

## Editorial: The Complexity of Reporting Race and Ethnicity in Orthopaedic Research

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Scientific research should serve the medical needs of everyone, regardless of race or ethnicity,

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but few would suggest that it now does. The NIH first sought to address disparities related to race, ethnicity, sex, and gender in healthcare research more than 20 years ago; among the goals articulated then were to “ensure that women and members of minorities and their subpopulations are included in all human subject research” [13]. But setting standards—whether by a federal agency in terms of balanced enrollment of research subjects, or by a journal that seeks to provide its readers with clear, accurate scientific reporting—is difficult, and can result in unintended consequences.

We have covered scientific-reporting standards on sex and gender in this space before [11], and those standards have since been adopted into the ICMJE’s recommendations on the topic [8, 19]. But at that time, we did not address race. In light of recent, updated guidelines from the FDA [23] and the NIH [14], this seems a good time to do so. We believe that the ideas that inform our standards will be of interest to all readers, regardless of whether they perform research or consume it in peer-reviewed journals.

From the standpoint of scientific reporting, race and ethnicity are potentially important both for genetic and sociocultural reasons. With respect to the former, patients of different races may have genotypic

differences that influence the efficacies or risks of particular treatments [15]. And on the latter, treatments may not be equally available to patients of different races (healthcare disparities) [20], or treatments may be differentially acceptable to patients of different races as a result of preferences arising from cultural differences or community norms [9].

But the concept of race as a genetic entity that can influence diagnosis or treatment carries little explanatory power in most of orthopaedics, and it is decreasing in importance across medicine more generally [24]. While there are genomic differences among individuals of different races, some studies have suggested that within-race genetic variation is as important as between-group variation; assuming that important genetic similarities exist within races may be as misleading as it is helpful [16, 27]. The United States is not just a cultural melting pot, it is a genetic blender [4], and racial genotypes, to the extent they ever really existed at all, have grown increasingly blurred in the United States and around the world [1]. Even conditions like sickle-cell disease have proven to be less-closely associated with race than was previously believed [26]. Given the power of genetic testing, there is little reason now to use race as a biological screening parameter [16].

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If the biological element of race is complicated, the social one is even more complex. We evaluate studies each year claiming that patients of one race or another are more likely to be readmitted to the hospital after surgery, or to experience treatment-related complications. Given that the biology of race cannot account for those findings, does the concept of race as a social construct might offer any explanatory power? In most studies, it does not. Factors like poverty, education, social support, and limited access to care are much more likely to cause complications that too frequently are tied to race [27]. And losing track of those confounding variables results in claims about race that may—intentionally or unintentionally—potentiate odious prejudices. If a study suggests that patients of one race are more likely to get infections after surgery, but does not adequately control for the myriad factors other than race that may be in play, the work may lend support to dated, pernicious stereotypes rather than shed light on the actual socioeconomic drivers of the problems being observed.

Moreover, many biomedical studies that analyze by race and ethnicity depend on self-reporting of those factors, which often is inaccurate [12, 18]. We certainly believe that every individual is free to identify with whichever groups (s)he wishes to; insofar as most of us are of mixed heritage, we are free to choose our social groups. But while self-identification may be the best way to categorize race and ethnicity for studies that focus on healthcare disparities among individuals of different ethnicities or races, we should be deeply suspicious of self-categorization by race if any part of the study's goal is to assess the biology of disease as it relates to genetic factors. For the reasons already noted, we also should be wary of studies that consider race as a risk factor for

complications of care or disease if they do not adequately control for relevant sociodemographic confounding variables.

There is no question that disparities exist in terms of access to and complications of orthopaedic care in the United States [5, 29]. We do not know whether they are a function of race [10], poverty, cultural preferences on the part of patients themselves [7], or some combination of those and other factors. But this much is sure: Discrimination is wrong, and disparities in healthcare caused by anything other than patient-driven preferences [25]

need to be corrected. As we seek to correct them, though, we must remain ever mindful that studies on these themes can both help underserved patient groups by increasing access or awareness, or harm them by stigmatizing or by falsely attributing findings to race that have little or nothing to do with it. Forcing all studies to report results by race will induce a large number of unplanned, post-hoc analyses, and the inevitable spurious statistical significance generated will result in misleading inferences. At the same time, since many studies will not be powered for those additional analyses,

**Table 1.** Definitions as Provided by the NIH [14] and FDA [23]

Term*	Definition
Minority group	A readily identifiable subset of the U.S. population that is distinguished by racial, ethnic, and/or cultural heritage.
Hispanic or Latino** (Alternatively, "Spanish Origin")	A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.
American Indian or Alaska Native	A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.
Asian	A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)
Black or African American	A person having origins in any of the black racial groups of Africa.
Native Hawaiian or Other Pacific Islander	A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

\*The categories provided here are considered minimums, both by the NIH and FDA. More-detailed analyses certainly are permitted and "may be important depending on the disease or condition" [23].

\*\*These terms refer to ethnicity; the five groups below this are racial groupings according both to the FDA [23] and the NIH [14]. The FDA [23] suggests first determining whether an individual is of Hispanic/Latino heritage (ethnicity), and then asking about race, since they are not mutually exclusive.

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potentially important findings will be missed as the result of Type-II error. Although others have recommended that all studies analyze results by race [3], for these reasons we cannot.

And yet it would be naïve or worse to suggest that racial bias is absent, either from the healthcare system broadly [6, 17, 28] or from common kinds of one-on-one doctor-patient office interactions [7, 21]. We must therefore seek every available opportunity to mitigate both structural biases in care delivery [20] and our own unconscious prejudices as we interact with patients from diverse backgrounds. With that goal in mind, we heartily recommend the work of Augustus A. White—a “giant among giants” in our profession [2] who ended a recent paper with a checklist for culturally competent care [28]. And we certainly agree with others who suggest that orthopaedic studies recruit and evaluate diverse populations of patients [22].

Which brings us back to the updated guidelines from the NIH [14] and the FDA [23], and how we plan to address these issues when evaluating manuscripts sent to *Clinical Orthopaedics and Related Research*<sup>®</sup>. We suggest that authors be mindful of the ethnic and racial classifications the NIH and FDA guidelines consider a minimum for reporting (Table 1) [14, 23], and use them as appropriate to the study being performed. The NIH requires Phase III clinical trials to analyze by race/ethnicity if prior research has found differences by race or ethnicity, or if prior studies are silent on the subject [14]. We agree with the NIH that if prior research has identified differences associated with race or ethnicity, future studies should continue to evaluate the connection. But because of the issues already noted, we will not insist on reporting by race or ethnicity in the biological research we evaluate unless prior studies have found race or ethnicity to be relevant to the topic under study.

Research on access to care, healthcare disparities, and bias in practice are becoming more-pressing topics. Going forward, we will ask that studies assessing them articulate how the authors categorized the races and ethnicities of study participants (by patient self-report, or using some other approach), and when appropriate, how they controlled for relevant confounding variables. Even where controlling for confounding is performed, it is rarely possible to attribute findings to a single factor, so we will ask for a thorough and thoughtful discussion of this limitation, and we will edit carefully to ensure that any inferences drawn are suitably modest.

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