IHPI BRIEF

Pulse Oximeters are Less Accurate in Hospitalized Black Patients

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The pulse oximeter, a device that first came to market in the 1980s, is an essential tool used to estimate patients' oxygen levels at home or in clinics and hospitals. The devices help guide critical medical decisions such as whether a patient needs admission to the hospital or should be provided supplemental oxygen. Pulse oximeters have been widely used to measure the oxygen levels of patients during the COVID-19 pandemic.

Given the widespread use of pulse oximeters for medical decision-making, it is critical that these devices work equitably for everyone. When pulse oximeters fail to identify someone with very low oxygen levels in the hospital, that person is less likely to receive supplemental oxygen and life-saving medical treatment.[1–4] It is also associated with an increased risk of organ failure and a higher likelihood of dying in the hospital.[1–4]

Studies dating back to 1990, 2005, and 2007 raised concerns that pulse oximeters may be less accurate in individuals with darkly pigmented skin.[5–7] These inaccuracies are thought to be due to differences in the amount of melanin in the skin, which is a substance in your body that produces skin, hair, and eye pigmentation. The amount of melanin may affect how light is transmitted by the pulse oximeter through the skin to measure oxygen levels.

Motivated by their experience using pulse oximeters to care for critically ill patients during the first wave of the COVID-19 pandemic, a team at the University of Michigan (U-M) studied whether pulse oximeters are less accurate in Black patients compared to White patients in three populations: 1) Critically ill adults in the intensive care unit, 2) hospitalized children, and 3) hospitalized Veterans. Oxygen level readings on pulse oximeters were compared to those measured by arterial blood gas—a more accurate measure obtained via a painful procedure involving drawing blood from an artery.

Pulse oximeters *are devices usually placed on a fingertip and used to estimate how much oxygen is present in the blood. These devices are non-invasive and can estimate oxygen saturation without having to draw a blood sample.*

A normal oxygen saturation *is 95% or higher. Oxygen therapy is typically started when oxygen levels are below 89%.*

Prescription pulse oximeters*, most often used in hospitals and doctors' offices, undergo clinical testing to confirm accuracy and are reviewed by the U.S. Food and Drug Administration (FDA). Over-the-counter pulse oximeters are sold directly to consumers and do not undergo FDA review.*

Takeaways from our research

Studies of three patient populations found that prescription pulse oximeters missed low blood oxygen levels at a statistically significant higher frequency in hospitalized Black patients than in White patients.

Critically ill adults in the intensive care unit [8]

11.7% of critically ill Black patients in a U-M cohort had low blood oxygen levels despite a normal pulse oximeter reading. In White patients, this discrepancy occurred 3.6% of the time. A study of patients hospitalized in intensive care units at 178 hospitals across the U.S. showed similar results.

Data sources: Data from patients hospitalized at Michigan Medicine (2020) and patients hospitalized in 178 U.S. hospitals. (2014–2015).

Children admitted to the hospital [9]

21.1% of Black pediatric patients had low blood oxygen levels despite a normal pulse oximeter reading. This discrepancy occurred less frequently among White children (15.6%).

Data source: Data from children aged 17 and younger admitted to Michigan Medicine between 2015 and 2020.

Adults hospitalized at U.S. Veterans Health Administration hospitals [10]

19.6% of Black Veterans had low blood oxygen levels despite a normal pulse oximeter reading. This discrepancy occurred less frequently among White Veterans (15.6%).

Such inaccuracies could lead to more than 75,000 instances a year where low blood oxygen is missed in a Black Veteran yet would have been detected if the devices functioned as well as they do in White Veterans.

Data source: Adult inpatient data from 2013–2019 from over 100 hospitals in the U.S. Veterans Health Administration.

What does this mean for health policy discussions?

These findings demonstrate that pulse oximeters more often provide inaccurate readings and may over-estimate oxygen levels in Black patients. This is especially concerning during the COVID-19 pandemic as it suggests that reliance on pulse oximetry to triage patients and provide supplemental oxygen therapy places Black patients with COVID at increased risk for poor clinical outcomes. Addressing the performance of these devices to ensure that Black patients with low oxygen levels do not go underrecognized and undertreated is extremely important.

It is also vital that physicians and nurses are aware of the general limitations of pulse oximeters, and especially the inaccuracies in patients with darkly pigmented skin.

The U-M research team outlined several considerations to help address this issue:

The Food and Drug Adminstration (FDA). Considering the new evidence related to inaccuracies in Black patients, the FDA could update its guidance on what data companies submit to demonstrate acceptable pulse oximeter performance. Current FDA Guidance for Industry and Food and Drug Administration Staff, published in March 2013, recommends that pulse oximeter testing studies include at least two darkly pigmented human subjects or 15% of the participant pool, whichever is larger. A requirement to include more subjects with dark skin pigmentation may improve the likelihood of identifying performance differences across patient groups.

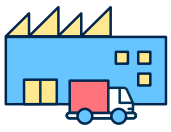
Updated guidance could also require that performance be separately tested and reported in darkly pigmented patients.

The FDA did issue an FDA Safety Communication in February 2021 about the accuracy and limitations of pulse oximeters, mentioning that several factors such as skin pigmentation can influence accuracy. But, the FDA could consider requiring additional information in device labeling, user manuals (adequate directions for use), marketing brochures, etc. to highlight this limitation and discuss how to use the devices appropriately to support patient care.

The FDA could establish registries for pulse oximeter information to monitor how products are being used and by whom, and which are most accurate.

The FDA could also consider requesting real-world, post-market surveillance and evaluation data on pulse oximeter performance. This would allow for earlier detection of any issues that arise, such as inaccuracies of measurement for certain populations. FDA, NIH or the Patent Centered Outcome Research Institute (PCORI) might also consider funding comparative research on the accuracy of pulse oximeters.

The FDA should work closely with hospitals, health care systems, and physician and nursing professional organizations to disseminate information related to the limitations of pulse oximeters or consider convening technical assistance calls or webinars on this issue.



Pulse oximeter manufacturers could include any currently available internal testing data in their marketing materials and brochures on device performance in Black patients or people with darkly pigmented skin to health care systems and physicians and nurses seeking to purchase the devices. Increasing the diversity of subjects used during pulse oximeter development and testing would further ensure their devices perform equivalently in everyone.

Hospitals, health care systems and major purchasers like the Department of Veterans Affairs could choose to only purchase pulse oximeters proven to perform equivalently in all patient populations, if the devices are labeled or rated on performance across populations.

Physician and nursing professional organizations could broadly disseminate information to their members on pulse oximeters and their limitations to ensure physicians and nurses are aware of these potential inaccuracies.

References

1. **Analysis of Discrepancies Between Pulse Oximetry and Arterial Oxygen Saturation Measurements by Race and Ethnicity and Association With Organ Dysfunction and Mortality.** Wong AI, Charpignon M, Kim H. et al. *JAMA Netw Open.* 2021 Nov 1;4(11):e2131674. PMID: 34730820. doi:10.1001/jamanetworkopen.2021.31674.

2. **Disparities in Hypoxemia Detection by Pulse Oximetry Across Self-Identified Racial Groups and Associations With Clinical Outcomes.** Henry NR, Hanson AC, Schulte PJ, et al. *Critical Care Medicine.* 2022 Feb;50(2):204-211. doi:10.1097/CCM.0000000000005394.

3. **Racial and Ethnic Discrepancy in Pulse Oximetry Delayed Identification of Treatment Eligibility Among Patients With COVID-19.** Fawzy A, Wu TD, Wang K, et al. *JAMA Intern Med.* 2022 May 31;182(7):730-738. doi:10.1001/jamainternmed.2022.1906.

4. **Assessment of Racial and Ethnic Differences in Oxygen Supplementation Among Patients in the Intensive Care Unit.** Gottlieb ER, Ziegler J, Morley K, et al. *JAMA Intern Med.* 2022 Jul 11. doi:10.1001/jamainternmed.2022.2587.

5. **Reliability of Pulse Oximetry in Titrating Supplemental Oxygen Therapy in Ventilator-Dependent Patients.** Jubran A, Tobin MJ. *Chest.* 1990 Jun;97(6):1420-5. PMID: 2347228. doi:10.1378/chest.97.6.1420.

6. **Effects of Skin Pigmentation on Pulse Oximeter Accuracy at Low Saturation.** Bickler PE, Feiner JR, Severinghaus JW. *Anesthesiology.* 2005 Apr;102:715-719. doi:10.1097/00000542-200504000-0004.

7. **Dark Skin Decreases the Accuracy of Pulse Oximeters at Low Oxygen Saturation: The Effects of Oximeter Probe Type and Gender.** Feiner JR, Severinghaus JW, Bickler PE. *Anesthesia & Analgesia.* 2007 Dec;105(6):S18-S23. doi:10.1213/01.ane.0000285988.35174.d9.

Our published research

8. **Racial Bias in Pulse Oximetry.** Sjoding MW, Dickson RP, Iwashyna TJ, et al. *N Engl J Med.* 2020 Dec 17;383:2477-2478. doi:10.1056/NEJMc2029240.

9. **Association of Race With Pulse Oximetry Accuracy in Hospitalized Children.** Andrist E, Nuppnau MS, Barbaro RP, et al. *JAMA Netw Open.* 2022;5(3):e224584. doi:10.1001/jamanetworkopen.2022.4584.

10. **Racial Bias and Reproducibility in Pulse Oximetry Among Medical and Surgical Inpatients in General Care in the Veterans Health Administration 2013-19: Multicenter, Retrospective Cohort Study.** Valbuena V, Seelye S, Sjoding MW, et al. *BMJ.* 2022 Jul 6;378:e069775. doi:10.1136/bmj-2021-069775.

Racial Bias in Pulse Oximetry Measurement Among Patients About to Undergo Extracorporeal Membrane Oxygenation in 2019-2020: A Retrospective Cohort Study. Valbuena V, Barbaro RP, Claar D, et al. *Chest.* 2021 Sept 27;161(4):971-978. doi:10.1016/j.chest.2021.09.025.

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