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Reply to Pandita et al

To the Editor—The coauthors and study staff agree with Pandita et al [1] regarding the importance of the finding that black race was associated with increased mortality in our comparative analysis of remdesivir vs standard care for severe coronavirus disease 2019 (COVID-19) [2]. More work needs to be done to understand this result and, in parallel, to address the institutionalized racism and unconscious bias that may underpin these findings. However, it is difficult to use the data from our study that compared a phase 3 clinical trial (SIMPLE-severe trial; GS-US-540–5773) with a contemporary, propensity-weighted real-world cohort to conclude that black patients were more than 2 times less likely to receive remdesivir. First, the phase 3 randomized, controlled trial was conducted internationally. As such, the observed proportion of black patients (14%) encompasses enrollment from regions in Asia and Europe where one would not expect to enroll patients who self-identify as black. In contrast, the real-world cohort enrolled 95% of patients from the United States and therefore had a higher percentage of black patients. Additionally, race data have been shown to be unreliable in electronic medical record systems [3]. Second, there was not complete overlap in study sites/regions between these 2 studies, further underscoring the inability to draw conclusions regarding access to an investigational drug based on the demographic features of the 2 cohorts. The between-cohort comparative analysis we performed required propensity weighting to balance potential differences; the observed distributions of race/ethnicity in nonweighted populations are not representative of the actual enrollment of the phase 3 trial or of the general hospitalized COVID-19 population. Finally, differences in study procedures between a clinical trial (written consent) and retrospective record collection in the real-world cohort (waiver of consent) could impact patient enrollment and diversity. Distrust of research, patients' concerns about being "experimented on," and fear of deportation affect willingness to participate in studies [4]. The study clinical investigators clearly recognized the obligation to patients to advocate and educate them on the risks, benefits, and the paramount role diversity serves in clinical trial participation.

Importantly, the SIMPLE-severe trial evaluated clinical outcomes (discharge, clinical improvement, and mortality) following remdesivir treatment (without a control group) by race and ethnicity and found that outcomes in non-Hispanic black and Hispanic patients were not worse than those of non-Hispanic white patients [5]. A recent study of remdesivir in 584 hospitalized patients with moderate COVID-19 included 19% black patients who received remdesivir (overall 17% of the patients were black, with 40% of US participants being black) [6]. Although the study demonstrated superiority of remdesivir over standard care with respect to clinical outcomes, results were not reported by race/ethnicity. Additional research on the effect of remdesivir in diverse populations and subgroups is needed. Given the extent of current data, we agree that continued enrollment, data generation, and reporting of COVID-19 in black and other underrepresented populations are needed to fully understand the COVID-19 epidemiology, disease course, and treatment outcomes.

Notes

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