


Discussion of Race and Ethnicity in Real-World Data Sources: Considerations for Medical Device Regulatory Efforts

Journal of Primary Care & Community Health
Volume 12: 1–2
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DOI: 10.1177/21501327211009700
journals.sagepub.com/home/jpc


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We read with great interest the recently published article by Dr. Tarver¹ expressing the need for more accurate methods of collecting racial and ethnic subgroup information in real-world data (RWD) sources and when evaluating medical devices in diverse populations. We commend the author for a timely article and thorough investigation of this important and sensitive topic. We would like to continue the conversation by providing additional considerations to those discussed.

Usage of accurate, thoughtful language supports the inclusion of and conveys respect for diverse populations. However, racial and ethnic categories can be ambiguous. Some individuals do not fit into one category and forcing them to choose just one designation can cause distress,² as Dr. Tarver acknowledges in her manuscript. To draw a parallel, gender and gender identity, the personal sense of one's own gender, is no longer considered to be binary. Gender can be ambiguous, non-conforming, or fluid; it cannot be assumed, and must be identified by the individual.³ Similarly, the 2020 U.S. Census asked for individuals to answer according to “how they identify” when stating their race,⁴ implying that race requires self-identification, as opposed to external designation. As Dr. Tarver emphasizes, race and ethnicity, like gender, should not be assumed by providers and should be self-identified in order to provide patient-centered care and contribute to the accumulation of robust RWD.

In addition, the race or ethnicity someone identifies with can be temporally and contextually inconsistent.⁵ For instance, a person born in Iran could identify as Middle Eastern, Asian, Persian, or Caucasian. In certain settings, this person might not identify as Middle Eastern to avoid Islamophobia in the United States, a concern which Dr. Tarver identifies as a barrier to accurate classification. Iran is located in Asia, so the individual could identify as Asian. However, “Asian” as a racial category is most often associated with East Asian countries. Thus, although this terminology might be geographically accurate, it would not represent the ancestry or nationality of this person. Finally, this individual could choose to immigrate to another part of

the world, and the race or ethnicity that they identify with might change. As race and ethnicity are social constructs that have changed over time and carry limited relevance to biology, anthropology, and genetics, it is difficult to draw valid conclusions from either in a medical or scientific research setting.⁶

Another consideration is the use of racial and ethnic categories in the global research context. Although there have been considerable improvements in scientific and medical research regarding racial and ethnic categories, much of the standardized language is only pertinent for the United States and not necessarily for the rest of the world. Language must be “accurate, clear, and precise, and must reflect fairness, equity, and consistency in use and reporting of race and ethnicity.”⁷ However, these same goals must also extend beyond the United States, especially in light of the international reach of many English-language medical and scientific journals. In some instances, a certain racial or ethnic category might be considered acceptable for a group of people in one part of the world and unacceptable for a group of people in another part of the world, in spite of common characteristics or ancestry. For example, the terms “Black” and “African American” both apply to people of African descent. However, depending on country of origin and/or personal identification, one of those terms may be inappropriate. These discrepancies are difficult to resolve, and they must be addressed when collecting race and ethnicity data in scientific or medical research that recruits participants or uses RWD of patients from different countries.

We acknowledge that recording racial and ethnic categories is a means of providing more information and ensuring

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a heterogeneous population in medical device assessment and clinical trials. To ensure that each individual can appropriately designate a relevant category, we suggest either significantly decreasing or increasing the amount of racial and/or ethnic categories, depending on the nature of the research. By decreasing the number of categories to a limited number (eg, “White,” “Black,” and “Other”), people who fall into an ambiguous category have a simple option to choose. This technique may also be useful when analyzing RWD where race or ethnicity has been reported inconsistently. Alternatively, for prospective data collection, by increasing the number of detailed categories (ie, rather than just an “Asian” category, offering “Central Asian,” “South East Asian,” “South Asian,” and “South West Asian” as options), and potentially allowing multiple choices, people who fall into multiple categories will be able to select every relevant category to their identity. Individuals could also be given the opportunity to provide their nationalities, which could provide additional useful information. Depending on the nature of RWD available (ie, if the RWD includes complete electronic health records and provider notes), information regarding specific racial or ethnic background may also be able to be gleaned from detailed chart review.

Dr. Tarver encourages the expansion of the use of RWD in research to answer clinical questions.¹ As the author identifies, RWD can be plagued with inconsistent or inaccurate reporting of racial and ethnic categories. We would like to suggest that RWD can also be used to provide socioeconomic metrics, such as zip code, level of education, insurance status, or annual household income. These socioeconomic metrics can provide additional relevant information to inform about both an individual and a population’s health and diversity, and to more accurately assess the heterogeneity of a study population.^{8,9}

The reporting of race and ethnicity in the scientific research field is important, especially when assessing the effectiveness of medical devices in a population. However, its accurate collection can be convoluted and fraught with challenge. By acknowledging the difficulty of the topic and offering additional considerations and suggestions, we hope to contribute to the common goal of producing equitable

scientific literature and more accurate assessments of medical devices.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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