Illustration by Chiara Vercesi

OPINION

Racism in Medical Tests

Many diagnostic assessments are inherently biased against people of color

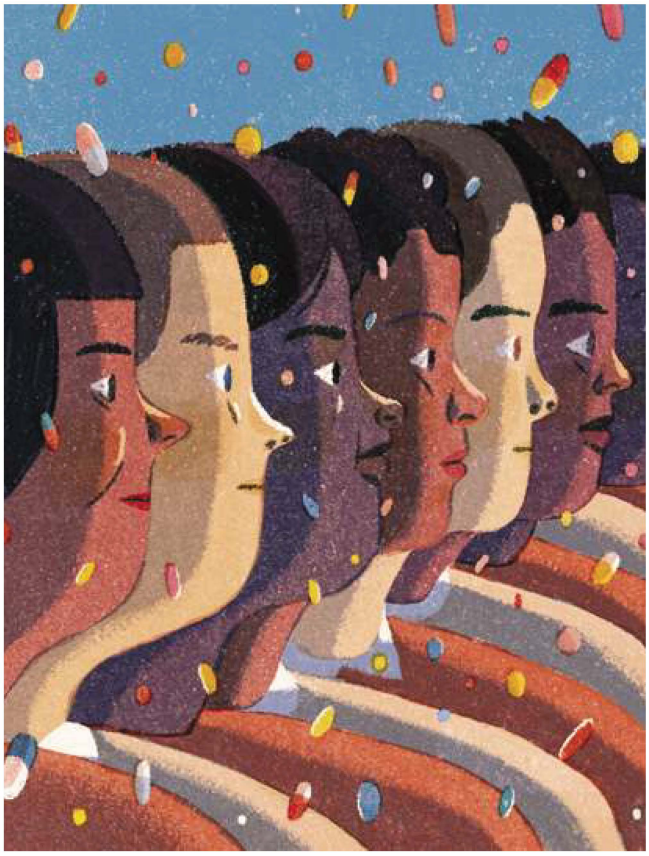
By the Editors

COVID-19 HAS WREAKED HAVOC on Black and Indigenous communities and other people of color, and U.S. medical institutions should be doing everything they can to root out and eliminate entrenched racial inequities. Yet many of the screening assessments used in health care are exacerbating racism in medicine, automatically and erroneously changing the scores given to people of color in ways that can deny them needed treatment.

These race-based scoring adjustments to evaluations are all too common in modern medicine, particularly in the U.S. To determine the chance of death for a patient with heart failure, for example, a physician following the American Heart Association's guidelines would use factors such as age, heart rate and systolic blood pressure to calculate a risk score, which helps to determine treatment. But for reasons the AHA does not explain, the algorithm automatically adds three points to non-Black patients' scores, making it seem as if Black people are at lower risk of dying from heart problems simply by virtue of their race. This is not true.

A recent paper in the *New England Journal of Medicine* presented 13 examples of such algorithms that use race as a factor. In every case, the race adjustment results in potential harm to patients who identify as nonwhite, with Black, Latinx, Asian and Native American people affected to various degrees by different calculations. These "corrections" are presumably based on the long-debunked premise that there are innate biological differences among races. This idea persists despite ample evidence that race—a social construct—is not a reliable proxy for genetics: Every racial group contains a lot of diversity in its genes. It is true that some populations are genetically predisposed to certain medical conditions—the *BRCA* mutations associated with breast cancer, for instance, occur more frequently among people of Ashkenazi Jewish heritage. But such examples are rare and do not apply to broad racial categories such as "Black" or "white."

The mistaken conflation of race and genetics is often compounded by outdated ideas that medical authorities (mostly white) have perpetuated about people of color. For example, one kidney test includes an adjustment for Black patients that can hinder accurate diagnosis. It gauges the estimated glomerular filtration rate (eGFR), which is calculated by measuring creatinine, a protein associated with muscle breakdown that is normally



OPINION

Clinical Trials Need More Diversity

It's unethical and risky to ignore racial and ethnic minorities

By the Editors

NEARLY 40 PERCENT OF AMERICANS BELONG TO A RACIAL or ethnic minority, but the patients who participate in clinical trials for new drugs skew heavily white—in some cases, 80 to 90 percent. Yet nonwhite patients will ultimately take the drugs that come out of clinical studies, and that leads to a real problem. The symptoms of conditions such as heart disease, cancer and diabetes, as well as the contributing factors, vary across lines of ethnicity, as they do between the sexes. If diverse groups aren't part of these studies, we can't be sure whether the treatment will work in all populations or what side effects might emerge in one group or another.

This isn't a new concern. In 1993 Congress passed the National Institutes of Health Revitalization Act, which required the agency to include more women and people of color in their research studies. It was a step in the right direction, and to be

Illustration by Lisk Feng

cleared by the kidneys. Black patients' scores are automatically adjusted because of a now discredited theory that greater muscle mass "inherent" to Black people produces higher levels of the protein. This practice inflates the overall eGFR value, potentially disguising real kidney problems. The results can keep Black patients from getting essential treatment, including transplants. Citing these issues, medical student Naomi Nkinsi successfully pushed the University of Washington School of Medicine to abandon the eGFR race adjustment in 2020. But it remains widely used elsewhere.

A 2019 study in *Science* examined an algorithm used throughout the U.S. health system to predict broad-based health risks. The researchers looked at one large hospital that used this algorithm and found that, based on individual medical records, white patients were actually healthier than Black patients with the same risk score. This is because the algorithm used health *costs* as a proxy for health *needs*—but systemic racial inequality means that health-care expenditures are higher for white people overall, so that the needs of Black people were being underestimated. In an analysis of these findings, sociologist Ruha Benjamin, who studies race, technology and medicine, observes that "today coded inequity is perpetuated precisely because those who design and adopt such tools are not thinking carefully about systemic racism."

The algorithms that are harming people of color could easily be made more equitable, either by correcting the racially biased assumptions that inform them or by removing race as a factor altogether when it does not help with diagnosis or care. The same is true for devices such as the pulse oximeter, which is calibrated to white skin—a particularly dangerous situation in the COVID pandemic, where nonwhite patients are at higher risk of serious lung infections.

Leaders in medicine must prioritize these issues now to give fair and often life-saving care to the people left most vulnerable by an inherently racist system. SA

sure, the percentage of women in clinical trials has grown significantly since then.

But participation by minorities has not increased much at all: a 2014 study found that fewer than 2 percent of more than 10,000 cancer clinical trials funded by the National Cancer Institute focused on a racial or ethnic minority. And even if the other trials fulfilled those goals, the 1993 law regulates only studies funded by the NIH, which represent a mere 6 percent of all clinical trials.

The shortfall is especially troubling when it comes to trials for diseases that particularly affect marginalized racial and ethnic groups. For example, Black Americans are more likely to suffer from respiratory ailments than white Americans are; however, as of 2015, only 1.9 percent of all studies of respiratory disease included minority subjects, and fewer than 5 percent of NIH-funded respiratory research included racial minorities.

The problem is not necessarily that researchers are unwilling to diversify their studies. Members of minority groups are often reluctant to participate. Fear of discrimination by medical professionals is one reason. Another is that many ethnic and racial minorities do not have access to the specialty care centers that recruit subjects for trials. Some may also fear possible exploitation, thanks to a history of unethical medical testing in the U.S. (the infamous Tuskegee experiments, in which Black men were deliberately left untreated for syphilis, are perhaps the best-known example). And some minorities simply lack the time or financial resources to participate.

The problem is not confined to the U.S., either. A study of trials involving some 150,000 patients in 29 countries at five different time points over the past 21 years showed that the ethnic makeup of the trials was about 86 percent white.

Drug regulators such as the Food and Drug Administration should create and enforce tougher requirements: for a drug to be approved for market, the patient panels of its clinical trials should closely resemble the makeup of the patient populations who will actually use the candidate medicine. And drugmakers should adopt their own testing policies, including strong standards for diverse patient groups.

The FDA currently requires drug developers to provide extra test results for a candidate drug that may have applications in a special age population—say, older patients. It could apply those same criteria regarding race and ethnicity. These requirements could even extend to a more diverse array of genetic subtypes. Some medicines are ineffective or dangerous in certain genetic populations. For example, carbamazepine, a medication used to treat epilepsy, can cause a severe skin disorder in patients with a particular gene variant found in some people of Asian heritage.

In 2015 the FDA launched the Drug Trials Snapshots program, which makes public the demographic details of clinical trial participants, including their age, sex and race. But the onus is on the patients and their doctors to seek out that information.

It's unethical and dangerous to approve drugs without making every attempt to certify their safety and efficacy. Yet by failing to include members of racial and ethnic minorities in clinical trials, that is just what the FDA is doing. SA

Illustration by Deborah Lee