

# Improving access to pulse oximeters that work on all skin tones



## Skin pigmentation bias in pulse oximeters

Simple technologies like pulse oximeters offer a lifeline to those who urgently need oxygen to breathe.

From newborns in respiratory distress to children with infectious diseases like pneumonia, these noninvasive tools can alert health workers to hypoxemia—a severe lack of oxygen—and help assess the need for oxygen therapy.

Yet, pulse oximeters are often not available in low-resource settings, suited for children who need them most, or perform accurately on darker skin tones.

**Growing evidence suggests that pulse oximeters can overestimate oxygen saturation in the blood of patients with darker skin pigmentation—leading to delayed or inadequate medical treatment, often with tragic consequences.**

- A [2020 study](#) (Sjoding et al.) found that patients who identified their race as Black were three times more likely than those who identified as White to have low oxygen levels that were missed by pulse oximeters.
- A [2022 study](#) (Henry et al.) found that the disparity in hypoxemia detection in patients with darker skin was associated with increased death.

## Barriers to access

The root causes of pulse oximeter inaccuracy in darker skin pigmentation are not fully understood.

### **Challenges in the design**

Pulse oximeters that use photoplethysmography (PPG) technology to estimate oxygen saturation (SpO<sub>2</sub>) in the blood<sup>1</sup> are not designed or tested to ensure satisfactory performance on dark skin tones.

Most pulse oximeters have been calibrated using individuals with low-melanin pigmentation, which means that the algorithms for device performance validation may not be not accurate for people with dark skin tones.

### **Limited guidelines, regulations, and standards**

At the same time, there are insufficient guidelines, regulations, and standards for device performance on individuals with darker skin pigmentation.

There is no clear global guidance—or adequate performance data available—to help countries choose the best devices for their populations.

So far, regulatory bodies such as the International Organization for Standardization, the United States Food and Drug Administration, and the United Kingdom Medicines and Healthcare products Regulatory Agency are working on this issue<sup>2</sup> but more needs to be done.

**With the increasing availability of low-cost pulse oximeters on the market, it is vital to identify the most appropriate technology to ensure *all* patients, regardless of skin tone, are accurately diagnosed.**

<sup>1</sup> PPG technology is used to measure the optical signals between the blood and surrounding tissue, eliminating the need for invasive arterial blood samples.

<sup>2</sup> The US FDA is gathering feedback ahead of a [public meeting in February 2024](#).

## A gateway to oxygen access for all children

**PATH's Tools for Integrated Management of Childhood Illness (TIMCI)** project aims to ensure affordable and appropriate tools to help health care workers identify critically ill children and refer them for treatment without delay.

Understanding the challenges associated with pulse oximeters on dark skin tones—and making this evidence available to everyone—is vital to ensuring access to appropriate devices that work on all skin tones.

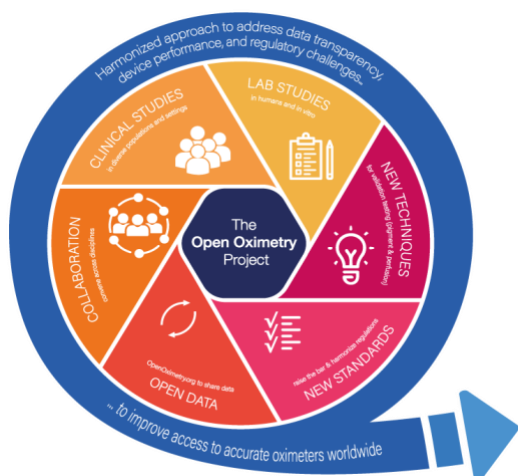
## The right technology for the right population

PATH, through its TIMCI initiative and with support from Unitaid, has partnered with the University of California San Francisco (UCSF) **Open Oximetry Project** to improve access to appropriate and accurate pulse oximeters for every patient, regardless of skin tone.

The interventions include:

- + **Testing and analysis to identify the root causes** of pulse oximeter inaccuracies.
- + **Recommending updates to testing processes, regulations, and standards** to the World Health Organization (WHO), global and national regulatory and procurement agencies, and manufacturers.
- + **Providing technical assistance** to help ministries of health identify the right technology for their populations.
- + **Disseminating open-source data** to manufacturers and innovators to accelerate the development of quality devices.

**Figure.** UCSF Hypoxia Lab and UCSF Center for Health Equity in Surgery and Anesthesia's Open Oximetry Project\*.



Source: University of California San Francisco.

The project will also investigate if the root causes of skin tone inaccuracy could affect other PPG-based measurements—for example, in [next-generation \(multimodal\) pulse oximeters](#) that provide more than one clinical measurement.

## An advocacy agenda

- + **Ensure minimal performance requirements are included in technical specifications** to guide both countries and the international agencies that procure pulse oximeters. As support, the landmark WHO [Increasing Access to Medical Oxygen](#) resolution acknowledges pulse oximeters as priority medical devices in key medical equipment lists.
- + **Encourage regulatory agencies**, such as the ISO and national regulatory agencies, to update their guidance to align with the new technical specifications, including ensuring more stringent testing requirements for more accurate devices.
- + **Alert manufacturers** to the proposed changes in technical specifications and testing protocols to give them the opportunity to improve their products if deficiencies are found.
- + **Equip national governments** with the new findings to demand evidence of accurate performance on darker skin tones before they receive pulse oximeters from manufacturers or international agencies.
- + **Encourage international agencies and donors to explore innovative financing models** to ensure that any upgraded medical devices—including next-generation pulse oximeters—would be available at an affordable cost for everyone who needs them.
- + **Have health care facilities** across Africa put in place new SpO<sub>2</sub> benchmarks to ensure that medical professionals adjust for the potential for pulse oximeter inaccuracies on darker skin pigmentation.
- + **Establish a plan for a device testing center in Africa** to improve the diversity of populations used for device performance validation to ensure appropriately calibrated devices and/or algorithms for increased accuracy.

For additional information, email [timci@path.org](mailto:timci@path.org).

*\*The Open Oximetry Project is co-funded by the Gordon and Betty Moore Foundation, the Robert Wood Johnson Foundation, the Patrick J McGovern Foundation, USAID and the US FDA.*