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Letter to the Editor

Diversity in probiotics and diversity in clinical trials: Opportunities for improvement

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To the Editor—We read the report by Rauseo et al[1] describing their randomized controlled trial of *Lactobacillus rhamnosus* GG (LGG) on antimicrobial-resistant organism (ARO) colonization. We agree that this pilot study leaves additional questions about the impact of probiotics on ARO colonization, and we hope future and larger studies will help to further answer this question. However, we were intrigued by the way the investigators approached the issue of race and ethnicity in the trial.

The investigators stated, "Diversity is an important quality of a healthy microbiome," referencing the fact that their use of a single organism probiotic may have influenced the results of the study.[1] According to the 2019 Barnes Jewish National Community Health Needs Assessment, the St Louis racial and ethnic breakdown of residents include the following: 47.2% White, 46.5% Black, 3.4% Asian, 0.3% American Indian/Alaska Native, 0.1% Native Hawaiian/Pacific Islander, and 4% Hispanic/Latino.[2] Considering these population demographics, we submit that the authors missed two important opportunities to address participant diversity in their clinical trial.

First, non–English-speaking participants were excluded from participation, with no further clarification nor scientific justification for this decision. We acknowledge that there may be potential challenges in budgeting time and financial resources, which may influence how researchers enrolled participants, but without further discussion from the authors, the reader would not be aware of these challenges if they exist. With an expanding immigrant population in the United States, exclusion of non–English-speaking participants from such trials will limit the generalizability of results.[3]

Second, in the description of demographics, the investigators chose to combine two racial groups (African American and Asian) into a single group called "nonwhite," without explanation or scientific justification for this discussion. They did not describe ethnicity of participants, so we do not know what proportion of their cohort may have been Hispanic/Latino, if any. The choice to categorize race into White and non-White when there were apparently only three racial categories to describe is concerning, particularly since 46.5% of the St. Louis population is Black. Categorizing race like this subconsciously reinforces White race as the "default" and races that are not White as "other."

Health Equity scholars like Boyd et al[4] have categorized the impacts of race and structural racism on scientific research and writing. They recommend rigorous standards for published material related to racial health inequities, which are critical to developing the science and language needed to understand and address these inequities.[4] We acknowledge that Rauseo et al did not intend to publish a paper focused on racial health inequities; however, we propose additional considerations for researchers and authors, institutional review boards, and journal reviewers and editors regarding race and ethnicity in publications, even if the focus of the article is not health inequities (Fig. 1).

We encourage researchers and authors to include costs of translation of study materials in their budgets in order to enroll participants who do not speak English and to ensure equity in screened and enrolled participants. Additionally, researchers and authors should provide justification for excluding or combining racial and ethnic groups and to avoid assigning White race as default in the analysis. Institutional review boards should include an ethical mandate of inclusion in underrepresented populations, including non–English-speaking subjects in their review criteria.[5] We hope that academic journals will invest in associate editors with expertise in diversity, equity, and inclusion to help navigate these issues in submissions, and that journals require authors to provide justification of any race-based analyses, language-based participant exclusion, and/or inequitable participant distribution in their studies (Fig. 1).

As we move toward building a more equitable future in healthcare, clinical research is an important area of focus. We call on both researchers and academic journals to commit to re-evaluate how they consider race in the design, conduct, and publication of clinical research.

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References

1. Rauseo AM, Hink T, Reske KA, *et al.* A randomized controlled trial of Lactobacillus rhamnosus GG on antimicrobial-resistant organism colonization. *Infect Control Hosp Epidemiol* 2021. doi: 10.1017/ice.2021.94.
2. 2019 Community health needs assessment and implementation strategy. Barnes Jewish Hospital website. https://barnesjewish.thehcn.net/content/sites/barnesjewish/2019_BJH_CHNA_w_Implementation_Strategy_Updated_12.14.20.pdf. Accessed June 2, 2021.

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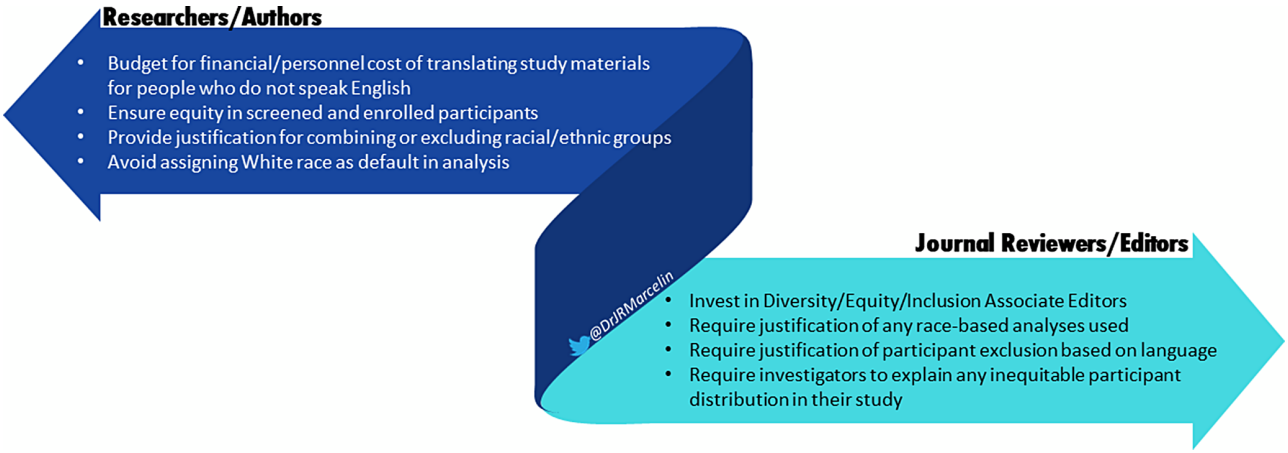

Fig. 1. Considerations for researchers and journals regarding race/ethnicity in publications not specifically focused on health inequities.

3. Jindal RM. Refugees, asylum seekers, and immigrants in clinical trials. *Lancet* 2020;395:30–31.
4. Boyd RW, Lindo EG, Weeks LD, McLemore MR. On racism: a new standard for publishing on racial health inequities. Health Affairs blog website. https://www.healthaffairs.org/do/10.1377/hblog20200630.939347/full/. Accessed June 2, 2021.
5. Strauss DH, White SA, Bierer BE. Justice, diversity, and research ethics review. *Science* 2021;371:1209–1211.

Re: Antimicrobial efficacy and durability of copper formulations over one year of hospital use

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To the Editor—I read with interest the article by Dr. Bryce et al[1] in which they aimed to describe the impact and durability of copper formulations over 1 year of hospital use. I believe the design used in this study to demonstrate efficacy warrants further review in context of the products being tested and the conclusions being drawn.

The study attempts to demonstrate the efficacy of several copper-formulated surfaces over the course of a year of use. Coupons of the selected materials were mounted on gaskets and affixed to handcart handles and laboratory benches. At 3, 6, 9, and 12 months, the coupons were each swabbed and plated, and the resulting CFUs were compared. The study concluded that all copper formulations had less bioburden than stainless steel at months 3 and 6 and that only 1 formulation had less bioburden than stainless steel at 12 months. Using these data, readers might assume that copper formulations are not consistently efficacious at killing bacteria and that some formulations are more effective than others. These assumptions, which can have significant impact on product reputation and adoptions, must be reconsidered due to significant issues in the study design.

Upon review, it appears that the study design did not accurately capture the way a continuous, self-sanitizing surface impacts bioburden. The method used in the study to test the efficacy of the surfaces after a year of use cannot provide the data required to support the conclusions drawn by the authors. A continuously self-sanitizing surface works to eradicate bioburden over time. Because every surface is constantly being recontaminated by the surroundings, at any given moment, all one can capture is a snapshot of what has fallen on it very recently. Any surface, even a self-sanitizing surface, can have high bioburden or low bioburden in any one of those moments. Taking snapshot samples at 3-month increments, as in this study, only tests the amount of bioburden accumulated since the last cleaning. Additionally, no information about the timing between cleaning and sampling was provided.

The results of the study provide evidence of this very issue: The contamination levels go up and down over the course of the months, without an overall trend. This amount of variability demonstrates how much the recent exposure can impact the bioburden at the time of testing.

I believe that more accurate designs to study the long-term continuous efficacy of copper products are represented in the literature. For example, Jinadatha et al[2] demonstrated the efficacy of biocidal surfaces by testing at 3-hour increments over a 30-hour period without cleaning in between. Using this same method at 3, 6, 9, and 12 months would demonstrate whether the product continues to kill bacteria after being in use. Alternatively, to test whether efficacy remains after a year of continuous use, the surfaces could be removed, kept in a sterile environment to prevent further contamination for 2 hours (per EPA public health claims), swabbed, and plated to count CFUs.

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