

Time to Rectify Colorblindness in Medical Research with Standardized Cohort Reporting

In 2021, the *New York Times* called out "Medical Journals Blind to Racism as a Health Crisis."¹ Indeed, the lack of racial health equity has been brought to the forefront of medical research news during the COVID-19 pandemic. Examples include the disproportionate morbidity and mortality of historically divested populations related to COVID-19, bias in artificial intelligence (AI) algorithms that perpetuate systemic racism, and lack of diversity in US clinical trials. While barriers to health equity in the context of race/ethnicity have been a constant, the increasing public spotlight on the colorblindness of medical research makes it imperative for our community to investigate the history behind our ignorance to correct it.

COLORBLINDNESS IN MEDICAL RESEARCH: HOW WE GOT HERE

As a nation built on the systematic massacre of indigenous peoples, it is unsurprising that American medical research, too, has roots grounded in racism. Scientific racism dates to the late 1700s when researchers published discoveries claiming to follow scientific principles to ratify a social racial hierarchy. Examples include anatomical studies measuring differences in size of skulls from Black and White subjects—morphometric variations inappropriately ascribed to differences in intelligence. Scientific racism would later underpin horrific experiments on Black populations, including physician J. Marion Sims' series of experimental operations on enslaved Black women without anesthesia nor informed consent in the development of his approach to vesicovaginal fistula repair.²

Sustained by a predominantly Western White supremacist society, scientific racism went on to fuel eugenics

movements that culminated during the 20th century with the harrowing actions of Nazi Germany in the Holocaust and World War II. Afterwards, in 1949, the United Nations Educational, Scientific, and Cultural Organization (UNESCO) stated "race is less a biological fact than a social myth,"³ and the atrocities put forth by scientific racism, eugenics, and associated genocide led to an avoidance, followed by ignorance, of race and racism in medical research.

However, the resultant colorblind approach adopted by the medical research community in the post-World War II era overlooks the significant impact of race and racism in health care and has allowed racial health disparities to grow within American society unchecked. Today, the medical community agrees that race is a social construct, not a biological factor, although the clinical significance of self-reported ethnicity remains controversial. Notwithstanding, persistent gaps in racial health disparities in post-World War II America have demonstrated that the need to start reporting racial/ethnic demographic data in research is not at all controversial—rather, it should be a standard best practice.

Against the backdrop of both the modern data-driven age and current events informed by our nation's history, the first step toward rectifying colorblindness in medical research is standardized data transparency. Presently, only 5% of medical literature,⁴ and less than half of US clinical trials,⁵ report race/ethnicity. Omitting racial/ethnic demographic data in research cohorts restricts our ability to define and address disparities in representation.

PITFALLS OF MODERN-DAY ETHICAL REGULATION OF MEDICAL RESEARCH

In 1991, the Department of Health and Human Services implemented the principles of the Belmont Report into the "Common Rule," a set of federal regulations for ethical conduct of research in humans that informs the jurisdiction of institutional review boards (IRBs). To combat scientific racism, the Common Rule stipulates that researchers provide specific justifications when conducting studies that include race. However, this regulation inadvertently

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dissuades researchers who are *not* conducting health disparities research from reporting race/ethnicity demographics in their studies. While the Belmont Report's principle of 'justice' designates that the "potential risks of research should be borne equally by the members of our society that are likely to benefit from it," the Common Rule fails to address the need for transparency and equity in representative cohort samples; and worse, it precludes regulation of transparency and diversity in cohort samples from the scope of the IRB. While the present-day IRB does protect population health studies from perpetuating racism, a new approach is vital to combat the separate issue of generalized colorblindness that dominates medical research today.

STANDARDIZED RACIAL/ETHNIC COHORT REPORTING

In modern medicine, patient management guidelines are derived from evidence-based medical research outcomes. However, research outcomes from opaque cohorts can skew evidence. Standardized reporting of race/ethnicity in research cohorts has been a topic of interest in the health equity research community since at least the late 1990s. There are many advantages to this anti-racism mechanism. With mandated standardized reporting, our community can at last begin to adequately quantify the extent of underrepresentation in research cohorts. From this foundation of data transparency, we can both appropriately allocate resources toward achieving equitable inclusion in research cohorts and minimize inappropriate extrapolation of treatment guidelines based on majority data from a single population. Moreover, while the community works to close gaps in representation, pervasive data reporting and sharing can power systematic reviews and meta-analyses to facilitate meaningful sub-analyses to aid health disparities research.

Contrarily, the societal disservice that is perpetuated by maintaining the colorblind status quo is not benign. Okah et al⁶ states that "colorblindness is an ideology or worldview that minimizes the role of systemic racism in shaping outcomes for people of color and attributes racial disparities to the bad choices and poor behavior of racial minorities." In medical research, one devastating result of the colorblind status quo is the consequent bias internalized by artificial intelligence algorithms secondary to unbalanced data sets. For example, a colorblind artificial intelligence algorithm for population health management published in *Science* determined that Black patients should receive comparatively less care as compared with White patients based on data sets reflecting unequal access to care between Black and White populations.⁷ Regarding medical devices, the colorblind approach employed in development of pulse oximeters results in overestimation of arterial oxygen levels in Asian, Hispanic, and Black patients as compared with White patients, contributing to inadequate oxygen supplementation in non-White patients with COVID-19.⁸ In development of treatment guidelines from retrospective and prospective cohort studies, colorblindness can skew

medical evidence and create treatment algorithms that overlook disparities from underrepresented populations.

RISE STANDARDIZED LABELS FOR RACE/ETHNICITY

A standard method of reporting should reflect US populations today, with room to evolve as our understanding of the relationship between racism and ethnicity continue to change. Research with Inclusion, Social Justice, and Equity (RISE; www.pledgetorise.org) is a health equity initiative with a mission to increase equitable representation of populations of color in medical research cohorts. The RISE standardized breakdown categories are updated by the initiative in accordance with current events. The current RISE standard breakdown categories are depicted in the [Table⁹](#) and mirror the racial/ethnic categories recognized by the Office of Management and Budget (OMB) and the US Census Bureau, with two modifications.

The first modification is disaggregation of the Asian racial category into East Asian, South Asian, and Southeast Asian. United historically to resist US imperialism and anti-Asian racism, today this category includes the greatest ethnic diversity and disparity of any racial group, with Southeast Asians suffering the worst disparities. Ongoing aggregated reports of these disparate groups ultimately underrepresents and weakens the needs of the diverse populations within this racial category.

Table RISE Standardized Labels for Reporting of Cohort Populations By Race/Ethnicity (Data Depicts US Population as Reported By census.gov[†])

Race/Ethnicity	Percentage (Replace With Study Data)
American Indian or Alaska Native	1.3%
Asian*	5.9%
<i>Consider disaggregation into East Asian, South Asian, and Southeast Asian</i>	
Black or African American	13.4%
Hispanic or Latino*	18.5%
<i>Consider disaggregation by racial category (eg, 'Black Hispanic/Latino' or 'White Hispanic/Latino')</i>	
Native Hawaiian or Other Pacific Islander	0.2%
Middle Eastern or North African (MENA) [‡]	0.4%*
White	59.9%
Other (eg, 2 or more races)	2.8%

RISE = Research with Inclusion, Social Justice, and Equity.

*Aggregated reporting of the Asian and Hispanic/Latino racial categories ultimately undermines all populations within these categories. Within data limitations, further racial disaggregation should be considered.

‡The projected MENA population⁹ is not currently recognized by the US Census Bureau as an ethnic category. This projected percentage has been subtracted from the White alone percentage that is listed on census.gov.

The second modification is the addition of the Middle Eastern and North African (MENA) category. As a self-protective measure, MENA immigrants identified as White to acquire citizenship in a country that, until 1956, only granted American citizenship to individuals considered Black or White. Today, approximately 3.7 million⁹ MENA Americans endure an enforced and paradoxical invisibility in addition to cultural- and nation-based discrimination. The current lack of recognition of the MENA population by OMB and the US Census Bureau severely undermines assessment of MENA health disparities.

It is important to note that the OMB currently recognizes the Hispanic/Latino category as an ethnicity rather than a race. This alludes to the breadth of both ethnic diversity and shades of color within the Hispanic/Latino category that is often perceived as monolithic. The Hispanic/Latino category includes individuals from Mexico, Puerto Rico, Central America, South America, and others (including those of Spanish descent).¹⁰ Many modern surveys are structured in a way that allow selection of a racial category in addition to Hispanic/Latino ethnicity, for example, one may select “Black or African American” followed by “Hispanic/Latino.” Within data availability, disaggregation of the Hispanic/Latino category is strongly encouraged.

The RISE standardized labels are intended to represent *minimum* racial/ethnic breakdown categories. Those conducting racial/ethnic health disparities research should consider reporting increased racial/ethnic granularity by further disaggregation towards country of origin within data availability.

SOLUTIONS FOR ANTICIPATED BARRIERS TO ADOPTION OF RISE STANDARDIZED COHORT REPORTING

While all clinical/biomedical researchers should adhere to (minimum) standardized reporting, it is ultimately the responsibility of medical journals and government/funding bodies to uplift this quality standard. Expectantly, there are barriers involved in any pursuit of progress. In anticipation of the concern for space limitations owing to supporting this standard, medical journals could consider exemption of race/ethnicity demographic data in submitted manuscripts from the allotted word/character count limitation. Alternatively, researchers could provide the necessary information as supplementary material.

To address concerns about the International Committee of Medical Journal Editors (ICMJE) guidelines recommending that “authors should define how they determined race or ethnicity and justify their relevance,”¹¹ we propose that authors could include variations on the following statement: “Racial/ethnic demographic data were provided in accordance with the RISE standardized categories and guidelines.”

We expect there to be profound limitations in the availability of demographic data. To address those gaps, authors may simply state the unavailability of such data. The widespread reporting of this void in data availability is in and of itself critical to illuminating the need to allocate resources to correct it.

Ubiquitous standardized reporting of racial/ethnic demographics in all relevant human-based medical research is a specific and achievable goal. Realizing this goal would bring our multi-faceted medical community one step closer toward equitable inclusion and treatment of all underrepresented populations in medicine.

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