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Strategies for Enrollment of African Americans into Cancer Genetic Studies

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Abstract

The enrollment of ethnically diverse populations in genetic and genomic research is vital to the parity of benefits resulting from research with biological specimens. Herein, we discuss strategies that may effectively improve the recruitment of African Americans into genetics studies. Specifically, we show that engaging physicians, genetic counselors, and community members is essential to enrolling participants into genetic studies. We demonstrate the impact of utilizing African American genetic counselors on study enrollment rates and implementing a two-page consent form that improved on a lengthy and inefficient consenting process. Lastly, we provided participants with the option of donating saliva instead of blood for study purposes. Descriptive statistics were used. Using the aforementioned strategies, recruitment goals for the Genetic Basis of Breast Cancer Subtype Study at Howard University (HU) were met. Our overall results yielded 182 participants in 18 months. Recruitment strategies that involve the engagement of physicians, genetic counselors, and community members may help researchers increase the enrollment of ethnically diverse and hard-to-reach participants into genetic studies.

Keywords

African Americans; Genetic counseling; Cancer genetic research; Research strategies

Background

Enrollment of ethnically diverse participants is essential in the ability of genetic and genomic research to help explain health disparities and promote health equity. Additionally, the inclusion of underrepresented minorities is paramount to validate our knowledge of

scientific observations and human disease. The paucity of minority representation in biomedical research has fostered global, national, and local collaborations to identify major contributions and best practices to address this systemic problem [1–8]. Some of the salient reasons minority populations remain underrepresented in biomedical research include the following: the mistrust of the medical community [9, 10], misperceptions of biomedical research [11], employment of unsuccessful and inconsistent recruitment strategies [10], lack of awareness of studies for which minorities are eligible [12], and lack of research studies that incorporate non-invasive methods preferred by minority populations [6, 13]. As we learn more about the direct impact of biological and genetic contributions to health outcomes, it will be equally as important to focus on issues that inadvertently exacerbate disparities such as the underrepresentation of minorities in biomedical research.

Rapid advancements in the field of genetics and genomics have revolutionized health care and the scientific enterprise. Despite recent developments in diagnostic and therapeutic options resulting from genomic research, all populations have not experienced equitable improvements in health [14, 15]. Similar to trends in disparate access, utilization, and health care provisions, ethnically diverse populations experience fewer health benefits attributed to genomic research because of their lack of representation in genetic studies, but not necessarily due to a lack of interest [6, 8]. In fact, several studies have demonstrated that African Americans are equally as open to support and express intentions of participating in genetics research [16–18] as they are other forms of biomedical research. Additionally, differences in level of support are more noticeable when the methodology is taken into consideration. For instance, some studies reveal that African Americans are less likely than other racial and ethnic groups to support genetic studies that require a broad consent for use of biospecimens in genetics research [19, 20], but other studies cite parity of biospecimen consent [21]. Considering the uncoupled links of African Americans' interests in genetic and genomic research and actual inclusion, focused attention and efforts to improve recruitment are warranted.

Recruitment of minorities into various biomedical research projects has received significant research attention [22–25]; however, studies focused specifically on strategies to engage African Americans in genetic-based research are more contemporary and less prevalent [26, 27]. Additionally, the effectiveness of strategies on African Americans' participation rates in genetic research ranging from community engagement to the impact of informed consent and the effects of racial concordance among researchers and participants have yielded variable results [24, 26, 28–30]. Based on our synthesis of the literature on effective recruitment strategies in Americans and building upon HU's historical reputable commitment to the Washington, DC community, herein, we discuss the strategies employed to recruit and enroll African American women into the Howard University Genetic Basis of Breast Cancer Subtype Study and present viable solutions that may gradually dismantle some of the hurdles precluding minority engagement in research and demonstrate that minority underrepresentation in genetic and genomic research is amenable to interventions.

Methodology

At Howard University (HU), an IRB-approved research study was proposed to identify genetic factors associated with the increased incidence and prevalence of triple-negative breast cancer in African American women. In order to improve the recruitment and enrollment efforts of women into the parent breast cancer study, this study was proposed as a supplement as the IRB approval allowed for future studies. Eligibility for the study included females who self-reported with a personal diagnosis of, or a family history of, breast cancer, ovarian cancer, or a cancer associated with a hereditary cancer syndrome. Recruitment of participants occurred in three different phases over a 15-month period (Table 1).

Multi-phase Recruitment

Phase I—During the first phase of the study (January 2010–June 2010), a research assistant with limited knowledge of genetics was used to recruit and enroll study participants into the breast cancer study. A 2-h informed consent process, which included the use of a ten-page consent form, was used to educate participants about study details. During this phase, participants were offered the option to solely provide biospecimens in the form of blood donations.

Phase II—In addition to the aforementioned strategies employed during phase I, several modifications were made to increase enrollment during phase II (June 2011–August 2011). One-on-one or group meetings between physicians and researchers were held to discuss collective benefits of research. During these meetings, researchers explained the translational effects of their research in optimizing health care practice. Physicians informed and referred eligible patients to the breast cancer study. Additionally, we employed African American recruiters to help us reach the African American population targeted for this study. We also tapped into the valuable network of community-based organizations and elicited their support and assistance in recruiting individuals for the breast cancer study. Instead of providing biospecimens in the form of blood samples, participants were now provided the option to provide a less-invasive saliva sample. Lastly, the informed consent process was reduced to 1.5 h to complete and involved a modified four-page consent form.

Phase III—During phase III recruitment (January 2012–September 2012), few modifications beyond the strategies employed during phase II were made. African American genetic counselors assisted with recruitment efforts and actively educated eligible patients about genetic research studies. Additionally, genetic counselors conveyed information about cells, chromosomes, genes, DNA, inheritance patterns, the roles of genes, the effects of mutations on risk for certain cancers, and the benefits and limitations of genetic testing. Most importantly, genetic counselors discussed the purpose of the research study and the importance of participation from minorities with potential participants. The informed consent process was reduced to 1 h and involved a revised two-page consent form.

Recruitment Sources—Several strategies were employed to increase the recruitment and enrollment of participants into this study. Physicians and nursing staff specialized in

oncological services (surgical, medical, and radiation oncology) were involved in identifying patients for the research study and informing the genetic counselor of the patient's eligibility. A genetic counselor sought patients with a current or previous diagnosis of breast, ovarian, or other cancers, or those identified by their healthcare providers. Additionally, tumor registries, churches, television and radio advertisements, and physician referrals were utilized. We also engaged the HU Cancer Center Community Outreach, Research, and Education (CORE) Core. The CORE and community-based organizations were engaged in phases II and III of the breast cancer study. With assistance from the CORE, key representatives were contacted and informed of the active genetic studies and the importance of including the African American populations in extant research. Flyers, brochures, presentations, and electronic announcements were created and disseminated throughout the community via respective conduits and partner organizations.

Results

Of the women recruited by a genetic counselor from January 2012–September 2012, 100% enrolled into the research study (discussed their personal/family health history and donated a biospecimen). Approximately 92 % of this subsample were symptomatic patients in oncology clinics (n=85). Asymptomatic participants (n=7) were first-, second-, or third-degree relatives of individuals with breast, ovarian or other cancers associated with hereditary cancer syndromes (Fig. 1).

During phase I (January to June 2010) (Table 1), the average time for the consent was 2 h, and the informed consent form was ten pages. Forty participants were enrolled during phase I, resulting in a recruitment rate of slightly less than seven per month.

As a result of strategies implemented in phase II, the rate of enrollment nearly tripled (Table 1). The engagement of physicians and community-based organizations and the use of an African American recruiter resulted in the recruitment of slightly more than an average of 16 participants per month for a total of 50 participants. Additionally, the informed consent process was improved with a four-page consent form that also led to a decreased average time for consenting. Using the “elements of consent guidelines,” as outlined by the United States Department of Health & Human Services, Office for Human Research Protections (OHRP), greatly increased our success in developing a two-page consent form that was both ethically sound and effective [31]. Precisely following the guidelines, we were able to greatly reduce the time for informed consent while increasing the efficiency of the communication between the patient and counselor. Notably, in phase II, participants were given the option to donate blood or saliva. The HU Internal Review Board (IRB) approved the revised consent form.

Phase III (January to September 2012). During phase III, an African American genetic counselor consented 92 participants using a two-page consent that resulted again in a reduced average time for consenting. Participants enrolled at a rate slightly greater than ten per month. After the introduction of genetic counselor in phase III, enrollment rates increased substantially, almost doubling rates observed in phases I and II. Data were not collected on the number of patients who were eligible versus those who actually enrolled

into the study. The ease of recruitment did not vary between symptomatic versus asymptomatic participants, being that the participants wanted to know more about the potential causes of their cancers and/or the potential causes of the cancers in their families, due to their family histories and perceived thoughts of an increased risk for inheriting a genetic predisposition to cancer.

Conclusions and Recommendations

The purpose of this article was to present strategies that successfully enhanced recruitment efforts of minority participants in cancer genetic research. Effective strategies in this genetic study included the following: (1) physician engagement, (2) utilization of culturally competent genetic counselors as recruiters, (3) a modified informed consent process, and (4) the option to provide a variety of biospecimens. Although researchers cannot erase the historical abuses committed at the expense of minority populations in the name of science, there are strategies that researchers can employ to address the lack of participation of underrepresented minorities in genetics research.

Clinician Engagement

Partial success of minority enrollment in some research studies has been attributed to the invaluable role of the physician. Although a large body of research reveals elements of physician distrust [32, 33], lack of cultural competence [34], and communication issues between racially discordant patient-physician dyads [35], some research indicates that physicians are essential in increasing minority participation in biomedical research [29]. For example, the African American Hereditary Prostate Cancer (AAHPC) Study was the first large-scale genetic study of African Americans conducted almost entirely by African American clinicians and scientists [29]. The study's recruitment strategies included tumor registries, churches, flyer/brochures, television, radio, and physician referrals; however, physician referrals yielded the largest number of participating families. Therefore, the ability of the trusted physician to initiate conversations about genetic research may be pivotal in facilitating improvements in African-American research participation.

In this study, physician involvement in the recruitment process and the dynamics of the patient-provider relationships led to increased enrollment rates of participants in this study. Since significant attention was devoted to obtaining and enhancing physician buy-in, cooperation between the physicians and researchers in fostering the HU breast cancer genetic study might have positively impacted participation rates. It is believed that physicians' understanding of the study's significance and their levels of comfort with promoting the study significantly contributed to the increased enrollment rates during phases II and III of the study (Table 1). Furthermore, previous research studies suggest that encouragement from one's physicians to participate in genetic research is better received and enrollment rates are improved when (1) physicians have developed interpersonal relationships with their patients, (2) physicians are adequately informed about research studies [36], and (3) physicians are experienced with the research process [37]. Conceivably, physicians who value and understand the benefits of research or have research experience (1) may be more effective in exposing their patients to the benefits of research, (2) are better equipped to introduce patients to research opportunities, and (3) may be capable of

positively influencing minority engagement in biomedical research. The impact that a physician's positive rapport with his or her patient-base has on the recruitment and retention of African Americans in research may conceivably be one of the most effective strategies to improving participation from an underrepresented population.

A barrier to obtaining eligibility versus recruitment versus enrollment data stems from the fact that there are several clinics at the HU Hospital that serve cancer patients daily and concordantly. For instance, there were eight or more physicians in surgical, medical, and radiation oncology providing care to cancer patients daily, where many of their patients were eligible for the research study; however, all could not be recruited at the same time. Therefore, we tailored an approach to recruit the most patients possible, by recruiting on days when physicians were more likely to give back biopsy results and have breast cancer clinics.

Utilization of Genetic Counselors

Persistent underrepresentation of African Americans in biomedical research has led many scientists to incorporate innovative strategies as a means of making their research more inclusive. One employable strategy that has yielded great success at Howard University is the incorporation of an ethnically diverse recruitment team equipped with formal training in genetics and genomics, such as genetic counselors. The genetic counseling profession has recently expanded into areas of public health, medicine, and research [38]. Furthermore, the emergence of personalized genomic medicine has resulted in an increased need for genetic counselors as health educators, patient advocates, and liaisons between the participant and the research investigator. This shift in thinking and the emerging role of genetic counselors in research, coupled with new DNA sequencing technologies present opportunities for investigators to obtain data from populations and participants that may have previously been difficult to reach. Not only are genetic counselors equipped with skills to make participants feel comfortable and safe in an area where confidentiality is paramount but they are also trained to identify appropriate research studies that may benefit their patients. These unique skill sets may facilitate health benefits for the patient and increased relevant genetic data for investigators. In addition, genetic counselors also increase participants overall understanding of genetics and allow for the expression of myths and misconceptions regarding genetic research, which otherwise might have inhibited enrollment.

Previous studies have highlighted the value of using genetic counselors to educate individuals about the importance of family health history and health disparities [26, 38, 39], but their role in the research informed consent process may also be influential. There are potential and perceived risks associated with participation in biomedical research ranging from physical, psychological, social, and economic. As a result, it is critical that the informed consent process discloses potential risks associated with participation in the study in addition to offering a safe space for individuals to address concerns, raise questions, and seek clarification on misperceptions about research [5, 40]. For the breast cancer study, utilizing a non-directive health care professional who is culturally sensitive to the values and psychosocial needs of the patients helped garner the trust that is central to obtaining participant consent.

The contribution of the genetic counselor in the recruitment success of African Americans into this research was invaluable. The genetic counselor assumed a versatile role ranging from educating patients about basic genetics concepts to thoroughly explaining the informed consent process and answering questions posed by participants. As a result, it enhanced our ability to recruit participants into our study. Additionally, it also created an environment where patients were encouraged to ask questions and felt comfortable doing so prior to providing consent to a study. It is noteworthy that HU is the only minority-serving institution with an academic genetic counseling program. Therefore, genetic counselors educated at HU are naturally poised to address the lack of representation of ethnically diverse participants in genetic and genomic studies. This was an effective strategy that garnered successful participation rates and support from a population that has persistently remained underrepresented in genetic research.

Engage and Partner with Community-based Organizations

Soliciting the support of community-based organizations was critically important to African American participation in genetic research at HU. The CORE group has had a longstanding history with community-based organizations and the African-American community. Specifically, the CORE develops and fosters community relationships and provides educational opportunities to community members interested in health promotion and disease prevention. Considering that community-based and engaged research efforts have yielded some success in the recruitment of minorities in previous studies [24, 41], HU tapped into its valuable resources to disseminate information about research studies and other resources available at the HU Cancer Center. Since previous literature has established that minority populations are often uninformed or are limited in their knowledge about biomedical research opportunities [11, 42], a community engagement strategy was also employed to increase minority awareness of other research studies for which they were eligible.

Improved Informed Consent Process

In all research, participants are expected to undergo a process that enables them to be fully informed of the purpose, risk, benefits, and protocol of the research studies they may choose to engage. Specifically, informed consent is the means by which a prospective research participant makes a decision about their contribution to research and their level of participation. With few exceptions, consent from participants, whether patients or healthy volunteers, must be obtained and documented in writing before the start of any research study-related procedure [43–45]. This informational process may occur in a number of ways, ranging from active recruitment and community outreach efforts to an individual's physician informing them of studies during a patient visit.

In general, the informed consent process is often characterized by lengthy interviews that may leave potential participants overwhelmed, disinterested, and less likely to enroll in research studies [46, 47]. While there is no clear professional consensus [48], the need for a clearer approach and a more effective informed consent process is apparent. Although the consent process was significantly longer in phase I, the collection of a detailed family health history was not included in the consent process, it is believed that the consolidation of the consent form to a two-page form played an integral role in maintaining the interest of the

participants while also maintaining its own integrity. This proved to be an effective way of ensuring that each participant was informed of the risks, benefits, limitations, and goals of the study.

For the breast cancer study, the improved informed consent process following recruitment in phase III was key to increasing the enrollment of study participants. Because of the length of the consent form and the time it took to consent a participant, enrollment rates in phases I and II were significantly lower than in phase III. Specifically, in phase III, enrollment involved education about the study by the genetic counselor, the participant signing consenting documentation, collecting of a detailed personal health history and/or family health history of cancer, and donation of a biospecimen (saliva or blood) for genetic evaluation.

Options for Biospecimen Donation

Another important aspect of minority underrepresentation in medical research is the participant's preference for non-invasive procedures. Some literature indicates that minority populations are reluctant to provide biological samples when invasive procedures are employed [11, 49]. Similar to the trends observed in HIV research [50], employing a protocol that provides participants with the option to provide non-invasive (e.g., saliva) or invasive (e.g., blood) biological samples may yield an uptake in African American participation rates in research. A recent study conducted in a college-age sample revealed that more than 50 % of individuals were willing to participate in a research study that required submission of a buccal swab [36]. Currently, many studies do not take participant preferences for sample collection into consideration.

Barriers persistently inhibit, reduce, or obstruct individuals' abilities to provide biological samples for genetic and genomic research or participate in biomedical research. Some of the challenges associated with participants' conditions and their participation included as follows: (1) increase the risk for lymphedema during a blood draw for breast cancer patients who have had their lymph nodes removed and (2) difficulty in providing saliva samples because of the effects of dry mouth. Since participants' health conditions may impact the type of specimen they are capable of providing, inclusion of a mechanism that provides options for the type of biospecimen may allay the sample collection concerns of African Americans in regards to biomedical research. In essence, African Americans' collective and personal experiences with research and medicine require us to employ culturally sensitive approaches when soliciting their support in research. The inclusion of minority populations in biomedical research is critical to the elimination of health disparities. Although recruitment barriers may vary depending on the institution, its reputation, and rapport with minority communities, this article provides effective strategies that may make genetic research more inclusive and useful in the health management of historically underserved and underrepresented populations.

Strengths and Limitations

This study contributes to the literature on methods to successfully increase minority participation in cancer genetics studies. It is noteworthy that this is the first study that we

know of that included an evaluation on the impact of minority recruiters, minority physicians, and a minority genetic counselor to successfully recruit ethnically diverse participants in cancer genetic studies. One of the main strengths of this study was our ability to measure the success of recruitment in the various phases after the implementation of changes. This study not only emphasizes the importance of including minority professionals in the recruitment of minority populations but also highlights the value of diversifying the genetic counseling profession and engaging minority genetic counselors in research efforts. Including a minority genetic counselor in this research study led to increased education among participants about existing research opportunities and increased awareness that their samples would specifically be used for breast cancer research purposes to address disparities that disproportionately impact Black women. This additional knowledge may have inspired women to engage in groundbreaking research efforts to help people who look like them and have similar experiences.

One of the limitations of the study was that it did not include control or comparison groups. Next steps to strengthen this study will include randomized controlled trials of independent studies to evaluate the impact of (1) minority genetic counselors, (2) a shortened informed consent process, and (3) minority recruiters. Furthermore, since subsequent phases of this study were improvements of previous phases, several limitations existed during the earlier portions of this study. During the phase I of this study, the recruiter was not trained in genetics or genetic counseling. Since the recruiter was not equipped with the formal skills to interview and collect pertinent cancer-risk information, this may have contributed significantly to the lower numbers of participants enrolled in the cancer genetic study. Additionally, the fact that we did not collect information to explain reasons individuals provided biospecimens prevented us from being able to attribute our recruitment success solely to our improved strategies. Future studies that further explore strategies to improve minority participation in cancer genetics research should also consider exploring the impact of research setting and institution on participation rates in diverse populations.

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Fig. 1.

Characteristics of the 92 participants enrolled by the genetic counselor during phase III (January 2012–September 2012). *Asterisk* represents symptomatic (received a cancer diagnosis) participants with no known family history of cancer and persons with a significant personal history of hereditary breast/ovarian cancers according to National Cancer Comprehensive Network. *Double asterisks* indicate the asymptomatic participant with an unknown family history of cancer was adopted and has no knowledge of the biological family health history

Table 1

Results of enrollment by date and strategies employed

Enrollment dates	Phase I	Phase II	Phase III
	January–June 2010	June–August 2011	January–September 2012
Physicians engaged		X	X
African American recruiter		X	X
African American genetic counselor			X
Community-based organizations engaged		X	X
Improved informed consent process		X	X
Average time for informed consent	2 h	1.5 h	1 h
Length of informed consent forms	10 pages	4 pages	2 pages
Biospecimen donation options	Blood only	Blood and saliva	Blood and saliva
Months	6	3	9
Total enrollment	40	50	92
Enrollment per month	6.67	16.67	10.22