



Pulse Oximetry: A Vital Tool with Important Functional Limitations for Patients with Dark Skin Color

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Abstract

Pulse oximeters measure SpO_2 (percent oxygen saturation of hemoglobin in peripheral blood). SpO_2 estimates SaO_2 (percent oxygen saturation of hemoglobin in the arterial blood). Thus pulse oximeters are vital tools for critically ill patients. However, they have technical limitations, including reporting SpO_2 values that overestimate SaO_2 in patients with dark skin color. This review briefly traces the history of pulse oximeter development, reports the extent of this measurement bias ($SpO_2 - SaO_2 =$ measurement bias), describes the clinical importance of this measurement bias, and discusses approaches to eliminating it. Depending on the population studied, oximeter measurement bias is between 50% and 860% greater for people with dark vs. light skin color. This bias means that patients with dark skin are 75% to 200% more likely to suffer occult hypoxemia ($SaO_2 < 88\%$ with concurrent $SpO_2 \geq 88\%$) compared to light skinned patients. Occult hypoxemia is associated with between 40% and 196% increased risk of in-hospital mortality. Because the extent of oximeter measurement bias increases as SpO_2 decreases, no one adjustment of SpO_2 readings will address this issue. Improvements in the algorithms oximeters use to determine SpO_2 values based on larger samples of subjects with a greater range of skin colors and/or improved hardware is needed. Nurses should be aware how skin color impacts oximeter measurement bias and can advocate for the adoption of the most accurate oximeters by their institutions.

Keywords: Pulse Oximeter, Race, Skin Color, Occult Hypoxemia.

INTRODUCTION

Pulse oximeters are devices that attach to an extremity (usually a finger in adults but other locations in small children)^{1,2} to measure the SpO_2 (percent oxygen saturation of hemoglobin in peripheral blood).³ SpO_2 is an estimate of SaO_2 (percent oxygen saturation of hemoglobin in the arterial blood).^{4,5} However, measurement of the SpO_2 is an attractive alternative to the determination of SaO_2 in clinical settings because pulse oximeters are non-invasive and provide continuous readouts whereas direct calculation of SaO_2 requires collection of arterial blood.⁵ Given the crucial importance of adequate oxygenation (and the avoidance of hypoxemia – low blood oxygen level) for life, the central role of the pulse oximeter has been recognized for decades and cannot be overstated.^{4,6,7}

Pulse oximeters are now ubiquitous for home use and in acute care settings including emergency departments, operating theaters, post anesthesia units, intensive care units (ICUs), and other acute care units where they are used to monitor both adults and pediatric patients.⁸⁻¹⁶ They are probably the second-most commonly used medical device worldwide (after the thermometer),¹⁷ provide important information for clinical decision making,¹⁸ and are included in the Standards for Basic Anesthetic Monitoring.¹⁹

While they have certainly proven their importance, as is

the case for any measurement device, pulse oximeters have technical limitations. Patients' skin characteristics, including natural skin color and applied coloring agents (henna and nail polish), all of which absorb light, can impact pulse oximeter readings.³ Findings that pulse oximeters more frequently report SpO_2 readings that overestimate SaO_2 for patients with darker skin, thereby possibly leaving hypoxemia unrecognized,^{11,12,14,20,21} have gained increasing scrutiny in the past several years as the Black Lives Matter movement has prompted a reckoning with institutional racism in healthcare^{22,23} and pulse oximeter readings have become vital tools in clinical decision-making for patients with COVID-19.^{15,16,18}

This narrative review briefly describes the history and technical function of pulse oximeters. It then explores the impact of patient skin color on the difference between SpO_2 values measured by pulse oximetry and the "gold standard" of SaO_2 values determined by arterial blood gas analysis ($SpO_2 - SaO_2 =$ oximeter measurement bias)^{20,24,25} and focusses on the clinical relevance of these differences. Because nurses routinely interpret SpO_2 readings from patients, this information is directly applicable to the practice of nurses in a range of practice settings. Finally, this review discusses how the healthcare system could (and should) address pulse oximeter measurement bias. This discussion will prepare nurses to participate fully in current efforts to eliminate (or

at least reduce) the clinical impact of oximeter measurement bias from skin color and effectively advocate for individual patients and patient populations.

MATERIALS AND METHODS

References were identified through searches of Google Scholar and MEDLINE (PubMed) using the terms “pulse oximeter” and “SpO₂” combined with “race”, “skin color”, and “measurement bias”. Additional references were identified from the bibliographies of the articles found in these searches. A total of 128 English language articles concerning human subjects were reviewed and 47 chosen for inclusion in this publication. Priority was given to articles of historical interest and to clinical studies published since 2020. In this review all reported measurement differences were statistically significant unless otherwise noted.

RESULTS

History & technical function of pulse oximetry: Pulse oximeters contain two light emitting diodes, one that emits red and one that emits infrared light, positioned on one side of an extremity and sensors for both light frequencies on the opposite side of the extremity. The sensors detect the light that is transmitted through the extremity without being absorbed. Deoxygenated hemoglobin transmits infrared light more readily while oxygenated hemoglobin transmits red light more readily.^{6,7,26}

Pulse oximetry, in its current form, was invented in 1974 by the Japanese electrical engineer Takuo Aoyagi.²⁷ Aoyagi was working on a method to measure blood dye concentrations with an ear oximeter to determine cardiac output by dye dilution (this was before wide dissemination of thermal dilution measurement of cardiac output with a pulmonary artery catheter) when he noted the pulsatile nature of light signals that had passed through living tissue. Aoyagi knew that these pulsations resulted from arterial blood flow into the capillary beds following cardiac systole.²⁶ He realized that measurements of light transmission at two wavelengths (one that was transmitted more readily by deoxygenated hemoglobin and another that was transmitted more readily by oxygenated hemoglobin) could be used to determine the percent oxygen saturation in the arterial blood if the two light signals at the peak of the pulsations (when the capillary beds were filled primarily with arterial blood) were compared to the signals at the trough of the pulsations (when the capillaries contain a mixture of arterial, capillary, and venous blood).⁴

If the light emitted by pulse oximeters passed only through blood, SpO₂ could be calculated with high accuracy using the Lambert-Beer law (the light absorbed by a substance in solution is directly proportional to the concentration of that substance in the solution). However, because they are noninvasive, pulse oximeter light needs to pass through various tissues, including skin, that scatter and absorb the

light.^{4,28} This necessitates the use of empirical algorithms to determine SpO₂ from oximeter signals.⁶ These algorithms vary among oximeters because different manufacturers use slightly different light wave lengths.⁴

The presence of cyanosis can indicate hypoxemia. However, because cyanosis observed by a healthcare provider has notoriously low sensitivity and high variability among reporters as a tool for detecting hypoxemia^{4,17}, the importance of this technology to the care of critically ill patients was quickly recognized. In 1986 John Severinghaus (the pioneer of blood gas analysis) referred to pulse oximetry as “arguably the most significant technological advance ever made in monitoring the well-being of patients during anesthesia, recovery, and critical care”.⁶ In 1995, pulse oximetry was called “arguably the greatest advance in patient monitoring since electrocardiography”.⁷

When pulse oximeters were developed, clinicians hoped that the measurement of light transmission at two wavelengths would eliminate the impact of patient-to-patient variation in other tissue characteristics, including skin color, on SpO₂ readings.^{4,6,26} However, device testing and algorithm development for pulse oximeters was historically done primarily with “light skinned” study subjects^{20,21,29} and the impact of skin color on pulse oximeter readings soon became evident. A 1990 study of 54 ventilated adult intensive care unit (ICU) patients found a higher average oximeter measurement bias (3.3%) for Black patients compared to a bias of 2.2% for White patients. Bias > 4% occurred in 27% of Black patients but 11% of White patients. Interestingly, for all patients studied, the average oximeter measurement bias was 1.7% when the SaO₂ was > 90% but rose to 5.1% when the SaO₂ was ≤ 90%.²⁹

Over the course of the following two decades, further evidence accumulated that: 1) pulse oximeters often have a larger positive (> 0) measurement bias for patients with dark skin color than for those with light skin color, 2) oximeter measurement bias tends to increase at lower SaO₂ levels, and 3) measurement bias varies across pulse oximeter brands. In the mid-2000s, experimental work with healthy subjects of different skin colors controlled SaO₂ by having subjects breathe an air-nitrogen-carbon dioxide mixture. At SaO₂ levels of 60-70% the average oximeter measurement bias was 3.56% for subjects with dark skin and 0.37% for those with light skin. At SaO₂ levels of 90-100% the bias was -0.18 for subjects with light skin and 0.17 for those with dark skin.²⁰ Follow up experiments using the same technique found qualitatively similar results with patients grouped by 3 skin colors (dark, light, and intermediate).²¹ Both of these studies also reported that the extent of measurement bias varied across three oximeter brands, a finding that supported earlier work with a larger number of oximeters.³⁰ (Note that measurement bias > 0 indicates SpO₂ > SaO₂ and bias < 0 indicates SpO₂ < SaO₂.)

Not all studies from this period found an impact of skin color on oximeter measurement bias. An observational study of 298 emergency department patients who received blood gas analysis while on pulse oximeters found no greater measurement bias for patients with dark vs. light vs. intermediate skin color. However, the median SpO₂ in this study was 95% while the median SaO₂ was 93%, levels that may have been too high to demonstrate differential measurement bias by skin color, and 32% of oximeter readings in patients with dark skin were deemed technically “suboptimal”.³¹

Occult hypoxemia and skin color: Current studies focus on the concern that oximeter measurement bias may cause occult hypoxemia (SaO₂ < 88% with concurrent SpO₂ ≥ 88%) with greater frequency in patients with dark skin. One such study gathered retrospective data (including race) from electronic databases on 39,186 patients admitted to intensive care in 80 centers between January 2020 and April 2024. Each patient’s initial SaO₂ reading was compared to their closest SpO₂ reading in the preceding 10 minutes. Twenty-one percent of Black patients and 13% of White patients with SpO₂ readings between 88-92% had occult hypoxemia. The risk of occult hypoxemia decreased at higher SpO₂ readings. However, even for patients with initial SaO₂ readings between 97-100%, 5% of Black but only 3% of White patients had occult hypoxemia.¹¹

Another multi-center study of 48,097 patients admitted to intensive care and other wards analyzed paired SpO₂-SaO₂ measurements from patients with SpO₂ readings in the 92-96% range being cared for in ICUs or receiving supplemental oxygen. Occult hypoxemia occurred in 11.4% of measurements from Black patients and 3.6% from White patients after adjusting for other demographic factors and comorbidities. (Race was self-identified.)⁸

Qualitatively similar results were obtained from analysis of 5,557 paired SpO₂-SaO₂ measurements (92%<SpO₂<96%) from mechanically ventilated patients in the medical ICU of a large center. In a multi-variable analysis with race extracted from the hospital database, 1.1% of the paired readings from White patients but 3.6% of the readings from Black patients showed occult hypoxemia. Interestingly, occult hyperoxemia (PaO₂>150 mm Hg) was identified in 4.7% of readings from Black patients and 2.4% of the readings from White patients.³² A greater risk of occult hypoxemia was also found among Black non-ICU inpatients in Veterans Health Administration hospitals. Occult hypoxemia occurred in 15.6% of the SpO₂-SaO₂ measurement pairs (SpO₂>92%) from White patients and 19.6% of the pairs from Black patients. (Race identified from the hospital database.)¹⁶

Occult hypoxemia and COVID-19: The COVID-19 pandemic has further highlighted the importance of accurate SpO₂ measurements. The World Health Organization recommends the use of SpO₂ values to define the severity of COVID-19

pneumonitis and to determine the need for treatments including supplemental oxygen,¹⁸ and many centers target the use of approved medications including remdesivir and dexamethasone toward COVID-19 patients based on SpO₂ values.¹⁵ For patients with COVID-19, age 66 years or older, who were admitted to an acute care hospital in New York City early in the pandemic, prehospital SpO₂ values (determined by Emergency Medical Services personnel) also predicted mortality risk and were thus important for triage. Patients with prehospital SpO₂ values > 90% had a 26% mortality rate but this grew to 54% for those with SpO₂ ≤ 90%.⁹

The potential impact of race/ethnicity on risk stratification and clinical decision making is demonstrated by the finding that paired SpO₂-SaO₂ values from 1,216 inpatients with COVID-19 showed occult hypoxemia in 3.7%, 3.7%, 2.8%, and 1.7% of readings from Asian, Black, non-Black Hispanic, and White patients respectively. (Race/ ethnicity was self-reported.) Because many patients had multiple pairs of measurements, this meant that occult hypoxemia occurred at least once in 30.2%, 28.5%, 29.8%, and 17.2% of Asian, Black, non-Black Hispanic, and White patients respectively.¹⁵ Not all studies have found this impact of race/ ethnicity on oximeter measurement bias among COVID-19 patients. A smaller study of 194 inpatients receiving supplemental oxygen found no differences in oximeter measurement bias by race.⁵ However this result could reflect the small sample size or the fact that each racial/ ethnic group was compared to the entire sample and not to the other groups.³³

Occult hypoxemia among pediatric patients: Premature infants are a population for whom pulse oximeter measurement bias could have a particularly deleterious impact because their blood oxygenation must be maintained within a narrow range of values to avoid the negative impacts of both hyper and hypoxemia.¹³ A total of 4,387 SpO₂-SaO₂ measurement pairs from 294 premature infants (gestational age < 32 weeks, birth weight < 1500 gms) in a neonatal intensive care unit were linked to the patients’ race (White or Black – other racial/ ethnic groups represented in numbers too low to allow analysis) from the birth certificate or parental identification. Occult hypoxemia (defined in this study as SaO₂ < 85% with matched SpO₂ ≥ 90%) was identified in 9.2% of measurement pairs from Black infants but 7.7% of measurement pairs from White infants, although this difference was not statistically significant.¹³ Another study of 9,023 SpO₂-SaO₂ measurement pairs from 1,061 pediatric inpatients ≤ 17 years of age who had at least one blood gas analysis found, in multivariable analysis, that measurements from Black patients were over twice as likely to indicate occult hypoxemia compared to those from White patients. (Race self-identified or identified by parents.)¹²

Occult hypoxemia, and clinical outcomes: The higher oximeter measurement bias and rates of occult hypoxemia among patients with darker skin color have important clinical implications. A retrospective study of 3,069 ICU patients not

receiving mechanical ventilation in a large medical center explored the correlations among SpO_2 , SaO_2 , supplemental oxygen administration, and race. In multivariable analysis which controlled for other demographic and clinical factors, Black, Asian, and Hispanic patients (race/ ethnicity obtained from the hospital database) each had lower SaO_2 levels for any SpO_2 value compared to White patients. The Black, Asian, and Hispanic patients also received a median level of supplemental oxygen that was 0.2 – 0.3 L/min less than that received by White patients. When oximeter measurement bias was added as a variable in the analysis, there were no longer differences in supplemental oxygen delivery by race.¹⁴ This study speaks only to correlation, and not to causation. However, the most obvious interpretation of these data is that higher positive oximeter measurement bias for patients with darker skin color may have left hypoxemia unrecognized and led to lower levels of supplemental oxygen administration.

Another retrospective study using the database of a large medical center, but with patients who had COVID-19, also found higher rates of occult hypoxemia among Black, Asian, and non-Black Hispanic patients than among White patients as described above.¹⁵ To determine the clinical significance of this occult hypoxemia, a further analysis was undertaken of 1,903 patients whose SpO_2 levels had not fallen below 94% and thus were not receiving oxygen but had $\text{SaO}_2 < 94\%$. (SaO_2 values were predicted from the fit of all SpO_2 - SaO_2 measurement pairs for each racial/ ethnic group.) Because $\text{SaO}_2 < 94\%$ was the threshold for supplemental oxygen administration, needed oxygen treatment would have been delayed for these patients. Compared to White patients, Black patients were 29% less likely to be recognized as eligible for oxygen treatment and non-Black Hispanic patients were 23% less likely. The risk of having oxygen eligibility unrecognized was not different between Asian and White patients.¹⁵

Two additional retrospective multicenter studies have found that occult hypoxemia is a risk for organ dysfunction and even in-hospital mortality. One study examined initial SpO_2 - SaO_2 measurement pairs with $\text{SpO}_2 \geq 88\%$ among 87,971 ICU patients. Occult hypoxemia was defined as $\text{SpO}_2 \geq 88\%$ with paired $\text{SaO}_2 < 88\%$. More Black patients (6.9%) and Hispanic patients (6.4%) experienced occult hypoxemia compared to 4.9% of White and Asian patients. (Race was identified from the hospital database.) Black patients also had higher SaO_2 variability for any SpO_2 than White patients. Sequential organ failure assessment (SOFA) scores differed only slightly for patients with vs. without occult hypoxemia at the time of the initial SaO_2 measurement. SOFA scores for White patients with and without occult hypoxemia averaged 5.27 and 5.22 respectively while those for Black patients averaged 4.98 and 5.26. However, 24 hours later, SOFA scores for patients with vs. without occult hypoxemia had diverged, averaging 7.2 vs. 6.3 for White patients and 8.2 vs. 7.3 for Black patients. The patients with occult hypoxemia also had higher in-hospital mortality rates compared to those without occult hypoxemia.

The authors note that, while these results do not address causality (it is possible that occult hypoxemia indicated more severe disease and thus explains the poor clinical outcomes) it is also possible that the occult hypoxemia, particularly if prolonged, contribute to the subsequent organ dysfunction and death.³⁴

A second study exploring links between occult hypoxemia and mortality examined 128,285 paired SpO_2 - SaO_2 measurements from 26,603 patients age ≥ 18 years in an ICU or during surgery. After adjusting for demographic and clinical factors, Black patients had a 65% higher risk of occult hypoxemia than White patients. (Occult hypoxemia risks for Asian and “American Indian” patients were not significantly different than for White patients.) Occult hypoxemia was associated with a 2.96 fold increased in-hospital mortality risk for patients during surgery and 1.36 for ICU patients.³⁵

DISCUSSION

Calls to address pulse oximeter measurement bias: Calls to address differential pulse oximeter measurement bias by race have come from within and outside the healthcare system. Several recent articles have suggested that manufacturers of pulse oximeters should test their devices with a sufficiently large sample of subjects to increase study power and specifically demonstrate that their devices perform adequately in patients with dark skin color, rather than only reporting aggregate data across all study subjects.^{36,37} A 2021 opinion piece in *The Lancet Respiratory Medicine* put it bluntly: “The differential inaccuracy of pulse oximetry is an example of systemic racism in health-care delivery that has not been addressed despite decades of evidence.”²³

In early 2021 three US Senators formally requested that the Food and Drug Administration (FDA) answer a set of questions about how the agency understands and is addressing this issue.³⁸ Shortly thereafter, the FDA issued a safety communication³⁹ and convened an advisory committee meeting to formulate a response. The committee report, published in 2022, discussed techniques for the determination of skin color for use in the assessment of oximeter measurement bias and recommended that future studies of pulse oximeter function include a larger number of study subjects and subjects with a wide range of skin colors.⁴⁰ While these recommendations are welcome, they do not address the immediate issue of differential pulse oximeter measurement bias by skin color.

Proposed approaches to address pulse oximeter measurement bias: The simplest response to the problem of differential oximeter measurement bias by race/ ethnicity would be for practitioners to make a point of service adjustment to oximeter readings for patients belonging to a race other than White. This approach has been called “--- the least bad approach in the immediate short term until a concrete solution is found”⁴¹ but it is inadequate for several reasons.

Oximeter measurement bias increases as SpO₂ decreases for patients of all races/ethnicities and is larger for patients with dark skin.^{8,11,29,42,43} Consequently, no one correction factor will eliminate this race-based bias and any correction factor that decreases false negative occult hypoxemia readings in patients with dark skin will increase false positive readings, potentially leading to unnecessary invasive SaO₂ testing.^{24,34} Furthermore, because melanin absorbs and scatters light, not just the size of oximeter measurement bias but the variability in the measurements is greater for patients with darker skin.^{16,32,42} Both the precision and the accuracy of pulse oximeters are lower for patients with dark skin, and both must be addressed to achieve racial parity in oximeter performance.²⁴

Another possible response to racial disparities in pulse oximeter performance is the development of new algorithms that perform adequately regardless of skin color for the estimation of SpO₂ by currently available pulse oximeters. This idea is not new,²⁹ however it requires that manufacturers undertake additional studies with larger numbers of people with a wide range of skin colors and demonstrate that their algorithms perform equally well for subgroups of people with different skin colors.^{23,43} This process has already begun for at least one oximeter brand,⁴⁴ but given the fraught history of racial categorization in the US, actual skin color tracks imperfectly with race and it is skin color rather than race that must be addressed by these new algorithms.^{24,45}

The market for pulse oximeters is huge. It was estimated at \$2.2 billion annually worldwide in 2021 and is expected to grow to \$3.4 billion by 2028. North America accounts for 49% of this amount and >80% of the money spent on pulse oximeters comes from hospitals.⁴⁶ Work from the 2000s demonstrate that some pulse oximeters have more measurement bias by skin color than others.^{20,21} This places hospitals in a position to push pulse oximeter manufacturers to improve their hardware to reduce, if not eliminate, race-based measurement bias from their devices by only purchasing oximeters with the best performance.^{16,25,37} There are also new technologies under development or testing that may eventually lead to improved pulse oximeter function but a total replacement of existing pulse oximeters would be very expensive and interim approaches to mitigate reduce potential harm to patients with dark skin may be necessary.^{25,47}

Ultimately, the problem of differential pulse oximeter measurement bias by race will be solved when the FDA approves only devices free of this bias. This approach has been advocated²³ but is unlikely to occur immediately due to cost considerations. Practitioners, including nurses, who use pulse oximeters are positioned to educate other healthcare professionals and patients about pulse oximeter measurement bias by skin color and to advocate in their institutions for the adoption of devices that minimize this problem.^{25,37}

CONCLUSION

This review found that: 1) Pulse oximeter measurement bias exists for patients of all skin colors, particularly at lower SpO₂ levels, but is greater for patients with dark skin than for those with light skin. 2) This differential measurement bias causes increased risk of occult hypoxemia in patients with dark skin. 3) Occult hypoxemia is associated with increased risk of delayed treatments and poor clinical outcomes including organ failure and in-hospital mortality.

A single point of service adjustment in SpO₂ readings from patients with darker skin will not be sufficient to address this problem. Additional testing of existing hardware with large and diverse study populations, reworking of the algorithms pulse oximeters use to determine SpO₂ readings, and/or improved hardware will be necessary. Hospitals control a sufficiently large part of the pulse oximeter market to demand these changes and nurses have an important role in advocating for hospitals making the purchase of pulse oximeters that do not have a measurement bias by skin color a priority.

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