

Biased tech could determine who gets life saving therapy

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Until her clinical rotation in the earliest months of the COVID-19 pandemic, Valeria Valbuena, M.D., then a surgical resident at University of Michigan Health, had never seen so many patients who looked like

her on the intensive care unit.

"Seeing the unit filled with Hispanic and Black people from all across Michigan was an out of body experience," she said, one that further fueled her interest in researching health disparities.

In late 2020, research led by her U-M colleague Michael Sjoding, M.D., assistant professor of Internal Medicine in the Division of Pulmonary and Critical Care Medicine, revealed a persistent discrepancy between tests commonly used to determine how much oxygen a person is getting, namely, the [pulse oximeter reading and the arterial blood gas test](#), in Black [patients](#).

That paper, published in the *New England Journal of Medicine*, sparked intense scrutiny of device makers by policymakers, including members of Congress and the Food and Drug Administration. The study received a fair number of criticisms, as well.

Some noted the relatively small number of patients in the study, or the lack of a certain type of statistical analysis, while others pointed to the fact that [blood oxygen levels](#) in hospitalized patients can fluctuate widely in a relatively short period of time, explains Valbuena.

Looking to see if that study's findings were really true among the sickest patients, Valbuena, along with Theodore J. Iwashyna, M.D., Ph.D., Sjoding and other U-M colleagues turned to the Extracorporeal Life Support Organization (also known as ELSO) registry, a comprehensive international database collated from hospitals which deliver extracorporeal membrane oxygenation, or ECMO. This life saving procedure, developed by Robert Bartlett, M.D., at the University of Michigan more than 40 years ago, is an advanced form of life support for patients with respiratory failure.

The ELSO database offered several advantages, including detailed race and ethnicity data.

"In the *NEJM* study, all patients were receiving supplemental oxygen, but there was no way to control for the degree of respiratory support they required," Valbuena said. "Some patients were extremely sick, while others were not intubated. One thing about this particular dataset that was beneficial is all patients were ill enough to require ECMO."

For their new study, the team again asked the question: What is the likelihood of a critically ill patient having what is known as occult hypoxemia, or unrecognized low oxygen levels, defined as an arterial blood gas level below 88% despite a pulse oximeter rating of 92 to 96%?

"For clinicians, if a pulse oximeter reads between 92 and 97%, we assume the patient is getting enough oxygen with whatever we are doing," explained Valbuena.

Combing the ELSO database, the study team found a discrepancy ten percent of the time in White patients. In Black patients, the likelihood of a discrepancy was 20%. That is, after statistical adjustment, Black patients were two and a half times more likely to experience occult hypoxemia compared to white patients. Furthermore, when they expanded their analysis to include Asian and Hispanic patients, they found that these groups' rates of occult hypoxemia were similar to that of white patients.

"That surprised me," said Valbuena, "The results made us think back to how we are using race as a surrogate for [skin color](#) and what that might mean for future studies."

The team took the analysis further to examine a seemingly unlikely scenario: The rate at which a patient would have a dangerously low blood

oxygen level, below 88%, on an arterial blood gas measurement while a pulse oximeter measured normal oxygen levels at 97% and above.

They found that the risk of this occurring in Black patients was three times higher than in white patients.

"Our sample size was small, so our confidence interval was definitely wide, but we saw the difference— and that was very shocking," said Valbuena. "What that means is there are real errors in interpreting single pulse oximetry measurements, even at a reading of 100%—and those errors are more likely in Black patients."

The discrepancy has dire implications. For instance, clinicians make minute-to-minute decisions based on pulse oximeter readings, determining when to intervene with a patient to ensure adequate oxygenation.

"When a patient's pulse oximeter reading goes down, which happens in the ICU all the time, we respond immediately. We change modes on the ventilator, administer additional gases, place them in the prone position until we get them to a place that is safe," said Valbuena. "But if I have a patient with severe respiratory failure whose pulse ox is reading 92-100, we are usually not going to do any of those things with the same urgency, which I feel is an important implication of both the *NEJM* findings and these findings. The maximum time one can be at oxygen levels below 88 without ensuing severe damage to vital tissues is usually a few minutes."

The findings raise troubling questions about the allocation of ECMO machines, which are considered an extremely scarce resource and one that for many with severe respiratory failure means the difference between life and death.

"If I have a patient A with severe [respiratory failure](#) due to COVID-19,

RSV or the flu and a normal pulse oximetry reading, and patient B, whose pulse oximeter is detecting low oxygen levels even with maximum support and they are not getting better, odds are I will prioritize them for the very elaborate process of initiating ECMO, while patient A—who might be Black—may be just as sick but I haven't noticed," said Valbuena.

The study is yet another proof point of an issue that's been acknowledged in medical literature, but not addressed for 30 years, noted Valbuena. And while it will take time for the known deficiencies of the technology to be corrected for, Valbuena says, clinicians can take action now by lowering their threshold of suspicion when caring for Black patients and any patient with dark skin who reports shortness of breath, considering pulse oximetry trends instead of single measurements, and ordering the gold standard arterial blood gas test.

Valbuena credits the visceral experience of witnessing the disparate number of critically ill minority patients early in the pandemic for raising a red flag that required more investigation.

"It is clear the system was not designed for Black and Brown patients."

More information: Valeria S.M. Valbuena et al, Racial Bias in Pulse Oximetry Measurement Among Patients About to Undergo ECMO in 2019-2020, A Retrospective Cohort Study, *Chest* (2021). [DOI: 10.1016/j.chest.2021.09.025](https://doi.org/10.1016/j.chest.2021.09.025)

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