental research funding is offered, internally by the institution, for project support. Thus, any supplemental financial motivation is frequently added after research is underway. Subsequently, the institution helps to incentivize the recruitment of additional minority patients. The passage below illustrates this theme.

"Investigators who need assistance financially just come and usually in a two-page proposal, say what it is and that's reviewed and if it's deemed within our mission and scientifically important and a well writing protocol, we'll provide the extra funding." (Referring clinician)

Most stakeholders believed that this process of adding supplemental support was helpful in terms of increasing minority recruitment when minority recruitment was deemed particularly difficult. However, stakeholders also mentioned that supplemental funds for recruitment were limited once the research was already underway.

Theme 4: Federal funding requirements for minority inclusion in clinical research motivate investigators to focus on minority recruitment

Interviewees also discussed the potential enhanced academic reputation of the institution by garnering or maintaining NCI Comprehensive Cancer Center designation. NCI-designated Cancer Centers receive designation for their scientific leadership and the depth and breadth of their research in basic, clinical, and/or population science while simultaneously following NIH guidelines for minority recruitment. Accordingly, institutions must adhere to federal guidelines mandating the inclusion of minorities in cancer clinical trials, and adherence to this mandate strongly influences receipt and maintenance of the Comprehensive Cancer Center designation. While discussing minority recruitment, the interviewee below demonstrates this theme in the passage below.

"We are part of a comprehensive cancer center and if we don't perform, in terms of entering all of our patients into trial, we may lose the designation as a comprehensive cancer center. Again, maintaining your designation as a comprehensive cancer center as we enroll patients in the GOG (Gynecologic Oncology Group) the more minority patients we enroll the more likely are we—to have our name acknowledged in terms of academic credit...but I guess the academic effort is really important and we want to have as many of our patients represented in trials as we can." (Referring clinician)

As noted above, research institutions that have a reputation based largely on cancer research must focus on maintaining this reputation in order to preserve academic prestige. Interviewees did not note the importance of NCI designation from the local community's perspective, that is, people in the area surrounding the center. The designation was primarily valuable within an academic context.

Furthermore, several participants highlighted the importance of recruiting minorities in order to receive funding for grants from the NIH. According to the interviewees, the NIH is the primary funding source for a large proportion of cancer clinical trials. Lacking minority participants may preclude a study from receiving funding for a particular trial and, henceforth, PI's and Cancer Center leaders are motivated by the fear of losing funding for a proposal or grant. In terms of incentivizing behavior, interviewees referred to this mechanism as a "stick" rather than a "carrot." The interviewee elicits this point in the passage below.

"I think that when, NIH reviewers are reviewing initial applications and there are, you put in, you describe what your minority, your expectations are for minority and gender participation, if the plan is not reasonable, then you, the consequences are that you wouldn't be funded, so those are pretty severe consequences, and I think that, once a study is funded, that if you're having difficulty with minority recruitment, then you, I imagine there could be consequences, but it, it's not really ever been an issue for me, except in that one cancer study, but that was a very short study. It was only for two years. If it would've been a longer study, I would have gone outside the university, I think." (Principal investigator)

In the above passage, the PI notes how her research most likely would not have been funded if she did not specify the level of minority recruitment as well as follow her planned accrual rates throughout the data collection and analysis processes. The passage below further demonstrates a similar perspective.

"If there were some carrot rather than just a whip, you know, my understanding of the process now is that we can only fail, you know, that—and the NCI will say, 'Hey, you're not enrolling enough trials. You're not enrolling enough minorities on trials,' you know. 'You're in trouble' or, you know, 'We're going to ding you for that' or whatever." (Principal Investigator)

Both of the above quotes reflect the concern that current impact of the NIH mandate for minority inclusion may punish noncompliance more than proactively incentivizing minority recruitment.

Theme 5: Some stakeholders favor a more race-neutral approach to participant recruitment rather than an emphasis on targeted minority recruitment

Although one of the main research questions of the EMPaCT study involved prioritization of minority recruitment, some interviewees shared that they did not make specific considerations or devote any special efforts toward minority recruitment. Instead, interviewees discussed a general philosophy toward inclusion of all patients rather than focusing solely on one group over another. In other words, stakeholders believed that recruitment of all human subjects should be equally prioritized rather than focusing on or targeting specific (traditionally underserved) groups. For example, one interviewee responded that she did not "distinguish between racial groups" when recruiting participants into cancer clinical trials. She was simply "happy to recruit whomever they could." Others suggested that minority recruitment was simply not a major concern as reflected in the passage below:

"Ok, I might be a bad interview person cause I don't know that I have concerns with anyone in particular (referring to minorities) being on a trial" (Research staff)

A principal investigator interviewee alternately stated, "Let's just say increase participation, period, because I don't worry, (if) it's minority or not." In short, interviewees who did not specifically focus on minority recruitment stated that the goal was not to focus on any one racial group, but rather to focus primarily on getting patients—of any race or minority status —enrolled into trials.

Discussion

To our knowledge, this study is the first to investigate stakeholder motivations about minority recruitment across the five NCI-designated Comprehensive Cancer Centers in the United States. The response data, based on stakeholder motivations, may inform effective multilevel strategies to increasing minority enrollment in cancer clinical trials. We offer a short discussion of potential multilevel strategies that could increase minority recruitment based on the emergent themes elicited from the qualitative data. Finding ways to increase the frequency of the themes or motivations mentioned in this study could help to increase minority recruitment in cancer clinical trials.

We found that some stakeholders did not have a motivation to recruit minorities or did not prioritize targeted minority recruitment, despite federal guidelines mandating minority recruitment. Rather, some stakeholders adhered to a belief that all human subjects should be recruited with equal fervor. There is an ongoing debate in cancer clinical trial recruitment; one perspective notes that stakeholders should target underrepresented groups in order to increase minority recruitment and retention [9], while another perspective states that raising recruitment among all groups will increase minority recruitment [10, 11]. Both views were expressed by our interviewees and we believe that both views may have merit. However, considering the latter—raising recruitment among all groups—has not dramatically increased minority recruitment, we suggest a targeted approach is worthy of discussion and perhaps warrants further implementation in cancer clinical trials.

Previous literature suggests that the enhancement of generalizability within clinical trial results was an important motivator for minority recruitment in cancer clinical trial research. In short, some stakeholders believed that ensuring the recruitment of minorities increased the generalizability of findings in their studies [12]. Researchers have discussed a potential mechanism for motivating stakeholders—based on the premise of maximizing generalizability—could involve journals mandating or encouraging the reporting of results by racial category [13–15]. Mandating the reporting of results by racial category would help motivate researchers and PI's to enroll adequate proportions of minority participants in clinical trials because not doing so might limit opportunities for publication and dissemination of one's work [15]. In addition, researchers and PI's would be cognizant of this issue throughout the research and data collection process. We do not suggest that falling short of an adequate number of minority patients should be an automatic rejection from a journal, but rather that minority representation would be one criterion for assessment and should be addressed as a strength or weakness in the manuscript submitted for publication.

In addition, we found that stakeholders used financial supplements to motivate stakeholders to recruit minority participants, including financial support of general trial recruitment efforts. Prior research has found a similar motivation for participant recruitment more generally; they found physicians were more likely to recruit participants if there was financial support to recruit participants into cancer clinical trials [16]. Although most interviewees did not advise the provision of financial support for minority recruitment specifically, some were amenable to the idea of providing supplements at the institutional level that may increase funds available for minority recruitment efforts within an ongoing trial. In light of this motivating factor, we suggest that institutions consider offering more financial support before a trial when investigators have a definite minority recruitment goal and have planned efforts outside of the standard recruitment approach to reach potential minority participants as well as supplemental support to fund recruitment efforts aimed specifically at increasing minority recruitment within an ongoing trial.

We found that federal government mandates continue to provide an important motivation to motivate stakeholders to recruit minorities. This is also reflective of a study by Taylor (2008) [17] in which investigators indicated that NIH guidelines were partially responsible for their attention to the inclusion of women, minorities, and children in clinical research. Our findings illuminate the importance of external funding and guidelines as a motivation for minority recruitment and highlight the importance of providing supplemental financial support rather than simply focusing solely on punitive measures for not meeting minority recruitment goals. As one participant framed minority recruitment promotion: "If there were some carrot rather than just a whip." As noted above, we suggest that providing supplemental support at the federal level to those stakeholders who are not meeting specified minority recruitment goals could increase minority recruitment in clinical trials.

This study has some notable limitations. It is a qualitative study based on the interviews at five NCI-designated Cancer Centers, thus the data may not be generalizable to other groups. Despite these limitations, our study population included the four stakeholder groups at the five different Cancer Centers in different regions of the USA who serve varying minority populations. The wide breadth of stakeholders, regions, and experiences with different racial and ethnic minority groups expands current contextual understanding of issues and clinical and research staff perceptions surrounding minority accrual to cancer clinical trials. In addition, this study is limited because it only focuses on minority recruitment and does not address retention of minority participants in cancer clinical trials. Although this study does not focus on retention, it is plausible that some of the motivations found in this study could be applied to retention. Other scholars have noted that strategies which improve recruitment also improve retention [1]. For instance, stakeholders with a social justice motivation for minority recruitment may also be motivated to retain minority patients in clinical trials for the same reasons. Furthermore, another avenue for future research could explore motivations for retention.

Utilizing the data from the 91 qualitative interviews with clinical and research stakeholders' (principal investigators, clinicians, research staff, and Cancer Center leaders) at five NIH-designated Cancer Centers, we identify motivations for minority recruitment in cancer clinical trials. Investigators noted being motivated by multiple factors related to broader

societal benefits as well as benefits to specific cancer clinical trials. However, further investigation is needed to determine how the information gleaned about motivations for minority recruitment can inform actual interventions or programs aimed at increasing minority enrollment in cancer clinical trials.

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Table 1

Inclusion criteria for participants in each stakeholder group

Stakeholder group	Screening criteria	
Cancer Center	Cancer Center director or associate director	
Leadership	Financial administrators	
Principal investigator (PIs)	• Therapeutic and/or nontherapeutic trials for at least 3 years before study enrollment	
Research staff	• Non-PIs involved in the "day-to-day" recruitment and/or enrollment of study participants to cancer clinical trials	
Referring clinicians	 Potentially includes nurses, recruiters, or other research personnel directly involved in the recruitment of human participants 	
	• At least 50% of time allocated to clinical duties	

Table 2

Characteristics of study population

	No. of stu	No. of study participants	S		
Characteristics	Total $(n = 91)$	Principal investigator $(n = 34)$	Research staff $(n = 33)$	Referring clinician $(n = 16)$	Cancer Ctr. leadership (n = 8)
Mean age (years)	51	46	52	48	60
Gender					
Men	43	21	3	12	7
Women	48	13	30	4	1
Race					
Caucasian	67	24	26	10	7
African American	11	3	5	3	0
Asian	13	7	2	3	1
Ethnicity					
Non-Hispanic	76	29	30	11	9
Hispanic	15	5	3	5	2
Mean number of years of cancer trial experience	12	11	10	13	24
Type of trial					
Therapeutic	27	4	19	2	2
Nontherapeutic	9	5	1	0	0
Therapeutic and nontherapeutic	56	24	12	14	9
Not indicated	2	1	_	0	0

Table 3

Emergent themes

Emergent	Emergent themes		
1	Minority recruitment increases generalizability of cancer clinical trials.		
2	Minority recruitment motivated by social justice.		
3	Minority recruitment motivated by supplemental financial support.		
4	Federal funding requirements for minority inclusion in clinical research motivate investigators to focus on minority recruitment.		
5	Stakeholders favor a more race-neutral approach to participant recruitment rather than an emphasis on targeted minority recruitment.		