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Training Needs of Clinical and Research Professionals to Optimize Minority Recruitment and Retention in Cancer Clinical Trials

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INTRODUCTION

More than 20 years ago, the National Institutes of Health (NIH) Revitalization Act of 1993 was signed into law resulting in the policy requiring —that women and members of minority groups and their subpopulations be included in all NIH-funded clinical research [1]. Despite this mandate, racial and ethnic minorities' rates[2] of participation in cancer clinical trials are low compared to non-Hispanic whites[3]. The low rates of minority participation take on an increased significance considering the racial and ethnic disparities in cancer incidence

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and mortality. National Cancer Institute (NCI) statistics [4] in 2016 reveal cancer incidence and death rates are higher among black men compared to white men for every tumor site except renal cell carcinoma. From 2003 through 2012 (the most recent data available), breast cancer mortality rates have declined annually in all races and ethnicities except among American Indians and Alaskan Natives. However, a striking divergence in long-term breast cancer mortality trends between black and white women emerged in the 1980s and has since continued to widen and by 2012, it was 42% higher in black women than in white women. [5]. Gastric and liver cancer incidence and death rates are twice as high in the Asian American/Pacific Islander population as in whites[4]. These disparities underscore the need to include members of racial and ethnic minority groups in clinical trials to better understand factors that contribute to racial differences in cancer outcomes. A wide range of efforts is required for successful minority recruitment in cancer clinical trials [6, 7].

Though the importance of increasing the recruitment of minorities to research trials has been widely acknowledged [6–8], the necessary components of minority recruitment training for clinical and research personnel are not well-established. A systematic review revealed that cultural awareness among health care providers and researchers as well as culturally-appropriate communication during clinical trial recruitment are necessary parameters for long-term success in the enrollment of African Americans [9–12]. The same facets of trial recruitment have been identified as necessary elements in the enrollment of Latinos [13] and Asian Americans[14]. In a recent study[15], a comprehensive, multi-faceted effort, including leadership support and center-wide policy change, was implemented to increase minority research participation. Although these studies presented cultural awareness as an important component of multi-pronged efforts to increase minority recruitment, none specified the nature or extent of minority recruitment training that would be appropriate. Another study [16], utilizing a network of community-based academic sites and focusing on improving cultural awareness, showed a 62% increase in minority participation in nontherapeutic cancer clinical trials.

As described, studies have shown that cultural awareness is associated with more effective minority recruitment. However, to our knowledge, no prior studies have assessed training needs to increase cultural awareness or prepare clinical and research personnel for minority recruitment with a specific focus on therapeutic cancer clinical trials. Thus, we explored training experiences related to minority recruitment among research and clinical stakeholder groups including 1) principal investigators, 2) research staff, 3) referring clinicians and 4) cancer center leaders at 5 NCI-designated cancer centers.

MATERIAL & METHODS

Study Design

The consortium for Enhancing Minority Participation in Clinical Trials (EMPaCT) was established in 2009 at 5 institutions: University of Minnesota, University of Alabama at Birmingham, Johns Hopkins University, 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 this analysis, we present the qualitative research findings from the portions of our interviews focused on experiences and

perspectives related to training for minority recruitment among clinical and research staff at the 5 cancer centers affiliated with EMPaCT.

Study Population

Qualitative interviews were conducted at each site among 4 key stakeholder groups: 1) principal investigators, 2) research staff, 3) referring clinicians, and 4) cancer center leaders. Investigators used administrative data on existing oncology studies and personal contacts to identify eligible participants. Participants in each stakeholder group were recruited based on group-specific eligibility criteria (Table 1).

Data Collection

Based on literature and content expert review, a specific interview guide was developed for each of the 4 key stakeholder groups. Further details with regard to interviewer training and administration of interviews are available elsewhere[8].

Data Analysis

All transcripts were assigned to pairs of coders for independent review in the second phase of coding. Coding agreement among all pairs of coders was assessed utilizing Kappa analysis to ensure quality control, and the average level of agreement on coded transcript excerpts was 99.7% between pairs of coders. Descriptive statistics were calculated to describe sample demographic characteristics. Further details on the qualitative analysis are available elsewhere[8]. We report only the analysis of those codes that were categorized as training needs of research professionals in minority recruitment and retention according to the organizational scheme of the codebook.

RESULTS

Our sample included 91 interviewees (Table 2). Men and women were represented almost equally among all interviewees and greater than 70% of participants (n=67) were white.

Theme 1. Research personnel are not currently being trained to focus on recruitment and retention of minority populations

Training for clinical trial recruitment was based largely on following general federal guidelines or clinical ethical principles without a specific focus on recruiting minority populations.

“You know I've had training in terms of you know enrolling people on clinical trials but I don't know I've had specifically had any training enrolling minority patients in clinical trials that I'm aware of.” (Research staff)

One principal investigator notes that minority recruitment was mentioned generally, but was never a focus of dedicated training.

“I did one training session sort of generic National Cancer Institute Guidelines Barriers, sort of general talks. You know people like Investigator X give different

lectures, different faculty meetings it's brought up so again it's just low level constant awareness that we should be looking at this.” (Principal investigator)

Another principal investigator adds that general research ethics training has included some portion on minority enrollment while recognizing that the attention paid to minority recruitment was minimal and likely inadequate.

“Everybody, as you know, goes through, you know, IRB and ethics training, and there is a small snippet of that training that relates to certain recruitment of minorities, but it really probably is not attentive enough, I don't think, to issues that relate to cultural sensitivity.” (Principal investigator)

The respondents stated that the typical clinical trial recruitment training did not include a focus on minority recruitment, but instead relied on hiring staff with sufficient oncology clinical experience and training them on general human subjects' recruitment. Experience in clinical care was considered an adequate transferable skill for recruiting patients to a clinical trial.

“Our research nurses have been nurses before. They have been oncology nurses before so they have taken care of patients. So we all have some experience and have dealt with many different clinical situations. So I think all of us have already learned on the job, and we talk, but we have nothing formalized in terms of education or training [of minorities].” (Principal investigator)

The evaluation of clinical experience as a sign of readiness for the effective recruitment of minorities was based on a presumption that health care professionals have vast experience in communicating with patients of all races and ethnicities and thus would readily be able to recruit minorities to clinical trials.

Theme 2. Training for minority recruitment and retention provides for specific focus on factors influencing minority research participation

While a few respondents expressed that specific training on minority recruitment strategies was not needed, many stated that focused training would be helpful since they were currently drawing from life experiences and obtaining insights from colleagues of different cultures, for added perspective.

“You know I'd look probably [go] online or, or talk to, I'd talk to colleagues probably who are of that race or ethnicity.” (Principal investigator)

A majority of the respondents endorsed the notion that some factors uniquely influence minority decision-making related to trial participation. Respondents reported that additional information or training, related to those factors could be valuable for persons involved in minority recruitment.

“If there is [sic] indeed, some factors that are out there that make a difference [in minority recruitment] having that knowledge. Because knowledge is very powerful just knowing that that is an issue.”(Research staff)

“You know, I think it would be, you know, always helpful to have sort of ongoing training through the cancer center about addressing specific ways that we could improve minority recruitment into trials and retention.” (Referring clinician)

Specifically, most respondents believed that understanding health seeking behaviors and patterns of health literacy amongst different ethnic groups would be beneficial, and incorporating such information in a training curriculum could be advantageous in increasing minority participation in cancer clinical trials.

I think some more context about historical and cultural perceptions. I think that is when the cultural training can be helpful. And not just minorities, but Hispanics, I mean any other, minorities at large, any other non-White groups, if you will, just to better -- I think if I could early on better understand potential barriers and perceptions that may exist in that specific ethnic or minority culture, then that could help my learning curve be shorter, if you will, or perhaps less steep because I already have some additional information rather than learn on my own and learn on the job; which is essentially how I did. (Principal investigator)

In addition to an improved understanding of race- and ethnicity-specific cultural barriers to participation, respondents reported that additional training would make them more effective communicators, which in turn, would increase minority patients' trust in physicians, nurses, and improve the overall processes of clinical trials. Respondents thought that these positive changes in patient trust might enable minority patients to be more open to the idea of participating in a clinical trial. A research staff member noted the importance of — remaining honest with potential minority participants to ensure that they had the necessary information as well as added support such as interpreters and social workers to increase the likelihood of trial enrollment.

Theme 3. Training on cultural awareness may help to bridge cultural gaps between potential minority participants and research professionals

None of the respondents reported having any formal training with respect to cultural awareness and its role in clinical trials recruitment or retention and the few who reported formal training were trained in the broader context of medical ethics. A majority of the participants stated that formal training with specific insights into different cultures could be helpful over the alternative approach of learning through trial and error. Respondents expressed concern that potential minority participants' perceptions of cultural discordance between themselves and staff could make these already sensitive conversations even more difficult.

“I think that that would be useful for anybody who's dealing with clinical trials and accruing patients, so that would be coordinators, nurses, physicians, you know. I think it would because some of the concerns, as challenging as I am a very pasty white Irish person I don't want someone to feel that I am either talking down to them or that I don't understand what their concerns are and be able to talk to a patient in a way that doesn't come off as condescending or too authoritative, dictator kind of, you need to do this, and it's very hard for us to walk in someone else's shoes, and so for additional training if it makes me a better communicator

and help to build trust with the patient I am all for anything that does that.”
(Research staff)

Interviewees also said that health care professionals, particularly physicians, were —well-educated but not culturally educated. Thus, stakeholders noted that training on cultural awareness could mitigate —biases that you need to overcome and in turn would help research staff to reach out to minorities.

In addition to favoring a concerted focus on minority recruitment, multiple respondents said that understanding the nuances of structure and function of family units and the gender dynamics across certain cultures would be beneficial in recruiting minority patients. For example, interviewees noted that there would be increased benefit of such training, especially during the process of recruiting male minority patients with prostate cancer, which requires potentially sensitive discussions about treatment effects on a man’s sexual function.

“You’re going to need to be culturally sensitive [to] things. Like we deal with a lot of issues because it is prostate that have to do with sexuality and things like that, so I’m sure that if you were doing a trial, which we did it in the past, you would probably need to be more aware of some things.” (Research staff)

Participants noted that training to increase cultural awareness might facilitate more effective provider communications in some of these potentially sensitive discussions around trial participation with minority patients. Furthermore, stakeholders thought that culturally sensitive insights that can be provided through recruitment training would alleviate both the research teams’ and the minority patients’ frustrations that stemmed from poor communication, based on a lack of cultural awareness among research teams.

“I think background, cultural background, would be very helpful. Sometimes you don’t always understand, you know, we’re talking to the patient here and the patient has a disease, yet, why is, you know, this person being the one asking all of the questions, and sometimes that’s -- as we oftentimes will be -- as, oftentimes we get told by the translators out, maybe outside of the room or something, that’s just, you know, that’s the way the family works, and so that’s one thing, but to understand that ahead of time would be helpful.” (Referring clinician)

A cautionary tale from one referring clinician highlighted the potential for an imbalanced training approach involving an extreme focus on training for minority enrollment to the exclusion of training on the fundamentals of human subjects’ recruitment. Thus, research and health care professionals should balance efforts to mitigate cultural discordance and build trust with their parallel efforts to adhere to the most ethical research principles.

“If they have the right sort of attitude in approach and the right intensity and the right toughness in what they are doing, they will be successful. So you teach them that and then it all flows. If you make it real specific about minority enrollment then you create unskilled people with a minority enrollment agenda and it doesn’t work. Under skilled in the key areas [and] agenda driven [-] that’s not a ticket to getting trusted.” (Referring clinician)

None of the respondents reported having diversity awareness training as a strategy towards clinical trial recruitment and retention although a majority of the stakeholders reported more general diversity awareness training as a part of employee orientation. These interviewees perceived their own lack of diversity awareness as a barrier in their understanding of minority patients' perspectives on health and illness. Respondents were aware that biases included but were not limited to race, accent, language, religion and gender. A research staff member added that diversity awareness training is crucial and would aid in bridging the cultural discordance between research staff and potential minority patients especially since the national and local populations have grown to be more diverse.

Though professional interpreters often bridge linguistic gaps during the trial recruitment phase, some interviewees also voiced concerns that interpreters' interactions with potential participants influence their decisions to participate in clinical trials.

“You're not always quite sure what spin the interpreter is putting on all this. And I don't - it would be an interesting I mean that might be an interesting thing to look at is seeing if you had some training for interpreters about that sort of cultural interpretation. Particularly as it pertains to research studies.”(Principal investigator)

Given that nuances around cultural factors, potentially influencing minority participation, could be lost in translation, respondents stated that there would be benefit to training interpreters on cultural awareness in the context of clinical trials.

Theme 4. Views differ regarding the importance of research personnel training to focus on recruitment of minority populations

While most interviewees identified specific aspects of training that would be useful for minority recruitment, a few respondents espoused a belief that no specific focus was needed for the recruitment of minorities. Instead, they stated that racial and ethnic designations should not influence recruitment and, thus, training should focus on the recruitment of all persons, regardless of race or ethnicity. In fact, some saw this race-neutral outlook as a more effective approach to recruitment for clinical trials since there was no inherent differentiation between racial and ethnic groups.

“I don't know if I have a specific strategy. I guess it's good because in a way that means that I don't differentiate. I just go case by case basis rather than putting the ethnic strategy or category in there” (Principal investigator)

Based on the perception that recruitment should not differ by race or ethnicity, respondents questioned the need for specialized training for minority recruitment.

Another objection to a focus on minority recruitment was rooted in the concern that race was a proxy for other factors. Building on the idea of race as an imperfect proxy for other factors more directly related to trial recruitment, one principal investigator suggested that socioeconomic factors actually supersede racial considerations in trial recruitment.

“I think that sometimes when I am dealing with someone who is poor, it doesn't matter whether they are White or Black. I think that the socioeconomic issues are -- The economic issues I think are incredibly powerful. I think once you move above

a certain socioeconomic stratum, my interactions with patients regardless of race or ethnicity are very similar.” (Principal investigator)

A few respondents in all 4 stakeholder groups suggested that the approach of communicating in lay terms was sufficient to ensure that all racial and ethnic groups were recruited. These respondents, promoting the universal effectiveness of using lay language in communicating with potential participants of all races and ethnicities, believed that clear communication, leading to optimal understanding of trials, obviated the need for a specific focus on minority recruitment.

“I try to recruit any patient who qualifies for the trial. You know? But if they are truly minorities then it would be interesting too but you know I find that many of our what you call minorities as I said before are highly educated so you just need to talk like a normal person you don't have to really I don't know what they would how would you teach a nurse or a me to speak differently. I think will work well with minorities as it does with anybody else.” (Referring clinician)

Consistent with the idea that it was not necessary to focus on minority recruitment training, participants emphasized that if training material conveyed comprehensive trial information, recruitment to clinical trials would automatically improve for all groups. This improvement in overall recruitment, would, in turn, increase the number of minority patients in clinical trials. All stakeholders acknowledged that training to ensure consistent communication of standardized information regarding complicated clinical trials is crucial to recruitment.

“The same thing that you would provide to clinicians and it should be provided to the research nurses or recruiters because it's a team and we all should say the same thing and know the same thing”. (Principal Investigator)

While not elevating to the level of a theme, a few respondents thought that factors, such as distrust or fear, impacted all racial and ethnic groups to a certain extent, supporting the notion that a focus on minority recruitment is not necessary. Interviewees stated that it is not uncommon for patients of all racial and ethnic designations to tell researchers or clinicians that they didn't want to be treated as —guinea pigs. Respondents also stated that potential participants' acceptance or refusal of invitations to enroll in clinical trials was related to fear of the disease or treatment and how well that fear is alleviated by research personnel.

Discussion

To our knowledge, this study is the first to explore the desire for training related to minority recruitment in clinical trials by cancer center stakeholder groups across 5 NCI-designated cancer centers. The study reveals research and clinical professionals do not routinely receive formal training on minority recruitment and identifies training needs at all levels (ranging from research staff to cancer center administrators) in order to develop effective approaches towards increasing minority enrollment in cancer clinical trials. The conventional thought of cultural competence as mastery of a finite body of knowledge may not be appropriate with regard to multicultural education training. Instead, cultural humility that incorporates an enduring dedication to self-reflection and learning is highly favored [17]. This approach may better enable research and clinical professionals to take into account some of the unique

cultural norms of racial and ethnic minorities during the trial recruitment process. Recruitment personnel's acknowledgement and consideration of such cultural norms may help to engender trust and increase the likelihood of potential minority participants' acceptance of enrollment opportunities [16]. However, no cultural roadmap can be provided to investigators, clinicians and staff to bridge all encountered cultural differences. In fact, a —one size fits all [18] approach to cultural awareness training may be detrimental to the goal of meeting the varied needs of diverse populations impacted by cancer. Customized training may address some of the divergent perceptions articulated by study participants.

Hence, our focus is on exploring avenues toward developing an educational and training intervention program in order to equip clinical and research staff with knowledge, tools, and skills to better understand and address sociocultural issues in the research setting. The Society of General Internal Medicine (SGIM) Health Disparities Task Force has provided specific recommendations and guidelines [19] for curricula targeting health disparities in a general clinical context. One of the recommendations of the Task Force is to acquire the skills to effectively communicate and negotiate across cultures, including trust-building and the use of key tools to improve communication, such as culturally appropriate language services.

Although the SGIM guidelines pertained to clinical care, we believe that they can be applied effectively in the recruitment of minorities to cancer clinical trials. Thus, based on our data and the above-mentioned recommendations, the authors propose a training program consisting of teaching effective communication skills that can navigate across cultures and deliver effective and understandable clinical trial information in a respectful manner that is also compatible with patients' cultural health beliefs and practices and preferred language. We recommend flexible learning options that include classroom training, live online virtual classes, training (in-person and/or case-based) on demand, and self-study courses. We believe that research teams can be taught how to elicit potential minority participants' health beliefs, accommodate these beliefs as much as possible. Furthermore, it is imperative that training programs be evaluated with regard to their ability to achieve goals of affecting the attitudes, knowledge and skills of learners.

A finding of interest in our study was the variety in responses about training, including the potential for negative and unintended consequences of having minority-focused recruitment strategies. In stating that a focus on racial and ethnic designations should not influence clinical trial recruitment training efforts, the respondents appeared to be conveying broader professional aspirations to deliver care and conduct research that transcends race or ethnicity[20]. Though this is an ideal goal, *Unequal Treatment*, a report prepared by the Institute of Medicine (IOM) [21], states that, at least, a portion of disparities results from — health provider bias conscious or unconscious, individual or institutional. Therefore, training for minority recruitment may be necessary to address health care and research professionals' implicit biases despite their collective efforts to provide care and conduct research in a race-neutral manner. Respondents believed that although more common barriers such as trial complexity and strict eligibility criteria exist for potential participants of all races and ethnicities, the added unique barriers more common to minority recruitment make enrollment of those subgroups even more difficult. For example, interviewees from all

stakeholder groups cited the need to allow sufficient time for decision-making when the clinical trial participant was processing important and complex information as vital to recruiting to clinical trials. This has significant bearing especially since oncology clinical trials have become progressively complex in design [22]. Previous research [23] has revealed that although patients, irrespective of race, might believe they have understood the information, actual understanding is inaccurate or incomplete. In order to overcome the pitfalls of trial complexity in the recruitment of potential minority participants, investigators may need to address general uncertainty as well as research distrust and unfamiliarity [24] which may be more prevalent among minorities. Our respondents added that training with a specific focus on communication and skills and cultural awareness may help to address both general barriers and minority-specific barriers that often hinder minority participation

Similar to other studies [25], our participants believe that decisions to enroll in cancer clinical trials are greatly enhanced when there is clear communication between the clinician and patient. There is evidence [25] to show that clinicians' increased cultural awareness can improve patient physician communication, thereby facilitating the reduction in health disparities. African American patients have been shown to have relatively equal levels of interpersonal distrust in clinical research compared to whites, but often higher levels of societal distrust in clinical research when compared to whites[25]. Clinicians with longitudinal relationships with African American patients may be best suited to build rapport and cultivate confidence in this subgroup. Referring clinicians may be the best ambassadors to introduce their minority patients to clinical trials while alleviating general skepticism about research participation. While researchers may have more fleeting interactions with patients, researchers' ability to gain trust among potential minority participants is important as well. In fact, our interviewees cited that research professionals are often unaware of their communication deficiencies, strongly reiterating the need for appropriate cultural communication skills training for all professional stakeholder groups.

This study has some limitations. Since it is a qualitative study based on interviews at 5 cancer centers, the data may not be generalizable to community-based physicians and researchers based at sites other than cancer centers. However, our interview participants represented 4 stakeholder groups at 5 different cancer centers in different regions of the United States with different local minority populations, allowing for the inclusion of multiple perspectives. Although the stakeholder data corresponds to only some of the data in the previous literature[8], we cannot rule out the possibility that stakeholders' views are informed both by their personal experience and previously published literature about cultural awareness with respect to clinical trial recruitment and retention.

Conclusions

Despite these limitations, our findings highlight the need for training in minority recruitment to cancer clinical trials. Our participants offered unique insights into their own training and identified educational needs that could help them recruit minority patients to cancer clinical trials. On this basis, tailored and regular training sessions are needed to enhance minority trial participation. Clinical trials provide effective and often improved cancer care without burdening the health care system. In addition, participation in trials increases access to state-

of-the-art care, a critical factor in minority communities that suffer disproportionately from cancer mortality. For ethical, social, and scientific reasons, trials require the recruitment of participants from diverse population groups. In order for us to achieve this goal, we need to reiterate that training clinical and research professionals in recruitment and retention strategies require some cultivation of cultural awareness and detailed, planned efforts to address the personal and contextual factors that influence minority enrollment. Without a defined training program for minority recruitment, researchers may be hindered in their ability to study the underlying causes of racial differences, thereby perpetuating existing health disparities.

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Table 1**Inclusion Criteria for Participants in Each Stakeholder Group**

Stakeholder Group	Screening Criteria
Cancer Center Leadership	<ul style="list-style-type: none"> • Cancer center director or associate director • Financial administrators
Principal Investigator (PIs)	<ul style="list-style-type: none"> • Therapeutic and/or nontherapeutic trials for at least 3 years before study enrollment
Research Staff	<ul style="list-style-type: none"> • Non-PIs involved in the —day-to-day recruitment and/or enrollment of study participants to cancer clinical trials • Potentially includes nurses, recruiters, or other research personnel directly involved in the recruitment of human participants
Referring Clinicians	<ul style="list-style-type: none"> • At least 50% of time allocated to clinical duties

Table 2

Characteristics of Study Population

Characteristics	No. of Study Participants				
	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	6
Hispanic	15	5	3	5	2
Mean number of years cancer trial experience	12	11	10	13	24
Type of trial					
Therapeutic	27	4	19	2	2
Non-therapeutic	6	5	1	0	0
Therapeutic and non-therapeutic	56	24	12	14	6
Not indicated	2	1	1	0	0