Pancreatic cancer trials fail to include minorities despite worse outcomes

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Despite the fact that certain racial and ethnic minorities get pancreatic cancer more often, are diagnosed at a younger age and die sooner, clinical trials fail to include representative proportions of non-White patients at every phase of study, according to research that was selected for presentation at Digestive Disease Week (DDW) 2021.

"We see disparities in representation across all kinds of clinical trials, so we were not surprised to see that it also occurs in pancreatic cancer trials. But hopefully we can make a change in that arena in the future," said Kelly Herremans, MD, lead researcher on the study and surgical research fellow at the University of Florida College of Medicine, Gainesville.

Researchers analyzed data from 8,429 participants in 207 clinical trials in the U.S. for treatments for pancreatic ductal adenocarcinoma on ClinicalTrials.gov, a national registry of clinical trial data. Gender was reported in 99 percent of the trials, while race and ethnicity were reported in 49.3 percent and 34.7 percent of trials, respectively.

Minorities were substantially underrepresented in trials:

- Black patients represented 8.2 percent of trial participants vs. 12.4 percent of the U.S. incident cases.
- Hispanic patients represented 6 percent of trial participants compared to 8.5 percent of the U.S. incident cases.
- Asian or Pacific Islander patients represented 2.4 percent of trial

participants vs. 3.3 percent of the U.S. incident cases.
- American Indians and Alaska Native patients represented 0.3 percent of trial participants compared to 0.4 percent of the U.S. incident cases.

White patients were overrepresented, making up 84.7 percent of the total trial participants, while they account for 82.3 percent of the total U.S. incident cases. In all, 54.8 percent of trial participants were male, and 45.2 percent female.

Pancreatic ductal adenocarcinoma is particularly deadly, with an estimated 5-year survival rate of only 9 percent. Diversity is important for clinical trials because previous research has shown racial differences in tumor biology, Dr. Herremans said. For example, Black patients have different rates of both somatic and germline mutations when compared to other racial subgroups, which means they may respond differently to treatment.

"We are treating everybody as if they were the same and their tumors would react the same to treatments, but it's important to look at the ancestral differences of tumor biology and therapeutic response," Dr. Herremans said.

Lack of diversity in clinical trials is often attributed to reluctance to participate due to historic wrongs such as the infamous 1932 Tuskegee Syphilis Study that left Black men untreated for many years to study the long-term impact of syphilis. But research has shown that Black patients are just as willing as White patients to be part of a clinical trial, Dr. Herremans said.

Lack of representation may be a result of systemic racism, provider biases that interfere with recruitment as well as study inclusion criteria, which can create impediments to enrollment, such as turning away

patients with obesity and diabetes, which have increased prevalence in minority populations.

"It is multifaceted, and regulations have been put in place that have tried to combat this problem, but over the last 15 years, we really haven't made much headway," Dr. Herremans said.

Provided by Digestive Disease Week