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Multilevel Analysis of Clinical, Physician, and Patient Barriers to Enrollment in the Gulf South Clinical Trial Network (CTN)

Abstract

Background:
Despite advancements in cancer research hinging upon the involvement of patients in clinical trials, participation in cancer clinical trials has been consistently underwhelming since its start in the mid-1900s. Barriers to clinical trial participation can be broken into two broad categories: patient and organizational. The current project will focus on identifying the organizational barriers seen in the Gulf South CTN, a community based clinical trial network. Particularly, we aim to compare screening, offering, and enrollment rates of patients across different types of facilities.

Methods:
A total of 5132 patients were screened for a cancer treatment clinical trial between August 2018 and July 2020 in the Gulf South CTN across 27 facilities. Patients' demographic characteristics and whether they were screened, offered, and enrolled in a clinical trial was collected at which facility. Facilities of the Gulf South CTN were divided into three categories – clinics, hospitals, and public hospitals (safety-net and other government hospitals) – and outcomes were compared using multilevel or hierarchical logistic regression model. Graphics were produced for each barrier using the meta package in R statistical software.

Results:
Facilities with fewer than 10 patients screened for treatment trials over two years were excluded from the analysis to prevent selection bias, therefore, 5074 patients from 19 facilities were included in analysis. The ineligibility regression model showed that there was no significant difference between the rates across the three facility categories (p=0.06) but identified the highest rate of ineligibility to be 96% in public hospitals (95% confidence interval [CI] = 76% to 99%). The trial offering regression model displayed no significant difference between facilities with respect to rate of trial offering (p=0.96), though clinics exhibited the highest rate (14%); overall rate of not offering a clinical trial was 10% (95% [CI] = 3% to 28%). The third graphic, declining participation regression model, did show a significant difference between facilities regarding the rate of declining participation (p=0.01), with public hospitals having the highest rate at 55% (95% [CI] = 14% to 43%).

Conclusions:
These results suggest that public facilities throughout the Gulf South CTN have the greatest barriers and, consequently, lowest clinical trial participation rate. On a different level, it is clear that there is a large variation of cancer clinical trial enrollment across all types of facilities. Further analysis and research on other individual and facility characteristics, like screening protocols, would provide greater insight to help progress cancer clinical trial patient enrollment.