

Barriers to Black patient participation in cancer clinical trials

Executive Summary

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The American Society for Clinical Oncology (ASCO) and the Association of Community Cancer Centers (ACCC) began a collaboration aimed at identification of strategies to increase participation in cancer clinical trials by under-represented populations, including Blacks. Healio, which began in 2013, is a website that publishes news and research for medical professionals in the health care system. As an initial step in this collaboration, Healio identified 29 articles* that describe the statistics and challenges of accruing diverse patients to clinical trials for all cancers. These articles were linked to the information ASCO members received about submitting ideas for this project to raise clinical trial participation among racial and ethnic groups. These articles along with five additional studies, which were posted or published between 2018 and 2020, consisted of both studies published in peer-reviewed medical journals and articles posted on the websites of Healio and other organizations. After disregarding four articles that were out of scope, 30 articles in total were summarized and reviewed.

Below are the key findings from these articles:

Known participation levels (of African-American Women in breast cancer associated clinical trials)

Although Blacks[†] represent approximately 15% of cancer patients in the US, only 4-6% of clinical trial participants are Black. To understand participation further, a participation-to-prevalence ratio (PPR) was calculated in which the percentage of African Americans among trial patients was divided by the percentage of African Americans with a given disease. A PPR of 1 means identical representation of African Americans in the trial population and the population with the disease. For breast cancer, the PPR was 0.29, indicating under-representation in trials.

Reported barriers to access by patients (as related to breast cancer clinical trials)

Barriers to Black patient participation in clinical trials can be categorized into several categories. Barriers are present at institutional, community, provider, and patient levels. Institutional barriers include those that are system-wide and involve how trials are designed. For example, trial eligibility criteria may result in exclusion of certain populations. Community barriers are those that are present at local geographic levels. An example is the location of a trial and the need to travel to it. Provider-level barriers include preexisting attitudes or negative biases by health care providers that may disproportionately affect minority populations. Finally, patient-level barriers are those that pertain to the characteristics of the patient and include factors such as socioeconomic status that may make trial consideration or participation more difficult. These barriers are complex and may interact with one another.

* These articles were provided to Kris De La Torre by Shirley Mertz. Thus, no exclusion/inclusion criteria were used, and no search of the literature using keywords was performed.

[†] Note that terms such as “Black”, “African American”, etc. are used according to the term used by the authors in the original article.

Legacy of unethical treatment of African-Americans by the medical system and mistrust

One important barrier to Black patient participation in clinical trials involves mistrust due to historic mistreatment of Black people. One well-known example is the Tuskegee syphilis study, which began in the 1930s and continued for 40 years, in which Black men with syphilis were purposefully left untreated to determine the natural history of the disease. The men in the study were misled, misinformed, and did not provide informed consent. Another example is that of Henrietta Lacks, a Black woman whose cervical cancer cells were taken in 1951 and used to establish the widely used cell line known as “HeLa” cells. Her cells were used for research without her knowledge or consent.

Recruitment and retention strategies of researchers engaged in cancer research to involve African-American women

Similar to the barriers to Black patient participation, progress and current efforts to increase trial participation can be classified into four categories: institutional-, community-, provider-, and patient-level impacts. Institutional-level impacts include various efforts by the NIH, FDA, other government entities, the National Clinical Trials Network, and pharmaceutical companies. Including more Black volunteers in clinical trial roles is also expected to increase diversity. At the community level, community engagement, trials run by diverse investigators, and local outreach efforts are expected to positively impact enrollment by diverse populations. Churches and other places of support in the community may be useful to increase education and recruitment of Black cancer patients. At the provider level, health care providers should mention trials to patients, acknowledge their biases, and undergo training to increase sensitivity. Efforts to involve more Black scientists and clinicians in clinical trials are also important. At the patient level, Black patients can discuss trials with family members, friends, their care team, and other trusted sources to help in the decision-making process. Social media use by Black patients may increase awareness about clinical trials.