

Spirometry clinical trial eligibility may differ with race-neutral equations

May 20 2024



More Black patients may be enrolled in COPD clinical trials when race-neutral equations used. Credit: ATS

Equations that don't use racially and ethnically adjusted spirometry results to help determine eligibility for chronic obstructive pulmonary

disease (COPD) clinical trials may lead to higher percentages of Black patients enrolled, according to research published at the [ATS 2024 International Conference](#).

"While other researchers have initiated investigations into the effects of adhering to the recent American Thoracic Society (ATS) guidance on utilizing Global Lung Function Initiative (GLI) race-neutral spirometry reference equations in clinical practice, our research has identified a gap in the literature regarding the impact of these equations on inclusion criteria in [clinical trials](#)," said lead author Frank Scirba, MD, professor of medicine, University of Pittsburgh School of Medicine and medical director, Pulmonary Physiology Lab, UPMC.

In 2023, an [expert panel](#) convened by the ATS issued a [statement](#) recommending that race and ethnicity no longer be considered factors in interpreting the results of spirometry.

For many years, race-specific equations or adjustments have been used to interpret pulmonary function test (spirometry) results. This approach requires results for Black patients to be lower—sometimes, up to 15 percent lower than for white patients.

"In our study, we saw a discernible pattern in which race-neutral equations tend to decrease the severity level for self-identified white subjects, while concurrently increasing severity for self-identified Black subjects," said corresponding author Chad Karoleski, BA, research IT specialist, University of Pittsburgh Emphysema COPD Research Center.

"This resulted in a GOLD stage shift which led to more Black subjects and fewer white subjects meeting typical spirometric inclusion criteria for COPD clinical trials."

Global Initiative for Chronic Obstructive Lung Disease (GOLD)

classifications are used to determine COPD clinical trial eligibility, with those testing at the GOLD 2 (moderate) and GOLD 3 (severe) levels typically deemed eligible.

To test the potential effects of the new guidelines, the team looked at participants from the [Combined Pittsburgh Lung Cohort](#), who had spirometry performed. The predicted values were calculated for both GLI ethnic-adjusted and GLI Global race-neutral equations to identify the FEV1 percent and resultant GOLD stage for each individual with each reference approach. They conducted an analysis of the shift in GOLD category overall and by self-reported race.

The researchers identified 3,716 (3,474 self-identified white and 242 self-identified Black) individuals with a baseline spirometry evaluation demonstrating an FEV1/FVC ratio

Overall, 1.6 percent of white and 8.3 percent of Black patients gained eligibility, while six percent of whites and 2.9 percent of Blacks were no longer eligible.

Spirometry is the most common [pulmonary function test](#) used to diagnose lung disease and determine its severity. FEV1 is the volume of air expired in the first second of a forced exhalation and is typically represented as a percentage of age-, height- and sex-adjusted predicted value (and recently recommended to exclude racial adjustment).

FEV1/FVC is a calculated ratio used in the diagnosis of obstructive disease. It represents the proportion of a person's vital capacity that they can exhale in the first second during a forced exhalation from full inhalation.

"We anticipate that our findings will stimulate further discussion and investigation into the development of appropriate inclusion criteria, guided by the ATS recommendation of using race-neutral spirometry

reference equations," said Mr. Karoleski.

"Future research will be needed to determine the implication of these shifts on appropriate clinical trial selection, while the role of the race-independent classification [STAR staging](#) in clinical trial selection, based exclusively on FEV1/FVC ratio, also warrants evaluation."

More information: Session: A27 – Emerging treatments and therapeutic strategies in COP: Results of clinical trials and observational studies impact of race-neutral spirometry reference equations on eligibility for chronic obstructive pulmonary disease clinical trials

Provided by American Thoracic Society

Citation: Spirometry clinical trial eligibility may differ with race-neutral equations (2024, May 20) retrieved 11 July 2024 from

<https://medicalxpress.com/news/2024-05-spirometry-clinical-trial-eligibility-differ.html>

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