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Letters

TO THE EDITOR

Low Asian Enrollment in Cardiometabolic Studies and the Importance of Trial Context



The systematic review by Azzopardi et al¹ assesses participation by Asian patients in seminal cardiometabolic trials during the preceding decade. The authors find that the proportion of enrolled Asian participants was 8.3%, which they describe as significant under-representation.

As a standalone statistic, however, this figure is difficult to interpret. For example, Asians are 7% of the U.S. population as a whole; compared with this baseline prevalence, 8.3% would seem to indicate adequate representation. On the other hand, compared with the baseline prevalence of Asian individuals in Asia-Pacific countries, this figure is clearly low. Adjustment for a given trial site's demographic composition, then, may be an important consideration.

Another difficulty arises in the authors' argument that inadequate Asian representation in trials may compromise a study's external validity because of differential treatment effects by race. Low enrollment of Asian participants impedes statistical power to detect presumed treatment heterogeneity, which is important, they note, because "as many as 1 in 5 approved therapies have meaningful differences in drug metabolism by race."

I would disagree with this framing of treatment differences as a putatively biological phenomenon. Many factors affect the observed variability of treatments, not least of which are profound sociopolitco-economic differences both within and between self-described racial groups. The systematic review by Azzopardi et al¹ would have benefitted from analysis of socioeconomic variables contained within its included trials.

In general, the term "Asian"—like any racial designation—may require substantial disaggregation to constitute a meaningful research category. Certainly, in the United States (where indeed many of the selected trials in this systematic review occurred), there are considerable differences in health literacy and health behaviors under this umbrella classification.² And, globally, income inequality among Asian economies has risen dramatically, inequitably affecting the life chances and, it stands to reason, cardiovascular outcomes of billions of Asia-Pacific residents.³

Adequate Asian racial representation in clinical trials is, of course, a worthy aim. But, clarity is warranted in defining this goal and the reasons for its importance.

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The author attests they are in compliance with human studies committees and animal welfare regulations of the author's institution and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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