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Moving beyond race-based drugs

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Prescribing certain medications on the basis of a patient's race has long come under fire from those uneasy with using race as a surrogate for biology when treating disease.

But there are multiple challenges to overcome before we can move beyond race-based treatment decisions, writes Duke University geneticist and bioethicist Charmaine Royal in a perspective piece published May 25 in the *New England Journal of Medicine*.

In "Will Precision Medicine Move Us beyond Race?" Royal and colleagues Vence Bonham of the National Institutes of Health and Shawneequa Callier of The George Washington University describe some of the thorny issues raised by race-based drugs.

When the first race-based drug, BiDil, was approved by the FDA a decade ago to treat African Americans with heart failure, advocates heralded it as a way to narrow health disparities between whites and blacks by targeting the group that suffered the most from the disease.

Yet the drug had not actually been shown to be more effective in African Americans than other patients, critics noted. What's more, it was only marketed to African Americans after efforts to obtain FDA and patent approval for use in the general population failed, leading many to question the commercial motivations for classifying it as an "ethnic" drug.

Race is also a common factor in prescribing ACE inhibitors, a class of

drugs used to treat high blood pressure and heart disease. ACE inhibitors have been shown to be less effective in blacks than whites, "but one result of using race to dictate therapy is that individual black patients whose hypertension would respond to ACE inhibitors may not be offered one," the authors say.

"What we even mean by race has always been murky and is becoming even more so given changing demographics," said Royal, an associate professor of African and African American Studies and director of the Center on Genomics, Race, Identity, Difference at Duke's Social Science Research Institute. Someone who self-identifies as black, such as President Obama, likely has ancestors from multiple so-called races.

Given the genetic diversity that exists within racial groups, and the similarities between different groups, it is likely that a drug labeled for use in African Americans will not work for all African Americans, and that some non-African Americans would also benefit from the drug.

But getting drug manufacturers and clinicians to go beyond a race-based approach won't be easy, the authors say.

The makers of the clot-inhibiting drug Plavix, for example, were sued by the Attorney General of Hawaii in 2014 for failing to disclose that the drug was less effective in patients with certain inherited forms of a liver enzyme called CYP2C19.

Sharing such information with the public likely would have decreased sales in the state, as the variants are more common in Asians, Native Hawaiians and other Pacific Islanders—who make up more than half of Hawaii's population—than in whites.

Technological advances in DNA sequencing and analyzing large datasets will continue to generate insights about the genetics underlying

differences in drug response. The data deluge will only further highlight the pitfalls of using imprecise race categories to prescribe drugs.

"Prescribing medications on the basis of race oversimplifies the complexities and interplay of ancestry, health, disease, and drug response," the authors write.

Eventually, optimizing drug treatments to a patient's unique genetic makeup, lifestyle, environment and other factors, rather than race, could help ensure that patients receive the right drug at the right dose—an approach called precision medicine.

"There are many hurdles to overcome if a precision medicine approach to health care is to replace the use of race in treatment decisions," the authors say.

One barrier to understanding the complex interplay between genes, environment and lifestyle is the lack of participant diversity in biomedical research and clinical trials. Addressing the problem will require recruiting more participants from minority groups to better reflect the diversity of the U.S. population.

We will also need cost controls for drugs found to be effective only in a few, the authors say.

Lastly, moving beyond race-based drug prescriptions will depend on the ability to equip health care providers with the resources and training they will need to collect and make sense of more types of data.

"Precision medicine is premised on the idea of improving health outcomes by generating and using many sources of personal data to more accurately group and treat patients," the authors say. "If the major challenges can be overcome, precision medicine could lead the way in

reducing and ultimately eliminating the use of crude racial and ethnic census categories in drug prescribing."

More information: Vence L. Bonham et al, Will Precision Medicine Move Us beyond Race?, *New England Journal of Medicine* (2016). DOI: 10.1056/NEJMp1511294

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