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The Use of Racial Categories in Precision Medicine Research

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Scholars have shown that promoting diversity and inclusion in precision medicine research is important for ethical and scientific reasons. The processes for classifying the populations that enroll in biomedical research, however, are often unclear, inconsistent, and poorly justified. Precision medicine research promises increasingly meticulous approaches to defining research cohorts and assessing the multivariate factors at the root of racial health disparities. Insofar as precision medicine is promoted to members of historically underrepresented populations as a tool for illuminating these factors, the use of race-based classifications is fraught with risks for society and medicine. This article examines the drivers and limitations of the ongoing use of race by investigators juxtaposed with recent efforts to enroll underrepresented populations in precision medicine research. *Ethn Dis*. 2019;29(Suppl 3): 651-658; doi:10.18865/ed.29.S3.651

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"And that's the promise of precision medicine -- delivering the right treatments, at the right time, every time to the right person."[1]
- President Barack Obama

Introduction

In the era of precision medicine research, investigators have the opportunity to capture the immense human genomic diversity within and across populations that are often underrepresented in genomic research studies and that suffer severe racial health disparities. Genomic approaches, however, are insufficient to address the various social experiences that often correlate with poor health.[2] Discrimination in housing and employment, inadequate access to health insurance, and implicit and explicit biases in medical care, for example, substantially impact health outcomes, long-term health, and health disparities.[3(p135),4(p38)] For these reasons, precision medicine studies that measure the effects of social, cultural, and environmental influences on health are essential to improve health outcomes.[5,6]

Like genomics, race is insufficient to account for the variety of complex factors and forces that influence individual health. Race is a social and political concept that was used historically to divide, track, and control populations, and reinforce social hierarchies.[7,8] The focus of this article is on the concern that the National Institutes of Health (NIH)[9] and the Food and Drug Administration (FDA)[10] promote the use of racial and ethnic categories created by the US Census Bureau's Office of Management and Budget (OMB) in biomedical research contexts, and that investigators rely on these categories even when they are not relevant.[3(p106),11(p504)]

Precision medicine research promises a new and meticulous approach to discovery that emphasizes the underlying and multivariate contributors to differences in health outcomes.[12,13] The "All of Us" Research Program sponsored by NIH, for instance, is collecting research data from multiple sources, including health surveys, health records, and digital health technologies.[13] Surveys request personal details, including information on age, race, sex, income, educational attainment, and geographic location.[13] The goal is for the All of Us data re-

pository to enable research into the underlying environmental and biological influences on disease, treatment response, and prevention.[13]

The All of Us enrollment survey includes the OMB census categories, additional options (such as "Middle Eastern or North African"), and a request that respondents select all of the identities that describe them.[14] In addition, the format of questioning is different from the census form: Hispanic, Latino, or Spanish is one choice among many others rather than a separate ethnic group. So far, the All of Us program has summarized data for only some of the racial and ethnic categories included on its survey: White; Black, African American, or African; Hispanic, Latino, or Spanish; Asian; More than one race/ethnicity; and Other.[15]

As federal funders and commercial entities aim to expand the diversity of enrollees in precision medicine research, it is important to address the limited success of existing federal guidelines that encourage the use of the OMB census categories in biomedical research.

It is too early to predict how All of Us investigators will approach race in their analyses. Recruitment began in May 2018 and the investigators reported meeting one fifth of the program's recruitment goal of 1 million participants.[13] As others have highlighted, there is immense opportunity for the All of Us program and other precision medicine initiatives to improve the study of underrepresented populations, and to do so using variables that are more specific than race in rigorous and transparent ways.[12]

To make progress, the field must confront investigators' use of race as a biological category,[16] and the often inaccurate, inconsistent, and poorly justified uses of racial categories in biomedical research.[3(p158),5,11(p507-513),16-18] Currently, NIH requires NIH-funded researchers to use the OMB census categories to demonstrate the inclusion of diverse research participants.[9] The FDA recommends the use of the OMB census categories when summarizing demographic, safety, and efficacy data.[10] While NIH requires investigators to certify that research cohorts are sufficiently diverse, the FDA does not have such a mandate.[9-11(p503)] In practice, researchers generally report their results based on the OMB census categories to both agencies, regardless of how many or how few participants are included in each category.[3(p106),11(p503)] Biological conclusions are then often described in terms of the OMB census categories.[3(p106),18(p23),19]

As federal funders and commercial entities aim to expand the diversity of enrollees in precision medicine research, it is important to address the limited success of existing federal guidelines that encourage the use of the OMB census categories in biomedical research. While the use of racial categories in research may prove useful in some ways (such as when investigators are examining the effects of racism on biology and health), careful consideration of how and when to disentangle the social category of race from discussions about differences in health outcomes is critical to move away from "race medicine."[20] In his remarks during a 2018 National Academies of Sciences, Engineering, and Medicine (NASEM) roundtable discussion on genomic medicine and health disparities, Dr. Otis Brawley explained that race medicine can potentially overlook the socioeconomic causes of health disparities.[20] This article argues that current race-based approaches are fraught with risks related to the development of sound scientific research practices and questions. Moreover, the OMB census categories are incongruent with growing population admixture and public dissatisfaction with census categories in the United States. The past decade has seen ongoing challenges related to individual identification with the OMB census categories, including an increasing number of people who "cannot find themselves"[21] on census forms.

At this pivotal moment for the field of precision medicine, when

researchers are engaging underrepresented communities and funders are developing new approaches to understanding health disparities, it is timely to carefully assess how race is operationalized in research and how racial differences are described in both peer-reviewed publications and publicly accessible news articles. This article focuses on the enduring role of the OMB census categories as a tool for describing participants in research. It argues in favor of policies that will facilitate the critical assessment of any decision to use racial categories in a precision medicine study.

Recruitment of Underrepresented Populations to Precision Medicine Research

Around the country, research institutions and community organizations are engaging members of minority communities in discussions about the potential long-term benefits of precision medicine research for diverse populations.[20,22] The June 2018 NASEM report entitled "Understanding Disparities in Access to Genomic Medicine" explains that an important phase in the development of accessible genomic services includes building a foundation of evidence that "demonstrates the positive effects of genomic and precision medicine on health outcomes."[20] This assertion is rooted in an optimistic perspective that precision medicine research has the potential to benefit the entire medical community, including community hospitals and underserved community clinics.[20]

The strong push for inclusion also stems from the significant concern that underrepresented populations will be left behind as precision medicine research advances. The lack of diversity and inclusion in genomic research has led to medical errors primarily impacting racial minorities and delayed understanding of human genomic diversity.[23-24] A major challenge for the field is to develop approaches for categorizing populations that capture genomic diversity and sufficiently assess the various determinants that influence health outcomes in populations. Trends in policy and practice indicate, however, that the imprecise use of racial classifications in biomedical research is persistent and possibly increasing.[3(p191),16,25,26]

Laws and Policies that Reinforce the Use of Racial Categories

Pursuant to OMB Directive No. 15, "Race and Ethnic Standards for Federal Statistics and Administrative Reporting," the OMB requires standardized uses of predetermined census categories in order to ensure uniformity across federal agencies.[27] Scholars report that racial categories have been used both to maintain social hierarchies in the United States and to track data for purposes related to enforcing civil rights laws.[7,8,28] The Fair Housing Act, the Home Mortgage Disclosure Act, and the Community Reinvestment Act, for example, were enacted to provide legal grounds for eradicating racial redlining.[28] In the mid-1980s, the US Congress responded to demands for greater inclusion of women and minorities in research by compelling federal agencies to develop guidelines designed to improve diversity and inclusion in clinical trials and biomedical research.[9,10] The resultant guidelines influence industry- and federally sponsored scientists' use of the OMB census categories when defining subgroup populations.[3(p106),11(p503),18(p23)]

The NIH Revitalization Act of 1993 (Pub. L. No. 103-43) led to the establishment of the 2001 guidelines entitled "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research."[9,11(p502)] These guidelines state "...that women and members of minority groups and their subpopulations must be included in all NIH-funded clinical research, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research."[9] Researchers must certify that they have made sufficient efforts to enroll diverse populations and that the resulting cohorts are adequately diverse.[9,11]

The Food and Drug Administration Modernization Act of 1997 (Pub. L. No. 105-115) led to guidelines on the inclusion of women and minorities in clinical trials,[10,11] including a 2005 guidance docu-

ment entitled "Collection of Race and Ethnicity Data in Clinical Trials," which was recently updated in 2016.[10] The 2016 guidelines do not require the inclusion of underrepresented populations in clinical trials, but recommend "a standardized approach for collecting and reporting race and ethnicity data in submissions for clinical trials for FDA-regulated medical products."[10] The guidelines explain that the classifications provide a minimum standard for "maintaining, collecting, and presenting data on race and ethnicity for Federal reporting purposes" that are consistent with OMB Policy Directive 15, but the FDA does not address the level of participation of different racial and ethnic groups in clinical trials.[10,11]

The Ongoing, Inconsistent Use of Racial Categories in Research Design and Findings

Some argue that the OMB census categories are useful for assessing differences caused by social determinants of health, racism, bias, and genetics.[29-31] Even when racial categories might provide value, however, the research norms related to the collection, annotation, and reporting of genomic variation among racially diverse populations are problematic.[3(p106),11(p512),16,17,32] For example, although the OMB remarked that the categories "should not be interpreted as being scientific or anthropological in nature,"[27] investigators who employ these racial taxonomies often fail to acknowledge the OMB's warning.[5,6,16,17,18(p23)] Further, as law professors Jonathan Kahn and Dorothy Roberts have shown through their research, the potential profitability of race-based products drives the characterization and application of biomedical and genetic data in racial terms, even when such representations are unwarranted.[3,25]

In 2016, the National Human Genome Research Institute and the National Institute on Minority Health and Health Disparities convened a workshop to discuss the use of self-identified race and ethnicity as scientific variables in research.[5,31] Several themes emerged from the workshop that might help guide future approaches to describing diversity.[31] One concern highlighted by workshop participants was that researchers must assess and evaluate race, ethnicity, and ancestry in ways that do not compromise scientific rigor or neglect the multidimensional nature of individuals' identities.[5,31] Another concern elucidated in a publication by Bonham, Green, and Pérez-Stable, is that "[r]ace and ethnicity are operationalized inappropriately when they serve as proxies for other demographic variables, such as an individual's socioeconomic status."[5] The authors provide an example of a study that examined African ancestry, education, and correlations with hypertension among Black patients. The study found that achieving an education beyond high school, rather than participants' proportion of African ancestry, was significantly associated with lower systolic blood pressure. The workshop and this example highlight an important dialogue about the value of considering new approaches to categorizing difference.[5,31]

By contrast, differentiating populations along racial lines has the potential to erode the impact of precision medicine studies by overgeneralizing results about populations with diverse ancestry. Dr. Perry Payne argued, for instance, that an FDA alert for carbamezepine overstated the evidence on ethnic populations at risk for an adverse reaction to the drug.[17] At the time of his investigation, only 2 of 37 Asian countries were included in the studies used to support the FDA label which indicated that "people with 'ancestry across broad areas of Asia, including South Asian Indians' are more likely to have the [human leukocyte antigen (HLA) allele]-B*1502 allele and should be screened for the allele."[17] The alert was based on data that represented far less than half of the global Asian population.[17]

Broad racial categories such as "Asian," "Black," and "African" obscure medically relevant genetic variation within population groups. A study by Baharian and coauthors reported, for instance, that historical events such as the Great Migration have influenced recent patterns of genetic diversity among African Americans.[33] A different study on the global distribution of the HLA-B*5701 variant, which causes severe hypersensitivity reactions in patients who take the drug abacavir, found that the prevalence of HLA-B*5701 within

populations with African ancestry differed (African Americans, 1%; Kenyan Maasai, 13.6%; Kenyan Luhya, 3.3%; Nigerian Yoruba, 0%).[34] The allele frequencies also varied greatly among populations that would be classified as Asian (ie, Chinese Americans, 1.2%; Chinese in Beijing, .6%; Japanese, 0%; and Indian American, 17.6%).[34] Since racial minorities have been historically underrepresented in genetic studies, there is much to learn about national and international patterns of genomic diversity within racial groups.[33] Precision medicine research, based on its data-intensive nature, should strengthen subgroup analyses and possibly create new subgroups based on combinations of different data.

A looming concern, however, is the potential financial value of race-based drug label guidance to commercial companies. Trends in pharmacogenomics and patent law show that companies are using race to classify research participants and to develop and patent products based on these categories.[3(p191),25] While the FDA has approved only one drug label indication for a specific racial group, drug labels and patent applications continue to report that race is medically or pharmacogenomically relevant.[3(p191),25]

The Application and Use of Racial Categories in Global Precision Medicine Studies

Given the influence of international genomic studies on discovery and the need to increase collaboration and research capacity across international borders,[23] precision medicine research policies in the United States should be globally minded. The FDA currently recommends that investigators use detailed characterizations of race and ethnicity to describe populations outside of the United States with greater granularity than the OMB census categories.[10] The FDA also recommends, however, that these "characterizations be traceable to the five minimum designations for race and two designations for ethnicity."[10,11(p503)] Similarly, the NIH requires all researchers, including those conducting research on foreign participants outside of the United States to follow US guidelines on the inclusion of women and minorities in clinical research.[9] Like the FDA, NIH encourages researchers to collect the level of detail about research participants that they deem appropriate, but to design studies in ways so that data can be aggregated into the required the OMB census categories. Ultimately, these federal policies permit investigators to rely on simplified US labels for racial and ethnic groups when investigating and describing populations in very different social and cultural environments.[11(p508)]

Imprecision in the US market may cause confusion in the global precision medicine environment. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) provides an example. ICH was formed to achieve greater harmonization among US, Japanese, and European pharmaceutical markets.[11(p505)] Nevertheless, the ICH Guideline Document E-5, "Ethnic Factors in the Acceptability of Foreign Clinical Data," recommends a framework for assessing the impact of "ethnic factors" on drug safety and efficacy that contradicts guidance provided by the OMB.[35]

Any future recommendations should be informed by such deliberations, empirical research on how investigators approach diversity and inclusion in research,[12] and lessons learned from engaging with diverse national and international communities.

ICH defines ethnic factors as genetic, physiologic, cultural, and environmental characteristics of a population.[35] On the one hand, the definition goes beyond the OMB census categories by including extrinsic aspects of one's environment and society in ethnic identity, but

on the other hand, this definition is inconsistent with the OMB's caveat (repeated in FDA guidelines) that race and ethnicity "should not be interpreted as being scientific in nature."[10(p9),11(p506),27] A closer look at such differences in international approaches can highlight potential areas for further discussion and potential consensus building.

Currently, federal policies do very little to steer precision medicine research in this direction. Professor Khan has reported that pharmaceutical corporations have voiced concern regarding inconsistent definitions of race, uncertainty about the accuracy of the definitions of race and ethnicity, and the inappropriate use of racial and ethnic categories in global drug markets.[11(p506-513)] According to Khan, these companies seek to standardize the use of race and ethnicity in order to ease operations in the global marketplace.[11] Small biotechnology companies, however, are more likely than large pharmaceutical companies to prefer the adoption of precise population categories informed by genetic knowledge.[11] The danger is that in the global marketplace, larger companies may promote race and ethnicity-based categorizations of populations at the expense of more detailed approaches.

Conclusion

As President Barack Obama explains in this article's opening statement, precision medicine aims to individualize treatment for every patient. To achieve this vision, precision medicine research must first illuminate how genes and environments affect human health. The OMB census categories are blunt tools for a field that is striving for nuance and precision.

Compelled by the lessons of eugenics, scholars have forcefully argued in favor of dispensing with the use of racial categories in biomedical research.[16] Others contend that racial categories may help facilitate deeper understanding about clinical outcomes and genetic risk factors.[30,32] The debate will continue. In the meantime, precision medicine researchers must follow transparent and rigorous processes as they define and examine increasingly diverse research cohorts.[5,12]

The major private and public funders of precision medicine research should continue to convene scholars from diverse disciplines, including those who research social determinants of health, to address the challenges raised when investigators categorize research participants. [32] Any future recommendations should be informed by such deliberations, empirical research on how investigators approach diversity and inclusion in research, [12] and lessons learned from engaging with diverse national and international communities. Successful frameworks will hold researchers accountable for how they use variables in research and promote the assessment of additional relevant factors that go beyond racial differences.[5,12] As the leading public funder of biomedical research in the world, NIH's All of US program is on track to collect one of the most comprehensive datasets featuring a significant percentage of traditionally underrepresented populations and is therefore helping to drive the future of precision medicine research. The potential for precision medicine research to translate into individualized treatment for all patients represents an exciting turning point in the progress of research and medicine: the path forward will shape precision medicine researchers' approach to studying underrepresented populations and, in turn, will determine the value of precision medicine research for all.

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