Black cancer patients better represented in publicly-funded clinical trials

22 June 2020

Black patients are better represented in taxpayer-funded clinical trials testing new cancer treatments compared to trials run by pharmaceutical companies—although black patients are not fully represented in cancer clinical trials, regardless of sponsor.

These are results of a study conducted by SWOG Cancer Research Network, a member of the National Cancer Institute's (NCI) National Clinical Trials Network (NCTN), the oldest and largest publicly-funded cancer trial network in the United States. For more than 60 years, SWOG and other NCTN groups have run thousands of trials that enroll about 20,000 patients each year. The results are published in JNCI Cancer Spectrum, and will be presented as a poster in the 2020 American Association for Cancer Research (AACR) Virtual Annual Meeting II held June 22-24.

Formerly known as the NCI Clinical Trials Cooperative Group Program, the NCTN is comprised of more than 2,200 cancer centers, academic medical centers, and community hospitals across the U.S. and around the world. The network plays an integral role in establishing the standard of care for cancer patients by testing new treatments, from chemotherapy, radiation, and surgical interventions to the new wave of immunotherapies and personalized drugs based on patients' unique genetic profiles. A companion network, the NCI Community Oncology Research Program (NCORP), runs prevention and cancer care delivery trials, and includes community and rural hospitals in its network, including sites with significant minority and underserved patient populations. About 25 percent of all NCORP trial volunteers are racial and ethnic minorities. Both NCTN and NCORP trials are designed by doctors, paid for with public funds from the National Institutes of Health (NIH) through the NCI, and powered by patient volunteers.

Joseph Unger, Ph.D., a SWOG biostatistician and health services researcher based at Fred Hutchinson Cancer Research Center, specializes in cancer disparities research with a focus on the impacts of insurance status, race and ethnicity, and income on health outcomes. For this study, Unger compared black enrollment in NCI-sponsored trials and industry-sponsored trials.

"It's a critical question," Unger said. "Trials are an important way—sometimes the only way—for cancer patients to receive potentially breakthrough drugs. Everyone can get cancer, so everyone should have the same access to investigational cancer treatments. In addition, it's very important from a scientific standpoint to evaluate new treatments in patients who reflect the demographics of the general cancer population."

To conduct the study, Unger and his team used three databases. One was the SWOG trials database, used as a proxy to estimate the rate of participation among NCI trials. In addition, Unger's colleagues—led by Kanwal P.S. Raghav, MD, of MD Anderson Cancer Center and Jonathan M. Loree, MD of BC Cancer—created a database of pharmaceutical company sponsored trials that supported new drug applications and included data on trial participation by race. Finally, the team used data from the NCI's Surveillance, Epidemiology and End Results (SEER) program, as well as data compiled by the U.S. Census Bureau, to estimate the expected rate of black participation in the cancers they studied.

Unger and his team analyzed data from a total of 358 trials—85 industry trials and 273 SWOG trials—that enrolled 93,825 patients being treated for 15 different cancer types. Enrollments spanned the years 2003-2018. The findings: In those 15 cancers, the rate of black enrollment in industry trials was 3 percent, compared to 9 percent in SWOG trials and 12 percent in the corresponding U.S. cancer population, according to the team's estimates.

"This study confirmed that black cancer patients are severely underrepresented in pharmaceutical company sponsored trials, with fewer than one in four of the expected number enrolled," Unger said. "Black representation in industry trials was also far below that of NCTN trials, with only one black patient enrolled for every three enrolled in NCTN trials."

These results can inform policy. The U.S. Food and Drug Administration, in partnership with AACR, is examining ways to improve representation of black patients in FDA registration trials. Registration trials are specially designed studies conducted with the expectation that the data they produce will be used to apply to the FDA for new drug approval, or to expand the uses of a currently approved cancer drug. Unger serves on this FDA and AACR task force.

"NCI sponsored trials have a broader mandate," Unger said. "They reach beyond just the major cancer centers to serve patients in a more diverse community-based clinical setting. This could serve as a model for pharma trials aiming to increase representativeness of all patients."

Unger's study was funded by the National Institutes of Health through National Cancer Institute grant award CA189974 and CA189873 and in part by The Hope Foundation for Cancer Research and the Michael Smith Health Professional Investigator program.

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Provided by SWOG