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# **The Fatal Flaw of the Pulse Oximeter** Racial bias led to faulty product design

BY REBECCA SOHN

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If someone is seeking medical care, the color of their skin shouldn't matter. But, according to new research, pulse oximeters' performance and accuracy apparently hinges on it. Inaccurate blood-oxygen measurements, in other words, made by pulse oximeters have had clear consequences for people of color during the COVID-19 pandemic.

"That device ended up being essentially a gatekeeper for how we treat a lot of these patients," said Dr. Tianshi David Wu, an assistant professor of medicine at Baylor College of Medicine, in Houston, and one of the authors of the study.

For decades, scientists have found that pulse oximeters, devices that estimate blood-oxygen saturation, can be affected by a person's skin color. In 2021, the FDA issued a warning about this limitation of pulse oximeters. The agency says it plans to hold a meeting on pulse oximeters later this year. Because low oxygen saturation, called hypoxemia, is a common symptom of COVID-19, low blood-oxygen levels qualify patients to receive certain medications. In the first study to examine this issue among COVID-19 patients, published in *JAMA Internal Medicine* in May, researchers found that the inaccurate measurements resulted in a "systemic failure," delaying care for many Black and Hispanic patients, and in some cases, preventing them from receiving proper medications. The study adds a growing sense of urgency to an issue raised decades ago.

**"We found that in Black and Hispanic patients, there was a significant delay in identifying severe COVID compared to white patients."**
**—Dr. Ashraf Fawzy, Johns Hopkins University**

Pulse oximeters work by passing light through part of the body, usually a finger. These devices infer a patient's blood-oxygen saturation (that is, the percentage of hemoglobin carrying oxygen) from the absorption of light by hemoglobin, the pigment in blood that carries oxygen. In theory, pulse oximeters shouldn't be affected by anything other than the levels of oxygen in the blood. But research has

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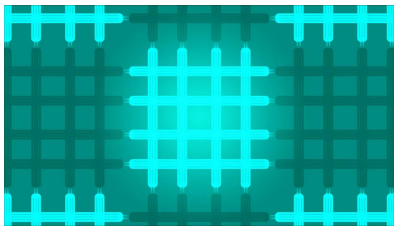

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To qualify for COVID-19 treatment with remdesivir, an antiviral drug, and dexamethasone, a steroid, patients had to have a blood-oxygen saturation of 94 percent or less. Based on the researchers' model, nearly 30 percent of the 6,673 patients about whom they had enough information to predict their arterial blood-gas measurements met this cutoff. Many of these patients, most of whom were Black or Hispanic, had their treatment delayed for between 5 and 7 hours, with Black patients being delayed on average 1 hour more than white patients.

"We found that in Black and Hispanic patients, there was a significant delay in identifying severe COVID compared to white patients," said Dr. Ashraf Fawzy, assistant professor of medicine at Johns Hopkins University and an author of the study.

There were 451 patients who never qualified for treatments but that the researchers predicted likely should have; 55 percent were Black, while 27 percent were Hispanic.

The study "shows how urgent it is to move away from pulse [oximeters]," said Rao, and to find alternatives ways of measuring blood-oxygen saturation.



Studies finding that skin color can affect pulse oximeters go back as far as the 1980s. Despite knowledge of the issue, there are few ways of addressing it. Wu says

Rao's lab is working on developing.

The researchers said one limitation of their study involved the way patients race was self-identified—meaning a wide range of skin pigmentation could be represented in each of the sample groups, depending on how each patient self-identified. The researchers also did not measure how delaying or denying treatment affected the patients clinically, for instance how likely they were to die, how sick they were, or how long they were sick. The researchers are currently working on a study examining these additional questions and factors.

Although the problem of the racial bias of pulse oximeters has no immediate solution, said the researchers, they are confident the primary hurdle is not technological.

"We do believe that technology exists to fix this problem, and that would ultimately be the most equitable solution for everybody," said Wu.

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# THIS CAD PROGRAM CAN DESIGN NEW ORGANISMS

Genetic engineers have a powerful new tool to write and edit DNA code

BY AMY CAYNE SCHWARTZ DOUGLAS DENSMORE FARREN ISAACS GIOVANNI STRACQUADANIO

18 OCT 2021 | 11 MIN READ |


Foundries such as the Edinburgh Genome Foundry assemble fragments of synthetic DNA and send them to labs for testing in cells. EDINBURGH GENOME FOUNDRY, UNIVERSITY OF EDINBURGH

**In the next decade,** medical science may finally advance cures for some of the most complex diseases that plague humanity. Many diseases are caused by mutations in the human genome, which can either be inherited from our parents (such as in cystic fibrosis), or acquired during life, such as most types of cancer. For some of these conditions, medical researchers have identified the exact mutations that lead to disease; but in many more, they're still seeking answers. And without understanding the cause of a problem, it's pretty tough to find a cure.

We believe that a key enabling technology in this quest is a computer-aided design (CAD) program for genome editing, which our organization is launching this week at the Genome Project-write (GP-write) conference.

With this CAD program, medical researchers will be able to quickly design hundreds of different genomes with any combination of mutations and send the genetic code to a company that manufactures strings of DNA. Those fragments of synthesized DNA can then be sent to a foundry for assembly, and finally to a lab where the designed genomes can be tested in cells. Based on how the cells grow, researchers can use the CAD program to iterate with a new batch of redesigned genomes, sharing data for collaborative efforts. Enabling fast redesign of thousands of variants can only be achieved through automation; at that scale, researchers just might identify the combinations of mutations that are causing

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