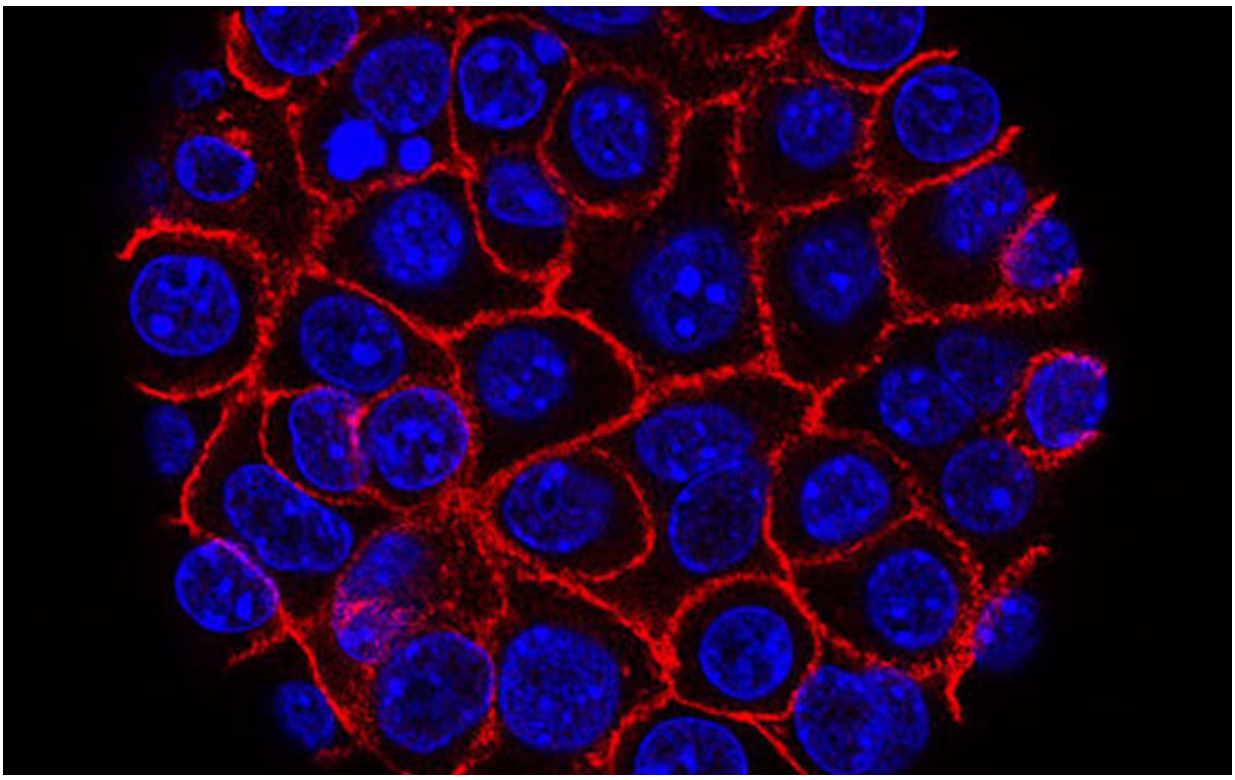
Some pancreatic cancer clinical trial eligibility criteria may be more likely to disqualify Black patients

October 6 2021



Pancreatic cancer cells (blue) growing as a sphere encased in membranes (red). Credit: National Cancer Institute

A simulated pancreatic cancer clinical trial screening process showed that Black patients were significantly more likely than white patients to

be excluded from clinical trials for a wide range of eligibility criteria, according to results presented at the virtual 14th AACR Conference on the Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved, held October 6-8, 2021.

Clinical trials determine the safety and efficacy of cancer therapeutics and pave the way to approval by the U.S. Food and Drug Administration. Previous research has proven that racial and ethnic minorities are significantly underrepresented in clinical trials.

Clinical trials that do not include diverse populations may present an incomplete or inaccurate picture of how patients will respond to various medications, explained the study's lead author, Andrea N. Riner, MD, MPH, a research fellow and general surgery resident at the University of Florida in Gainesville. "Inequitable representation of participants leaves gaps in our knowledge, limits opportunities to receive investigational therapeutics, and subsequently perpetuates disparities in survivorship."

In this study, Riner and colleagues at VCU, under the mentorship of Jose G. Trevino, MD, surgeon in chief of VCU Massey Cancer Center, examined the criteria that are typically used to determine whether a patient will qualify for a trial. She explained that many trials use criteria that have been in place for a long time. However, depending on several factors, "these criteria may not be medically justifiable."

Riner and colleagues simulated a screening process for a pancreatic cancer clinical trial, using data from patients with pancreatic ductal adenocarcinoma who sought care at VCU Massey Cancer Center in Richmond, Virginia, from 2010-2019. They compiled common eligibility criteria for phase II and phase III pancreatic cancer trials listed in clinicaltrials.gov, and modeled inclusion and exclusion based on clinical variables determined from billing codes and medical records.

The criteria that had the highest propensity for exclusion of Black patients were related to nutrition and infectious diseases. They included:

- Albumin, a marker of nutrition (14.07 percent of Black patients were excluded, compared with vs. 7.91 percent of white patients)
- HIV (3.136 percent of Black patients were excluded, compared with 0.286 percent of white patients.)
- Hepatitis B (1.742 percent of Black patients were excluded, compared with 0 percent of white patients.)
- Hepatitis C (9.06 percent of Black patients were excluded, compared with 3.43 percent of white patients.)

Several other criteria also disproportionately excluded Black patients, although the results did not reach statistical significance. The only criteria that excluded more white patients than Black patients was a history of prior cancer treatment. Fourteen percent of white patients were excluded based on prior cancer treatment, compared with 9.06 percent of Black patients. This difference reflects more white patients receiving neoadjuvant therapy for their current pancreatic cancer, Riner explained.

When researchers removed certain criteria that they felt were not crucial to patient safety or well-being, the difference in eligibility was minimized, Riner said.

"The results of our study confirmed our suspicion that standard criteria lead to significantly fewer Black patients being eligible for pancreatic cancer clinical trials than white patients," Riner said. "We are creating bias in who may even qualify to participate, and we are sometimes doing so without a truly valid medical reason to exclude someone."

Riner said the study could be used to inform modifications to existing clinical trial enrollment.

"Modifications should be made on a trial-by-trial basis given the range of therapeutics being investigated," Riner said, noting that chemotherapy trials may require different criteria than immunotherapy trials based upon how the drugs work. "These decisions could be made between the sponsor of the trial and an advisory board of medical experts that would be able to decide which criteria are absolutely necessary."

"Alternative eligibility criteria can improve the diversity of participants, provide more equitable access to investigational therapeutics, and reduce disparities in survivorship, without compromising patient safety or study results," Riner added.

One limitation of the study is that it was based on data from a single cancer center, so the results may not be generalizable to the broader public. Also, based on the demographics of the patients in the study, researchers were only able to compare eligibility between patients who identified as Black or white. Riner said the team suspects their findings may be applicable to other minority groups, but further research would be necessary to confirm the results.

More information: Conference: www.aacr.org/meeting/aacr-virt … dically-underserved/

Provided by American Association for Cancer Research