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U-M RESEARCH UNCOVERS BIAS IN MEDICAL DEVICES, DRIVING FDA ACTION

During the peak of the COVID-19 pandemic, researchers at the University of Michigan identified a troubling trend: patients with critically low oxygen levels were receiving normal readings from pulse oximeters.

The incorrect reading on these devices, designed to measure blood oxygen levels, were leading to delays in essential care. Concerned about the reduced accuracy of pulse oximeters in Black patients, U-M researchers analyzed pulse oximetry records collected during routine care in hospitalized patients. The researchers compared the oximeter values to those of arterial blood gas tests, a more specialized test considered the "gold standard" for measuring oxygen levels that is occasionally performed after pulse oximetry.

Upon comparing pulse oximeter readings with the direct blood tests, researchers confirmed that the devices consistently overestimated oxygen levels in individuals with darker skin tones. This disparity resulted in many patients not receiving the necessary oxygen or advanced care promptly. The study revealed that this life-threatening inaccuracy may have contributed to higher COVID-19 mortality rates among Black residents in Michigan.

This breakthrough was made possible due to research infrastructure funded by the National Institutes of Health (NIH). It enabled researchers to swiftly analyze patient data and confirm that the inaccurate readings were a widespread issue, not an isolated occurrence.

"We simply would not have been able to conduct this research if it weren't for the data infrastructure investment that allowed us to rapidly access and analyze U-M patient data," remarked Dr. Michael Sjoding, associate professor of internal medicine at the Medical School.

The results had an immediate impact on national healthcare policy, spurring the U.S. Food and Drug Administration (FDA) into action. In 2021, the FDA issued a safety communication warning about the inaccuracy of these devices. Advisory panels validated the data and confirmed the issue, leading to substantial regulatory changes. Earlier this year, the FDA announced new draft guidelines, requiring pulse oximeter manufacturers to test devices on a much larger and more diverse patient population, ensuring accuracy across all racial groups.

The work carried out by U-M researchers extended beyond Michigan, influencing national healthcare policies and enhancing patient safety throughout the country. "It's been one of the most gratifying experiences of my career to see the evolution of this research – from our initial study to subsequent follow-ups and now to the proposed changes in FDA regulations that will ultimately improve patient care," Sjoding said.