



The Importance of Enrolling Diverse Populations in Clinical Trials

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LEARNING OBJECTIVES STATEMENT

By the end of reading this paper, you will be able to:

- Evaluate the role of clinical trials in breast cancer research
- Demonstrate knowledge about medical mistrust in communities of color
- Communicate the ways clinical trials have become more ethical

INTRODUCTION

Advances in breast cancer treatment and technology would not be possible without clinical trials. However, participants of these trials have remained racially homogeneous. Research shows that people of color are significantly underrepresented in clinical trials. Clinical trials must be racially and ethnically diverse; otherwise, the research produced will not adequately represent all communities impacted by breast cancer (Trant et al. 499; Saini et al. 605). Disparate clinical presentations and outcomes for Black and white women with breast cancer have been well documented. Developing equitable laws and healthcare guidelines regarding breast cancer involves enrolling diverse populations in clinical trials. Black women should be fully educated and encouraged to participate in clinical trials. Including more people of color in clinical trials would better understand the effectiveness of current breast cancer interventions. Barriers to diversity in clinical trials include socioeconomic obstacles, a history of corrupt government-sanctioned medical research that has shaped modern medicine, cultural and racial bias in healthcare, and a lack of knowledge and understanding of what clinical trials entail.

BARRIERS TO GETTING DIVERSE POPULATIONS IN CLINICAL TRIALS

Gender and racial/ethnic representation look different across clinical trials. The FDA's Drug Trials Snapshot disclosed that 56% of all participants were women, and 8% were Black or African American (FDA). The U.S. population includes 51% women, and 12% non-Hispanic Black individuals, according to the 2020 Census data (Census). Breast cancer clinical trials do not enroll the same participants. Breast cancer clinical trials are mostly composed of women. Recent data from Breastcancer.org states that only 2-9% of the FDA-approved breast cancer treatments, research supported by clinical trials, are composed of Black participants. If the racial disparities among breast cancer clinical trials do not improve, "oncology standards based on data primarily on non-Hispanic white patients are at risk for not being generalizable" (ASCO Daily News).

Several barriers lead to the low participation of women of color in breast cancer clinical trials. One area that has been investigated has been the subject of inviting patients to clinical trials. Some research demonstrates that physicians are not more likely to invite one racial group to participate in clinical trials than the others (Trant et al. 500). However, conversations with Black breast cancer patients tell us that they rarely, if ever, hear about clinical trials in the early phases of their breast cancer diagnosis. There is also an issue with how the information about clinical trials is presented to the patient. Research illustrates that the more culturally tailored medical information is, the easier it will be for patients to understand and receive it (Husain et al. 740). Taking the extra step in designing culturally competent materials for clinical trials allows non-white racial and ethnic groups to learn about critical information from a mutual place of understanding. There has been a push to diversify the research teams conducting clinical trials in the last decade. Medical News Today reports that increasing racial diversity among team members can help enhance the clinical trial participation experience. Addressing these barriers can drastically alter participation in breast cancer clinical trials while simultaneously increasing the trust among participants.

Socio-economic status and type of insurance are two driving forces behind low participation rates among Black women in clinical trials. Researchers Obeng-Gyasi et al. (48) found that Black women are more likely to be uninsured or utilize government-based insurance such as Medicare or Medicaid than white women. The discrepancies in insurance are significant because their research study found that Black women with government-sponsored insurance were less likely to complete their chemotherapy trial and have higher mortality rates overall (Obeng-Gyasi et al. 45).

In addition, the length of the study, taking time off work, childcare, concerns with side-effects of the trial, lack of family support, transportation to and from the trial, and lack of respect from researchers were hurdles experienced by trial participants (Rivera-Díaz et al. 51). The Rivera-Díaz et al. (50) study queried Puerto Rican women who had participated in clinical trials before or women who had never completed one. All the women in the study had various stages of breast cancer. Things such as the length of the study, taking time off work, childcare, being concerned with side-effects of the trial, lack of family support, transportation to and from the trial, and lack of respect from researchers were experienced by trial participants.

Participants who had never completed a clinical trial stated that they were interested in them but did not know all the necessary information to weigh the pros and cons of participating (Rivera-Díaz et al. 60). For example, some participants were not told about the side effects of the clinical trial; they took issue with this because they were not aware the trial would negatively impact their current medications. The women were also frustrated that the researchers were not as communicative as they could have been during the clinical trial. Women in the study wanted to know its progress. However, they felt like the researchers were not respecting them as participants who devoted time

and effort to following the clinical trial's guidelines. The medical profession's perceived cultural bias and insensitivity prevented these women from the possible benefits of participating in a clinical trial.

PAST WRONGS IN THE MEDICAL SPHERE

There are several reasons why communities of color are apprehensive about engaging in clinical trials. Western medicine has a sorted past when it comes to medical practices in the name of research. Historically, marginalized communities have been used in unethical and often barbaric practices in the name of science. An example includes enslaved Africans in America subjected to experimental surgeries by Dr. J. Marion Sims, the "Father of Gynecology." The atrocities of Nazi Germany on imprisoned Jews led to the Nuremberg trials and the conviction of Nazi doctors for war crimes in 1947. Unethical treatments led to an international standard for medical ethics in research involving human participants. However, in the United States, unethical practices still persisted in medical research. In the 1950s, Puerto Rican women were used as guinea pigs to test the effectiveness of birth control pills before it was FDA-approved to administer to women in the U.S. (The Washington Post). Between 1932 and 1972, the "Tuskegee Study of Untreated Syphilis in the Negro Male" was conducted by the U.S. Public Health Service and the CDC. 400 Black American men were followed with syphilis, where known treatment was withheld to document the clinical course of the disease. Although monetary reparations were given to survivors and families of the Tuskegee Syphilis Study, minority populations still associate negative consequences when participating in research (Scharff et al. 885). Although ethical standards have improved significantly and more stringent oversight has been implemented in modern clinical trials, a lot still has to be done to build trust in the community.

INCLUSIVE CLINICAL TRIALS

Although the underrepresentation of racial minorities in clinical trials has been a long-standing issue, some changes have been implemented to create future clinical trials that are more diverse than those in the past. The National Institutes of Health (NIH) Revitalization Act of 1993 mandated the inclusion of women and minorities in all NIH-sponsored clinical trials (Saini et al. 605). Hundreds of clinical trials are financially supported by the NIH. A requirement for diversity in clinical trials by the NIH pushes other agencies to do the same thing. Another initiative to increase diversity in clinical trials was launched by the American Society of Clinical Oncology (ASCO) and the Association of Community Cancer Centers (ACC). The purpose of their partnership was to bring researchers together to create new strategies to boost the participation of racial and ethnic minorities in clinical trials (Saini et al. 608).

One way to increase the participation of minority groups is to increase medical professionals to be present in neighborhoods where patients reside, so that they can dive deeper into community outreach by medical professionals. According to Trant et al.'s (500) research, the scholars found that community health workers were not utilized as much as they could have been to share knowledge about clinical trials. Things such as hosting focus groups to disseminate clear and direct information to the community are beneficial. Focus groups run by community health workers, especially when racial and gender characteristics are considered, can help dispel myths about clinical trials. After conducting their research study, Trant et al. (500) found that medical providers at the Yale Cancer Center invited patients to participate in clinical trials at similar rates. However, the scholars still found a gap in knowledge and understanding about clinical trials, which hindered participation.

Another way clinical trials have been made to be more equitable today than in the past has been the creation of the Belmont Report. The Office of Human Research Protections states that the National Commission initiated the Belmont Report for the Protection of Human Subjects of Biomedical and Behavioral Research (HHS). This governmental body was tasked with detailing the foundational ethical principles to regulate the manner of all types of research that involved human participation. These guidelines were debated for nearly four years. By 1976, the Belmont Report identified the ethical regulations in research studies with individuals (HHS).

CONCLUSION

When clinical trials are designed to be racially and ethnically inclusive, researchers demonstrate a commitment to ensure breast cancer research data is representative of all communities. As clinical trials become more racially and ethnically diverse, the benefits of breast cancer intervention for women of color will become more evident. Creating ethical research standards has also helped build and secure trust from communities that research studies have harmed. More education and community outreach by medical providers are needed to reduce mistrust and rebuild broken bridges between them and communities of color.

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Patient Perspective for Paper 2

Enrolling Diverse Populations in Clinical Trials

Interviewers: Chelsea Morris and Virginia Leach

Patient Expert: Se’Nita Harris

In addition to the Inclusion Pledge Paper Series, breast cancer warriors have been asked to describe their experience with each topic. Patient advocacy-based organizations should want to increase the literature of breast cancer research and create space for patients to share their experience, inspire others, and build a community of love and support.

Interviewer: What has been your experience participating in clinical trials?

Se’Nita: Because I was initially diagnosed with Stage 2 metaplastic breast cancer at the age of 37, I was scheduled to have a mastectomy. Originally, I was supposed to have a lymph node axillary dissection to remove all of my lymph nodes. The first trial I signed up for would have been in the form of a lottery, and I would’ve been unsure if I would receive the procedure at all. However, once I sought out a second opinion and was told I had breast cancer in the TNBC form, I did not have to proceed with that clinical trial.

Interviewer: What was the clinical trial process like?

Se’Nita: The process of signing up and filling out the paperwork for that particular clinical trial was straightforward. Due to the nature of the trial, the staff needed to measure my arm before moving along in the process. Upfront, the risks of participating in the clinical trial were explained to me in terms of me getting lymphedema. I was told that the risk was minimum or about the same if I did not participate in the clinical trial. That helped me determine the rationale of moving forward to join in the clinical trial.

Interviewer: Were you offered to join other clinical trials?

Se’Nita: Yes, after being correctly diagnosed, I was called to participate in a light study while undergoing chemotherapy. This was the type of study I was looking forward to. I am the type of person that gets nauseous quickly, so I wanted to sign up for this trial to hopefully minimize the risk of experiencing symptoms like nausea. I was also committed to working my job while undergoing chemotherapy. I didn’t want to disrupt my life with other symptoms like headaches and fatigue, so I was all for it if there was a chance of minimizing the symptoms. The clinical trial consisted of wearing specialty glasses with a bright light around them. They reminded me of space glasses! I was instructed to wear glasses for 30 minutes every morning. It definitely took time, sacrifice, due diligence to plan to wear them around my schedule. During the weeks we were in treatment, participants needed to complete a sleep-based log that included the timeframe of sleep time, wake-up time, and if any naps were taken in between. The sleeping times of participants were verified by wearing a watch each night while treatment was in process.

Interviewer: Can you talk more about the explanation of risks in participating in this clinical trial?

Se’Nita: I had done a lot of research about women participating in clinical trials while undergoing chemotherapy. These individuals were in clinical trials that focused on light therapy, so when I saw that and received the call to participate, I said to myself: “This is a good opportunity.” The light study was not too much of a risk for me because there were no medications or procedures involved. I only had to be concerned about using the device I was given. To me, the benefits outweighed the risks. Looking back, the side effects of being in chemotherapy definitely impacted my moods. During times of high frustration, I found myself taking off the watch in the middle of the night and then putting it back on once I felt better. Ultimately, it was an easy process, and I’m proud to say that I never threw up during chemotherapy. I did have some headaches and experienced other minor symptoms. Still, they were greatly minimized due to the success of the clinical trial.

Interviewer: Overall, how would you describe participating in this clinical trial?

Se’Nita: Joining this clinical trial was a good experience for me. I was asked to complete surveys while wearing the watch, and I was able to keep a record and check in to see how I was doing during the chemotherapy treatment process. From week to week, I was able to see how my thoughts and feelings changed over time. It was a check-in for the researchers, but it was also a check-in for me.

Interviewer: I’m really glad you said that. We often don’t hear about clinical trials asking participants what their opinions are and what feedback can be provided. It’s not just about the collected data, but it’s also about how the participants feel about the process.

Se’Nita: The questions they asked surprised me because some of them didn’t cross my mind. Asking participants about their quality of sleep, the number of nightmares, and other taboo topics gave voice to things we often don’t share with others and keep to ourselves.

Interviewer: Lastly, is there anything you wish you had known before participating in the clinical trial? Do you have advice you would give to others considering joining clinical trials?

Se’Nita: One thing I would suggest is to be mindful of the time commitments of the clinical trials. Things can always change per the request of the researchers. Sometimes, the dates of the clinical trials can be extended. Knowing this can help plan your time accordingly. I would also say that patients have rights in the clinical trial space. Patients always have the option to “bow out” of clinical trials if they no longer want to participate in the process. Obviously, the type of trial will depict how easy it is to remove oneself from the process. Since the clinical trial I was in was considered a technical one and not one that involved drugs or surgery, I could’ve stopped participating at any time. Since the timing of signing paperwork is typically followed up with the procedure or use of drugs right away, it can be much harder to remove oneself from the process since it starts so quickly. Always read the information presented to you and ask clarifying questions on things that remain unclear!