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“Social determinants of clinical trial enrollment in the Gulf South Clinical Trials Network”

Cancer clinical trials are designed to answer specific questions in clinical research and are important to advancing strategies for prevention, detection, and improved treatment of cancer. For a long time, health inequities among minorities revealed worse health. There is a need to recognize the macro-level conditions that impact representation of minorities in clinical trials to improve health and wellness. The objective of this retrospective cross sectional study was to explore patterns and types of barriers experienced by patients screened for cancer clinical trials in the Gulf South Clinical Trials Network (GS CTN).

The GS CTN is 1 of 14 undeserved minority NCI Community Oncology Research Program sites, where at least 30% of the patient population belongs to minority or underserved populations. We queried the GS CTN administrative patient database for patients screened for a clinical trial from August 1, 2018 to July 31, 2020. The primary outcome was defined to identify barriers in clinical trial enrollment belonging to structural, physician or patient domains. Each case was categorized as, ineligible for the trial based on protocol requirements (structural domain), trial not offered by the physician (physician domain), patient declined enrollment into the trial (patient domain), or patient enrolled in the trial (no barrier). The overall distribution of patient status by patient characteristics was compared via chi-square tests. For cancer treatment clinical trials, analyses were stratified by sex. In addition, sub analyses for female breast cancer treatment trials and a large breast cancer screening or control trial were conducted. All statistical analyses were performed in SAS version 9.4. The graphics were produced using Microsoft Excel and R statistical software.

There were 4,656 patients screened for cancer treatment clinical trials in the study period. Women made up the majority of patients (66.7%, n=3,108). Overall, less than 10% of patients screened for a treatment trial were enrolled, 7.2% of women and 15.4% of men. It has been observed that the top three types of cancer in the sample were breast (42.2%), genitourinary (15.2%), and gastrointestinal (10.2%). Furthermore, among men screened for treatment trials, Black men had a lower rate of enrollment compared to white men (10.2% vs 18.1%), which was largely due to a greater rate of ineligibility (82.6%). Similarly, Black women had the lowest rate of enrollment in cancer treatment trials (5.7%). However, for both sexes, the greatest rates of enrollment were in genitourinary (25.5-32%) and neurological (19.1-19.7%) cancers, while the lowest rates were observed in head and neck cancers (0-2.5%). Female breast and gynecological cancers had relatively low enrollment rates, largely due to high ineligibility (88.7% and 94.2%).

In this study of a community oncology network, we observed that the primary barrier to cancer treatment clinical trial enrollment has been ineligibility. Rates of ineligibility were greatest for head and neck cancers and female breast and gynecological cancers. Recently, NCI, the American Society of Clinical Oncology and the Federal Drug Administration have all prioritized expanding eligibility for clinical trials. More inclusive trial eligibility is vital to ensure adequate representation in clinical research and move towards health equity.