

Black patients more likely to be excluded from prostate cancer trials

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Micrograph showing prostatic acinar adenocarcinoma (the most common form of prostate cancer) Credit: Wikipedia, [CC BY-SA 3.0](https://creativecommons.org/licenses/by-sa/3.0/)

Clinical trials can offer patients access to cutting-edge treatments with the potential to extend their survival and shape the standard of care in the future. As of last year, more than 400 prostate cancer clinical trials were being conducted to find interventions to extend the lives of patients. Despite the fact that black men face higher rates of prostate cancer and are more at risk of dying from the disease, black patients are

underrepresented in clinical trials. A team of investigators from Brigham and Women's Hospital studied a potential barrier that may be disproportionately preventing black patients from enrolling in these trials: lab test results. They found that more than half of the studies conducted used laboratory values that varied by race, disproportionately excluding black men.

Their results are published in *JAMA Oncology*.

"Something as simple as a lab-value exclusion criteria may serve as yet another barrier to allowing African-American patients to take part in randomized trials," said corresponding author Paul Nguyen, MD, of the Department of Radiation Oncology at BWH. "We hope that this message will reach researchers who are designing clinical trials and setting entry criteria: we need to be cognizant that the criteria we choose may inadvertently make it harder for African-American patients to participate."

Lead author Marie Vastola, a research assistant in Radiation Oncology at BWH, and colleagues examined a list of 401 prostate [cancer clinical trials](#) collected from [clinicaltrials.gov](#) and investigated the use of serum creatinine (sCr) and absolute neutrophil count (ANC) to determine a patient's eligibility for the trial. sCr is used as a measurement of kidney function, but varies by race - black patients tend to have higher sCr concentrations than white patients or patients of other races or ethnicities. ANC is measured to determine the health of a patient's immune system. But up to 8 percent of black patients may have benign ethnic neutropenia, a condition that decreases ANC levels but does not affect the immune system. Without adjusting for race, both measurements may disproportionately exclude black patients from a clinical trial.

The team found that 47.9 percent (192) [clinical trials](#) used either sCr

alone and/or required participants to have an ANC of 1.5×10^9 cells/L or higher, criteria that disproportionately excluded [black patients](#).

"Adjusting for race-based differences in clinical trial eligibility criteria may add slight logistical challenges, but these adjustments could prevent qualifying individuals from being excluded from trials solely because of laboratory differences caused by their race," said Vastola.

More information: *JAMA Oncology* (2018). [DOI: 10.1001/jamaoncol.2017.4658](#)

Provided by Brigham and Women's Hospital

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