Race and Ethnicity in Medical Research: Requirements Meet Reality

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ace and ethnicity are commonly reported variables in biomedical research, but how they were initially determined is often not described and the rationale for analyzing them is often not provided. JAMA improved the reporting of these factors by implementing a policy and procedure for doing so. However, still lacking are careful consideration of what is actually being measured when race/ethnicity is described, consistent terminology, hypothesis-driven justification for analyzing race/ethnicity, and a consistent and generalizable measurement of socioeconomic status. Furthermore, some studies continue to use race/ethnicity as a proxy for genetics. Research into appropriate measures of race/ethnicity and socioeconomic factors, as well as education of researchers regarding issues of race/ethnicity, is necessary to clarify the meaning of race/ethnicity in the biomedical literature.

Despite years of commentary and critique regarding the problems in assessing, analyzing, and reporting data on race, reporting the race of participants in studies and analyzing outcomes based on race remain ubiquitous in the medical literature. While the criticism has helped the terminology to evolve, use of race as an explanatory variable generally has not evolved. In medical research, whether a given variable should be measured and analyzed should depend on its importance to the outcome, its ability to help explain variation in the outcome, and the plausibility of the assumption that it may be linked in some way to the outcome. While in many cases race does not meet these criteria, race or ethnicity have been treated as explanatory variables for so long that the question of whether race is truly relevant has been lost. When race is used as a variable, however, the task of researchers and medical editors is to ensure that the assessment of relevance is as accurate as possible, the criteria for categorizing race are described precisely, and the limitations of race as an explanatory variable are recognized.

In medical research the assumption that race is an important factor is widespread. This may derive from the use of race as a patient descriptor throughout medical training. Medical students traditionally learned that patients' histories begin with "this is a [insert patient's age, presumed race, sex] who presents with a chief complaint of...." In medical editing, peer reviewers sometimes ask that race be reported and analyzed even when originally omitted. However, medicine is hardly

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unique in its preoccupation with race. Reporting and analyzing medical studies by race may reflect the significant role, both real and perceived, that race plays in the broader society. The ubiquitous importance of race and racial perception in society was exemplified by the gender and racial gaps that former Harvard President Lawrence Summers inadvertently highlighted in his recent, controversial remarks,¹ and the marked racial inequities exposed by the experiences of New Orleans victims of Hurricane Katrina.²

Scientific research must be reported accurately to allow interpretation and replication. However, the terms used to describe race and ethnicity often have been inaccurate and inappropriate. The terms "Latino/Hispanic," "Asian," 4 and "white" or "Caucasian" 5 have all been criticized for inaccuracy and ambiguity. The problem is compounded when observers such as researchers or clinicians classify individuals by race based on

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skin color and appearances, but even self-classification raises issues.⁶ In some areas of the United States, fully one-quarter of individuals checked more than one box indicating race/ethnicity in the 2000 census.⁷ In addition, translating descriptions of race/ethnicity from the native language in which a survey was administered can lead to additional measurement error.⁸

Despite the many difficulties posed by categorizing race, in some instances it can be important to assess race and ethnicity. First, reporting race can suggest whether the populations studied reflect the diversity of the population to whom the results might be applied. Clinicians, in particular, may need to know whether the characteristics of the study population are comparable to the population the clinician treats. For example, major cardiovascular risk factors were first defined in the middle-class white population of Framingham, Massachusetts, but it was unclear whether these risk factors were applicable to more diverse populations. In fact, the risk factors do predict cardiovascular disease in more diverse populations, but the relative importance of specific risk factors varies by the racial and ethnic background of the population.9 For similar reasons, the National Institutes of Health (NIH) requires that race and ethnicity be measured and reported in

funded research, in part to ensure that traditionally understudied non-white populations are included.¹⁰

Race also may be used as one of several parameters to determine whether randomization has been successful. This assessment may be useful to readers as one description of the population of research participants, but the existence of the variable tempts the researcher or reviewer to request results by race whether or not such analysis is appropriate. If such analyses are conducted without considering other contributing factors such as socioeconomic differences, the results may lead to incorrect interpretation and implications.

The third reason to assess race and ethnicity is that racial disparities in risk factors, treatment, and outcomes are common in the United States and race must be measured if reasons for the disparities are to be studied. Racial disparities often persist after controlling for socioeconomic measures such as income and

education. However, the reasons underlying disparities are more complex than differential treatment or racism by clinicians. In a 2004 study, Elizabeth Bradley and colleagues found that when both admitting hospital and race were assessed, health care disparities varied primarily by hospital rather than by race; the association of

disparities with race was a result of blacks being cared for in hospitals with worse process of care. ¹² Another 2004 study, by Peter Bach and colleagues, found that physicians treating black patients were less likely to be board-certified and had less access to high-quality specialists, diagnostic imaging, and ancillary services. ¹³ These studies suggest that interventions to reduce health disparities will need to address more than socioeconomic differences. Eliminating disparities will require a nuanced understanding of patient care, quality of care, and behavior of clinicians and patients.

Katrina Armstrong and colleagues found that African-American women with a family history of breast or ovarian cancer were significantly less likely to undergo genetic counseling for *BRCA1/2* testing than were white women with a family history of breast or ovarian cancer, even after adjusting for socioeconomic characteristics, perceptions about breast and ovarian cancer risk, attitudes about the risks and benefits of *BRCA1/2* testing, and discussion of testing with the primary care physician. ¹⁴ Therefore, the discrepancy in testing must be related to other factors, perhaps skepticism about genetic testing, given the troubled history of sickle cell screening and resulting discrimination. ¹⁵ Simply assessing race and rudimentary measures of socioeconomic status such as income and education does

not permit exploration of the complex attitudinal and behavioral factors that may have some association with skin color.

A fourth reason for assessing race is related to the tenuous connection between race and genetics. Genetic factors associated with drug metabolism can enhance or reduce a drug's effectiveness or adverse effects. In some cases, some of these genetic tendencies may be associated with a particular race. However, when race is used as a proxy for what presumably is a genetic marker for susceptibility to a given drug's effects, some members of the population who may benefit from the drug will be excluded from treatment and some members of the population targeted for the drug will not benefit. A statistical difference in drug response between different racial or ethnic groups should be the starting point for genetic studies, not the final conclusion resulting in different drug indications by race.

Recent results of conflating race with genetics to target specific populations can be seen in the misguided approvals of the medications BiDil and rosuvastatin. BiDil, a combination drug consisting of isosorbide dinitrate and hydralazine that acts by dilating blood vessels and is used to treat congestive heart failure, was approved in the United States to be marketed for black patients only.18 Rosuvastatin (Crestor), a hydroxymethylglutaryl-coenzyme A reductase inhibitor that reduces cholesterol levels, was approved in the United States to be labeled with a different starting dose for Asian-American patients than white Americans because higher dosages in Asian Americans appear to increase the risk of rhabdomyolysis¹⁹, a condition in which muscle breaks down and may lead to kidney failure. Assuming BiDil's effectiveness is explained by some interplay of genes more common among blacks than whites, a number of blacks treated with this compound will not benefit because they lack the necessary gene(s), and a number of non-blacks with the genes will not be targeted to be treated with a potentially effective compound.²⁰ For rosuvastatin, assuming its metabolism does differ by genotype, these genes will not be shared by all Asians and absent in all non-Asians; the genetic mechanism should be sought to identify and protect patients at higher risk of rhabdomyolysis. Furthermore, the approval of drugs with racial indications removes the incentive pharmaceutical companies might otherwise have to invest in additional research to determine the underlying genetics. Finally, drug approval for a specific racial group has disturbing implications for patient care. Should a clinician ask a patient to self-describe race to determine whether the patient is a candidate for a particular drug? Should

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clinicians make that judgment on their own? How is the clinician to explain that the patient's race is an important consideration in determining care without raising suspicions of bias? The idea that certain racial characteristics make an individual more or less likely to respond to treatment seems a pernicious concept to codify in medical care, and reinforces the concept that race is an important characteristic to assess, regardless of the evidence.

Given that some legitimate reasons to assess race exist in medical research, the measurement and reporting of race should be as accurate and transparent as possible. Efforts to improve reporting span more than a decade. In 1993 in "Use of Race and Ethnicity in Public Health Surveillance," the Centers for Disease Control (CDC) stated that "the reason for analyzing race and/or ethnicity should be given, approaches to measurement of race and ethnicity should be specified, and findings should be interpreted" and "the limitations of race and ethnicity data should be clearly stated and communicated to persons and organizations using the data."21 The BMJ (British Medical Journal) published guidelines in 1996 stating that researchers should collect a range of information to determine whether ethnicity, culture, or race is important.²² The journal stated that, in addition to collecting data using categories established by the Office of Population Censuses and Surveys, researchers should collect hypothesis-driven information such as "country of birth, parents' country of birth, mother tongue, special diets, religions practiced, and years in the UK," as well as socioeconomic status. The Guidelines of the International Committee of Medical Journal Editors state that "when authors use variables such as race and ethnicity, they should define how they measured the variables and justify their relevance."23 In 2003, Judith Kaplan and Trude Bennett suggested that researchers measuring and reporting race should address three challenges: account for limitations in racial/ethnic data, distinguish between race/ethnicity as a risk factor versus risk marker, and avoid contributing to the racial/ethnic division of society by avoiding reinforcing stereotypes in referring to racial/ethnic groups.²⁴

Despite these guidelines and policies, reporting race in the medical literature remains problematic. In 2001, Fred Rivara and Laurence Finberg noted in the *Archives of Pediatrics & Adolescent Medicine* that "Analysis by race and ethnicity has become an analytical kneejerk reflex, accompanying every table that examines

demographic differences in groups, such as age and sex."²⁵ They stated,

In future issues of the *Archives*, we ask authors to not use race and ethnicity when there is no biological, scientific, or sociological reason for doing so. Race or ethnicity should not be used as explanatory variables, when the underlying constructs are variables that can, and should, be measured directly (for example, educational level of subjects, household income of the families, single vs. two-parent households, employment of parents, owning vs. renting one's home, and other measures of socioeconomic status).

In November 2004, a *Nature Genetics* editorial stated "the use of race as a proxy is inhibiting scientists from doing their job of separating and identifying the real environmental and genetic causes of disease."²⁶

Many studies have shown that authors often do not define race and ethnicity, have no rationale for including them, and use variable terminology. One study evaluated studies of asthma in children published in 1991-93 and 2000-02 in *JAMA*, *New England Journal of Medicine*, *Pediatrics*, *Journal of Pediatrics*, and *Archives of Pediatrics & Adolescent Medicine*. Coding of race/ethnicity largely used the categories "white" (78.7%) and "black" (89.4%). Fewer reports coded "Latino" (55.3%) or "Asian" (14.9%).

A second study evaluated clinical trials of diabetes, cardiovascular disease, HIV/AIDS, and cancer, published from January 1989 to October 2000 in *Annals of Internal Medicine, JAMA*, and *New England Journal of Medicine.*²⁸ Of 253 eligible trials, forty percent did not report race and forty-six percent that reported race/ethnicity used only one or two racial/ethnic categories. Results were analyzed by race/ethnicity in two trials.

The NIH requires that race and ethnicity be assessed using the Office of Management and Budget (OMB) roster of five categories with a separate designation for Hispanic ethnicity.²⁹ However, the NIH *does not* require that authors consider thoroughly the implications of race in their study and measure other factors that might confound apparent associations of outcomes with race, such as socioeconomic status. NIH policy may encourage researchers to report race but not fully consider the implications of assessing race in their studies.

Editors can require that authors report and analyze race and ethnicity carefully, but editorial policy is rarely sufficient to change research methodology. Explicit editorial policies on this appear uncommon. In a 1998 survey of health journals, most editors did not perceive race reporting to be a concern, and only seven of the

twenty-three editors of health journals surveyed had written policies pertaining to race and ethnicity.³⁰

I surveyed studies published in *JAMA* in the month of April 2004. Of the eighteen studies included in my sample, eight reported race/ethnicity. Only one of the eight stated how race/ethnicity was determined. In that study participants self-designated race/ethnicity choosing from four categories. In a second study race/ethnicity presumably was determined by self-report as well because the study was a survey, but how race/ethnicity was assessed was not specified. Four of the eight studies were NIH funded, while only one of the studies not reporting race was NIH-funded. None of the studies discussed why race was reported or analyzed, and only three of the eight included some measure of socioeconomic status. None included genetic analysis.

This small sample confirmed results of previous studies by showing substantial limitations in reporting and analysis of race and ethnicity and suggested substantial room for improvement. To address these limitations in race and ethnicity reporting, JAMA developed an explicit policy about reporting race and ethnicity published in an editorial in October 2004.31 This policy states that when reporting race, ethnicity, or both, authors should (1) describe who designated race and/or ethnicity for an individual (self-designation generally is preferred); (2) provide the race/ethnicity categories, whether categories were combined, and, if so, how; (3) state why race and/or ethnicity is believed to be relevant to the particular study, based on past literature or the authors' hypotheses, to facilitate critical evaluation of race and ethnicity as constructs within the study. In addition, if race, ethnicity, or both are being used as proxies for other more difficult-tomeasure variables, the rationale for doing so should be stated, and researchers should attempt to measure directly as many variables as possible, such as socioeconomic status, education, urban versus rural location, or average income by ZIP code.32

Editorial policy without enforcement is generally not sufficient to change behavior, so *JAMA* took several additional steps to encourage compliance with the policy. The requirements were added in an abbreviated form to the "Instructions for Authors" and included in letters to authors seeking manuscript revision. If the manuscript was ready to be accepted but the information was still missing, the pre-acceptance checklist included a request for the missing information. The manuscript's copyeditor made a final check, requesting missing information on the typescript.

Approximately one year after my original assessment and three months after the publication of the editorial and the institution of the additional steps, I surveyed *JAMA* again to evaluate our progress. Of thirty-six

studies published in *JAMA* in the months of February and March 2005, I excluded two; one reported a cost-effectiveness model without original patient data and another was conducted in primates. Sixteen reported race/ethnicity, a proportion similar to that before the intervention; all of those were written by authors from the United States. Of the eighteen not reporting race/ethnicity, only eight were from authors in the United States.

Fifteen of the sixteen studies reporting race/ethnicity stated how race/ethnicity was determined. Race was self-defined in twelve, categorized by the investigator in one, and determined from chart review in two. Of the fifteen studies that defined race/ethnicity categories, one used one category (listing percent white only; this was also the one study that did not define how race was categorized); three used two categories (black/white; white/Ashkenazi in a study of BRCA markers, mixing race and ancestry; and black/non-black); three used three categories (Hispanic/non-Hispanic/unknown; white/black/Asian; and Hispanic/non-Hispanic black/ non-Hispanic white or other); three used four categories (white/Asian/African-American/Hispanic; non-Hispanic white/non-Hispanic black/Hispanic/ other; and black/Hispanic/white/other); two used five categories (both using white/black/Asian-Pacific Islander/Hispanic/other); two used six categories (non-Hispanic black/non-Hispanic white/Hispanic/Asian/ other/unknown and white/black/Hispanic/Asian-Pacific Islander/American Indian/unknown), and one used seven categories (white/black/Native American/ Asian-Pacific Islander/mixed race/other/Hispanic).

Eleven of sixteen studies justified why race/ethnicity was reported (one study included justification but did not report race/ethnicity). Of the eleven that were justified in the text, seven were NIH-funded, while of the five that were not justified, three were NIH-funded. Some stated that reporting was required, for example for the Food and Drug Administration. The combination of race/ethnicity reporting occurring solely in U.S. studies in this sample and U.S. government requirements suggest that U.S. investigators may be more likely to present and analyze race/ethnicity without necessarily having considered whether the study hypothesis warranted it.

Only four of the sixteen studies describing race/ethnicity included some measure of socioeconomic status; two of these were funded by NIH. Socioeconomic status typically was reported in dichotomous measures of income (</> \$1700), education (e.g., finished high school or not, some college or not, or eight or fewer years of school), type of insurance (private versus public), or work situation (paid worker/unemployed/disabled).

While these rough measures of socioeconomic status help acknowledge the societal issues that confound race, they cannot begin to address the complexity of the social and cultural milieu suggested in the study by Bach and colleagues,³³ for example. The Hollingshead scale measures socioeconomic status based on education and occupation, but it has been criticized for not being validated or updated.³⁴ Education attainment, income, occupation, preventive care, asset holdings, and environment (including the physical environment and pollution as well as the social environment and crime) are all factors that are potentially important to health disparities.³⁵ Personal and cultural beliefs may also have a role as suggested by Armstrong and colleagues' study of genetic counseling for *BRCA1/2*.³⁶

Assessing socioeconomic status in the United States is a substantial challenge, but comparing socioeconomic status across countries is even more difficult. Some studies have explored innovative ways of measuring socioeconomic status to permit cross-cultural interpretation. Investigators conducting a study in Tanzania assessed the number of occupants and rooms in the house, the type of roof construction (thatch versus tin), and access to electricity.³⁷ In a study of medication use across European countries, the authors used the definition "economic difficulties in the prior thirty days that precluded the individual from being able to pay for prescribed medications, heating, medical care, adequate nutrition, and home help or home care."38 While the validity and reliability of such innovative measures must be evaluated, they suggest that cross-cultural measures of socioeconomic status could be developed.

Previous studies of race/ethnicity reporting in medical journals and my brief assessment of *JAMA* yield several conclusions. First, it is possible for a biomedical journal to improve authors' description of how they measured race and ethnicity, but policy statements are not sufficient. Implementing changes in process such as *JAMA*'s can improve such description, but ensuring that authors provide a hypothesis-driven rationale for reporting race/ethnicity is more difficult.

Second, authors are simply collecting race/ethnicity data to fulfill reporting requirements rather than investigating a particular explanatory variable, they may also be unlikely to assess the important variables confounding analyses by race. This issue requires evaluation. While editors will not be able to correct the lack of a hypothesis-driven rationale for assessing race/ethnicity, they can require authors to consider the implications of measuring race/ethnicity in their study, analyze related measures such as socioeconomic variables when available, and discuss the potential role of unmeasured confounders when reporting results by race/ethnicity.

Socioeconomic status measures require considerably more investigation to be standardized and capable across studies. Further, assessment of only two or three categories of income or education is unlikely to explain the confounding of race by socioeconomic status. The existence of substantial healthcare disparities by race and socioeconomic status makes establishing valid and reliable tools to measure SES and increased reporting of SES an important research priority.

Finally, in studies claiming racial associations as a basis for genetic causation, genetic factors should be measured directly or the rationale for not measuring them given, with an explanation of when and how such work will be done.

JAMA's policy and implementation demonstrates the feasibility of taking the initial step of improving reporting of how race and ethnicity were assessed. However, the goal of getting researchers to consider carefully the rationale for analysis by race and ethnicity is more elusive. Accomplishing that goal and improving measurement of the variables related to health disparities and to genetics will require concerted and coordinated effort by researchers, funders, and editors.

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