Differential Pulse Oximeter Accuracy, Occult Hypoxemia Prevalence, and Clinical Outcomes by Patient Race/Ethnicity

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PREFACE

The VA Evidence Synthesis Program (ESP) was established in 2007 to conduct timely, rigorous, and independent systematic reviews to support VA clinicians, program leadership, and policymakers improve the health of Veterans. ESP reviews have been used to develop evidence-informed clinical policies, practice guidelines, and performance measures; to guide implementation of programs and services that improve Veterans' health and wellbeing; and to set the direction of research to close important evidence gaps. Four ESP Centers are located across the US. Centers are led by recognized experts in evidence synthesis, often with roles as practicing VA clinicians. The Coordinating Center, located in Portland, Oregon, manages program operations, ensures methodological consistency and quality of products, engages with stakeholders, and addresses urgent evidence synthesis needs.

Nominations of review topics are solicited several times each year and submitted via the <u>ESP website</u>. Topics are selected based on the availability of relevant evidence and the likelihood that a review on the topic would be feasible and have broad utility across the VA system. If selected, topics are refined with input from Operational Partners (below), ESP staff, and additional subject matter experts. Draft ESP reviews undergo external peer review to ensure they are methodologically sound, unbiased, and include all important evidence on the topic. Peer reviewers must disclose any relevant financial or non-financial conflicts of interest. In seeking broad expertise and perspectives during review development, conflicting viewpoints are common and often result in productive scientific discourse that improves the relevance and rigor of the review. The ESP works to balance divergent views and to manage or mitigate potential conflicts of interest.

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Operational Partners

Operational partners are system-level stakeholders who help ensure relevance of the review topic to the VA, contribute to the development of and approve final project scope and timeframe for completion, provide feedback on the draft report, and provide consultation on strategies for dissemination of the report to the field and relevant groups.

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Disclosures

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The findings and conclusions in this document are those of the author(s) who are responsible for its contents and do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. The final research questions, methodology, and/or conclusions may not necessarily represent the views of contributing operational and content experts. No investigators have affiliations or financial involvement (*eg*, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.

Executive Summary

Evidence Synthesis Program

KEY FINDINGS

- Pulse oximeters likely overestimate Black patients' blood oxygen saturation level (moderate strength of evidence), though recent studies in contemporary hospital and health system settings suggest that modern pulse oximeters possess some degree of bias and considerable imprecision regardless of patient race/ethnicity.
- Occult hypoxemia is likely more common among Black patients compared with White patients (*moderate strength of evidence*). Asian, Latino or Hispanic, Native American or Indigenous, or other or mixed race/ethnicity patients may also experience occult hypoxemia more frequently than White patients (*low strength of evidence*).
- Evidence is insufficient to draw conclusions about clinical outcomes attributable to race/ethnicity biases in occult hypoxemia, but available studies provide suggestive evidence that Black patients with undetected hypoxemia could experience poorer treatment delivery and clinical outcomes than White patients with undetected hypoxemia.
- Clinicians should be aware of the risk for occult hypoxemia in patients with darker skin pigmentation. Evidence from hospital and health system settings relevant to the VA also suggests that the amount of bias in pulse oximeter readings could vary substantially from patient to patient regardless of their race/ethnicity.

Pulse oximeters are used in many clinical settings and provide a rapid and noninvasive means of measuring oxygen saturation. Despite this utility, pulse oximeters may over- or underestimate a patient's arterial oxygen saturation (SaO₂). Overestimating oxygen saturation is especially concerning when pulse oximeter readings of peripheral oxygen saturation (SpO₂) indicate a normal blood oxygen level while a patient is actually in a hypoxemic state—a situation known as *occult hypoxemia*. Potential clinical impacts of occult or undetected hypoxemia include delayed or inadequate treatment, premature treatment de-escalation or discharge, and ultimately, greater morbidity and mortality.

Inaccurate pulse oximeter readings can occur for a variety of reasons, including severe anemia, excessive blood carbon monoxide levels, impaired circulation (hypoperfusion), and patient movement. Because pulse oximeters rely on the transmission of light through the skin to estimate SaO₂, skin pigmentation level may also influence pulse oximeter accuracy. Differences in pulse oximeter accuracy by patient race/ethnicity have been observed in clinical settings for several decades, but the COVID-19 pandemic has heightened concern that pulse oximeters may routinely be less accurate in patients with darker skin pigmentation.

The COVID-19 pandemic has also drawn attention to whether racial or ethnic minority patients are at greater risk of occult hypoxemia due to pulse oximeter inaccuracy. A widely discussed retrospective study published in late 2020 analyzed nearly 50,000 paired SpO₂–SaO₂ measurements, finding that the prevalence of occult hypoxemia was over 3 times greater among Black or African American ("Black") patients compared with White patients (11.4% versus 3.4%). Additional studies reporting occult hypoxemia prevalence by patient race or ethnicity have since been published. Most utilize large health system databases and also report data on pulse oximeter accuracy, which goes some way to addressing the sparsity of accuracy data in racial and ethnic minority patients in the pre-COVID-19 literature.

The aim of the present review was to provide an up-to-date synthesis of evidence on racial and ethnic disparities in the accuracy of pulse oximeters, the prevalence of occult hypoxemia, and clinical outcomes associated with occult hypoxemia. This review was developed in response to a request from the Veterans Health Administration (VHA) National Hospital Medicine Program and Office of Specialty Care Services.

CURRENT REVIEW

Thirty-four primary studies and 1 existing systematic review and meta-analysis on pulse oximeter accuracy met eligibility criteria. Eighteen studies were included in the identified systematic review, which together provided 21,269 paired oximetry observations from 3,176 patients. We located 4 recent observational studies that reported pulse oximeter accuracy data in sufficient detail for meta-analyses; together these studies contribute 241,680 new paired observations in 102,841 patients. We also identified 11 observational studies that reported occult hypoxemia prevalence and 4 studies that examined the association between occult hypoxemia and clinical outcomes by patient race/ethnicity. Most newly identified studies used data from patients receiving acute care in academic or community hospitals or health systems.

In Black patients, pulse oximeters appear to overestimate blood oxygen saturation by an average of 1.5% compared with CO-oximetry in arterial blood (pooled mean bias = 1.54, 95% CI [0.99, 2.10]), based on 37,562 paired observations in 14,626 patients. Mean bias among Black patients was considerably larger than among White patients (0.62, 95% CI [-0.08, 1.32]; N_{Obs} = 154,286) or patients identifying as Asian, Latino or Hispanic, Native American or Indigenous, or other or mixed race/ethnicity (0.31, 95% CI [0.09, 0.54]; N_{Obs} = 71,101). Precision of pulse oximeter readings was comparable across race/ethnicity groups, with pooled standard deviations (SDs) from 1.61 to 1.98.

In recent studies that contribute most available oximetry data, mean bias was larger in all race/ethnicity groups compared with earlier evidence. The most substantial increase from older studies was among Asian, Latino or Hispanic, Native American or Indigenous, or other or mixed race/ethnicity patients (from 0.31% to 1.41%). Precision estimates were comparable across groups but considerably larger than in earlier studies (pooled SDs from 4.30 to 5.23), indicating greater variability in bias between patients. The calculated accuracy root mean square error (A_{RMS}) for all accuracy data was 1.64 for Black patients, 0.78 for White patients, and 0.75 for Asian, Latino or Hispanic, Native American or Indigenous, or other or mixed race/ethnicity patients. A_{RMS} values in newly identified studies were 2.57, 1.83, and 2.03, respectively.

The pooled prevalence of occult hypoxemia was highest among Black patients (11.4%, 95% CI [4.6, 25.5]; N = 34,869) and Asian, Latino or Hispanic, Native American or Indigenous, or other or mixed race/ethnicity patients (9.7%, 95% CI [3.2, 26.1]; N = 25,130), compared with White patients (6.5%, 95% CI [2.8, 14.2]; N = 109,286). Corresponding prevalence ratios (PRs) are shown in the figure below. Compared with White patients, the prevalence of occult hypoxemia was 71% greater among Black patients (pooled PR = 1.71, 95% CI [1.43, 2.06]) and 42% greater among Asian, Latino or Hispanic, Native American or Indigenous, or other or mixed race/ethnicity patients (pooled PR = 1.42, 95% CI [1.10, 1.84]). For Black patients, an even larger disparity was apparent at the observation level (pooled PR = 2.04, 95% CI [1.64, 2.54]; *Nobs* = 76,177). Similarly, in several studies that reported odds of occult hypoxemia adjusted for potential confounders, Black patients had twice the odds of occult hypoxemia compared with White patients (95% CI [1.15, 3.41]; N = 8,410).

Group	Ν		Pooled Prevalence Ratio (95% CI)
Black			
Patients	34869		1.71 [1.43, 2.06]
Paired Observations	76177		2.04 [1.64, 2.54]
Asian, Lat./Hisp., NA/Indig			
Patients	25130	· · · · · · · · · · · · · · · · · · ·	1.42 [1.10, 1.84]
Paired Observations	89243	₽	1.33 [1.06, 1.68]
Asian			
Patients	5407	H	1.37 [0.92, 2.04]
Paired Observations	15683	•	1.38 [0.90, 2.10]
Latino/Hispanic			
Patients	9142	⊢	1.49 [1.14, 1.94]
Paired Observations	33888		1.42 [1.03, 1.95]
		30% more 1 prevalent	00% (2x) more prevalent

Occult Hypoxemia Prevalence Ratios by Patient Race/Ethnicity

Notes. All prevalence ratios use White patients as the reference group, and the dashed line corresponds to a prevalence ratio of 1.0 (no difference in prevalence compared with White patients). *N* indicates the number of patients in the race/ethnicity group shown and does not include the number of White patients comprising the reference group. Patients reported as *Other race/ethnicity* are included in the group *Asian, Lat./Hisp., NA/Indig* (Asian, Latino or Hispanic, Native American or Indigenous).

One recent study used approximately 30,000 paired SpO₂–SaO₂ observations from patients treated in VHA surgical and general (non-intensive) care settings, and may provide the most applicable evidence to the VHA setting. The study found larger bias and worse precision in Black VHA patients compared with White patients, and reported occult hypoxemia prevalences that were among the highest of any included study: 19.6% for Black patients, 16.2% for Hispanic or Latino patients, and 15.6% for White patients. The difference in likelihood of occult hypoxemia between Black and White patients remained after controlling for patient sex, age, and comorbidities (p < .001). Black patients also had a higher likelihood of occult hypoxemia on their first oximetry reading taken the same day (*ie*, Black patients' probability of hypoxemia was more varied among readings than that of White patients).

Finally, we found few studies examining the association between occult hypoxemia (or differential pulse oximeter accuracy) and clinical outcomes by patient race/ethnicity, and evidence was insufficient to make firm conclusions about this relationship. Nonetheless, there does appear to be some signal that Black patients with undetected hypoxemia could experience poorer treatment delivery and clinical outcomes compared with White patients with undetected hypoxemia.

Re-assessing oxygen saturation in arterial blood more routinely, particularly in patients that show signs or symptoms of arterial hypoxemia, has been suggested as one step to reduce the risk of occult hypoxemia and subsequent harms. Another approach suggested to mitigate this risk is to raise the oxygen saturation range to 94–98%, though this may increase risk of hyperoxemia. Applying a skintone-based correction factor to readings from currently available pulse oximeters has also been discussed, but such adjustments have a controversial history and may have limited efficacy because the accuracy and reliability of pulse oximetry readings is influenced by a number of factors that cannot be accounted for in a single correction factor. A broader recommendation has been to revise guidelines for pulse oximeter validation studies, in particular to require enrolling more patients with darker skin pigmentation, testing oximeters under real-world health care conditions, and incorporating perfusion into validation requirements. At the same time, it has been acknowledged that addressing biases in pulse oximeter readings and in the care that follows from those readings requires fundamental advancements in the technologies used for routine, noninvasive oxygen saturation monitoring.

CONCLUSIONS

Pulse oximeters likely overestimate Black patients' blood oxygen saturation level, increasing the risk for unrecognized or occult hypoxemia. Occult hypoxemia occurs to some degree in all races/ethnicities but is likely more common among Black patients compared with White patients. Findings of this review underscore that clinicians should be aware of the risk of occult hypoxemia in patients with darker skin pigmentation. Moreover, while pulse oximeter readings are on average fairly similar to arterial oxygen saturation levels, evidence from hospital and health system settings relevant to the VA suggests that the amount of bias could vary substantially from patient to patient regardless of their race/ethnicity. This finding implies that incorporating conventional race or ethnicity-based correction factors into pulse oximeters would not eliminate disparities in occult hypoxemia risk. Although proposed changes to clinical practice to accommodate bias and imprecision in pulse oximeters may help to mitigate harms in the near-term, advancements in noninvasive oximeter technology are needed. As the largest integrated health system in the United States, the VHA is uniquely positioned to cultivate innovations in oximeter technology.