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Race and institutional factors play an important role in pharmacogenomic trial participation

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Cancer therapy has evolved from a "one-size-fits-all" type of treatment plan to a personalized approach based on a patient's type of cancer, the protein and genetic markers found in their tumors and their response to therapy. Important aspects of the personalized approach are pharmacogenomic studies that analyze associations between genetic variations and patient drug responses. Moffitt Cancer Center researchers have published a study in the *Journal of the National Cancer Institute* that analyzed the participation rate of patients in pharmacogenomic trials.

The development of personalized therapy requires a high number of patients from all races and ethnic backgrounds willing to participate in large National Cancer Institute (NCI)-sponsored studies that analyze genetic markers associated with particular tumors and therapeutic responses. For the majority of these trials, patients enroll to be in the treatment portion of the trial and are not required to participate in the genomic analysis. If they choose to participate in a genomic analysis, patients need to give consent and be willing to donate tissue and or blood samples.

Moffitt researchers wanted to evaluate the participation rate in the pharmacogenomic analysis portion of NCI-sponsored trials. They looked at demographic and participation data from seven large phase 3 trials that occurred between 2002 and 2013. The trials included 8,456 patients with either Hodgkin's Lymphoma, breast, gastric, colorectal, colon,

pancreatic or prostate cancer.

They discovered that the majority of patients, 81 percent, were willing to participate in the pharmacogenomic portion of the clinical trial. They also found that white patients were almost twice as likely to participate in the tests as African American patients.

"As the field of oncology moves to biomarker-driven therapy, there is a concern that important minority groups are being inadvertently left out of the very research that will find the 'right' marker to guide therapy for people in their community," said Howard L. McLeod, PharmD, medical director of the DeBartolo Family Personalized Medicine Institute at Moffitt.

When the researchers evaluated why racial differences existed, they found that the type of institution a patient is treated at plays an important determining factor in pharmacogenomic study participation. Patients treated at well-supported sites had higher participation rates for both whites and nonwhites than smaller less-supported sites. Importantly, the researchers discovered that as racial diversity increases at a hospital site, the participation rate for both white and nonwhite patients decreases.

"This suggests that the infrastructure of the clinic is a driver of differences in enrollment in these biomarker studies, not merely a patient's heritage," explained McLeod.

There are a number of factors at the patient, physician, institution and community level that serve as incentives or hindrances for clinical trial participation, including beliefs and attitudes, awareness, opportunities and resources. The Moffitt researchers believe that future studies need to determine why less supported clinical institutes are not offering more sophisticated studies in the hope that pharmacogenomics participation rates could increase for all minority groups.

More information: *Journal of the National Cancer Institute*, jnci.oxfordjournals.org/conten … djv188.full.pdf+html