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The Open Oximetry Project: Safe and Accurate Pulse Oximeters for All Skin Tones

by Daryl Dorsey, BS; Fekir Negussie, MPH; Elizabeth Igaga, MMed; Tyler Law, MD, MS; and Michael Lipnick, MD

Pulse oximetry has long been a cornerstone of patient safety both inside and outside the operating room. However, data emerged during the COVID pandemic revealing health care disparities that may be linked to underperformance of these essential devices. Most notably during the pandemic, patients with darker skin tones experienced delays in treatment.¹ This delay can lead to worse health care and health outcomes. Although these concerns have persisted for years with relatively little attention prior to the pandemic, increasing data on potential harms from inequitable device performance have renewed interest from the public and regulatory agencies.^{2,3} There is a need to understand and address the root cause of pulse oximeter performance issues in patients with darker skin tone.

The Open Oximetry Project, spearheaded by University of California San Francisco's Hypoxia Lab and Center for Health Equity in Surgery and Anesthesia, was formed as a collaborative initiative to tackle this issue. This group's foundational goal was to uncover why some pulse oximeters underperform in patients with darker skin tone and to develop solutions to promote equitable performance. The project has multiple facets, including (1) data collection in healthy human volunteers as well as critically ill patients; (2) data sharing through an open-source data repository and open-access website (OpenOximetry.org) providing device performance data; (3) communication of best practices with health care providers, and convening a collaborative community of stakeholders from around the world (Figure 1). The Open Oximetry Collaborative Community is one of 18 entities formally recognized by the United States (US) Food and Drug Administration (FDA) (https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-health-care-challengestogether) that brings together clinicians, engineers, researchers, device manufacturers, regulatory agencies, and patient safety advocates, including the Anesthesia Patient Safety Foundation (APSF). This is to prevent duplication of efforts, to share knowledge, and to accelerate progress towards more equitable standards and guidelines that will serve the full spectrum of patients worldwide.

EDUCATION

One initiative that has been undertaken by the OpenOximetry.org Collaborative Community is the creation of educational content to



Figure 1: Key facets of the Open Oximetry Project are shown in the infographic wheel, including clinical and lab studies, new techniques, standards, open data sharing, and global collaboration to improve access to accurate oximeters. Reproduced with permission from the Open Oximetry Project. Available at: <u>OpenOximetry.org/about.</u>

inform clinicians on how to optimize pulse oximeter use and to minimize health and health care disparities. Through a series of online stakeholder meetings and asynchronous design processes involving collaborators from numerous geographies and disciplines, the project has created a customizable infographic that outlines the best practices for pulse oximetry use. This online tool (https://openoximetry.org/infographic-builder/) allows users to download a pre-made infographic or to customize and build their own using templates created by the project team (Figure 2, next page). Users can fully customize the infographic content to address the needs and specific challenges of their institution, selecting from a range of options, each highlighting a key aspect of pulse oximetry for areater relevance to their unique context. Topics covered included "How to Place a Probe," "How to Obtain a Reliable SpO₂ Reading," "Known Limitations," "SpO $_2$ for Clinical Decisions," among others.

LABORATORY STUDIES

Another key focus of the Open Oximetry Project involves performing validation testing for pulse oximeters in the UCSF Hypoxia Lab. The Hypoxia Lab, founded by Dr. John W. Severinghaus in 1958, has been one of the leading centers for investigating the effects of hypoxia in the body as well as the discrepancies seen in the pulse oximeter's accuracy in darker skin tones. Healthy participants volunteer in controlled desaturation studies with SaO₂ plateaus between 70–100%, allowing the lab to test and compare the performance of various pulse oximeters as compared to gold standard arterial blood gas analysis. The project has focused ©2025 Anesthesia Patient Safety Foundation. All rights reserved. Reprinted with permission from Anesthesia Patient Safety Foundation. Copying, use and distribution prohibited without the express written permission of Anesthesia Patient Safety Foundation.

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Pulse Oximeters May Have Variable Performance in Patients with Darker Skin Tones

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on independently testing pulse oximeters that are representative of global markets, especially those found in low and middle-income countries.

The project has published findings for 20 devices and plans to release data on an additional 20 in the coming months (Device Update meeting). To date, these results have been mixed, demonstrating highly variable performance of devices on the market, many with positive bias in people with dark skin pigment, some with negative bias, and some without apparent bias. Of note, definitions for clinically relevant levels of bias are evolving, and the team is actively working and refining methods to optimize sample size and improve detection of biases and definitions of biases linked to skin pigment.

COLLABORATION WITH REGULATORY BODIES

The Open Oximetry Project also collaborates closely with regulatory agencies, including the US FDA and the International Organization for Standardization (ISO). The team actively shares data through their open data repositories with the intention of informing updated regulatory guidelines and standards that address disparities in device performance. The team has been working to develop and publish new protocols for pulse oximeter regulatory testing, and also is developing new protocols to ensure that diversity of skin pigment is included in research cohorts an element that has been lacking to date. We are hopeful that through this ongoing collaboration, we can contribute to the development of standards that ensure all pulse oximeters are rigorously tested and validated to be effective across all skin tones and clinical scenarios so that clinical decision-making is based upon the most reliable data.

OUR FUTURE GOALS

We are fortunate to work alongside partners like APSF, whose commitment to patient safety aligns perfectly with our mission. Together, we are pushing forward on the path toward more

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Improve the use of pulse oximetry in your health facility!

We've created a simple process to help you **build your own pulse oximetry infographic**. You can choose from preset information tiles each addressing different areas of best practice so you can prioritize issues most relevant in your setting. Follow the steps below and in seconds you will have a custom infographic to download and share. (Individual images can be downloaded here). This tool is currently in beta testing. <u>Download</u> our premade infographic



Step 1/6



Figure 2: The Infographic Builder, an online tool developed by the Open Oximetry Project allows users to create or customize infographics on best practices for pulse oximetry use, enabling health care providers to tailor the information to their specific needs and improve clinical decision-making. Reproduced with permission from the Open Oximetry Project. Available at: OpenOximetry.org/infographic-builder.

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Diversity of Skin Pigment Needs to Be Included in All Research Cohorts

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equitable health care technology and greater inclusiveness in patient monitoring. The work is far from over, but through continued efforts, we believe that substantial strides can be made in closing the gaps in pulse oximetry performance and ensuring that every patient receives accurate, reliable care. We plan to release performance data on an ongoing basis and are working to open a medical device development laboratory in East Africa to expand global research capacity and improve representations of diverse populations in medical device research and development. Daryl Dorsey, BS, is a medical student at the University of California, San Francisco.

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The authors have no conflicts of interest.

REFERENCES

- Fawzy A, Wu TD, Wang K, et al. Racial and ethnic discrepancy in pulse oximetry and delayed identification of treatment eligibility among patients with COVID-19. *JAMA Intern Med.* 2022;182:730–738. PMID: 35639368.
- Leeb G, Auchus I, Law T, et al. The performance of 11 fingertip pulse oximeters during hypoxemia in healthy human participants with varied, quantified skin pigment. *EBioMedicine*. 2024;102:105051. PMID: 38458110.
- Sjoding MW, Dickson RP, Iwashyna TJ, et al. Racial bias in pulse oximetry measurement. N Engl J Med. 2020;383:2477–2478. PMID: 33326721.