

## Pediatric Pulse Oximeter Accuracy

1 Pulse Oximetry Accuracy in Children with Dark Skin Tones: Relevance to Acute Lower  
2 Respiratory Infection Care in Low- and Middle-Income Countries.

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Acute lower respiratory infections (ALRI) are the leading post-neonatal cause of death in children under 5 years old. There is a high prevalence of pediatric ALRI-related hypoxemia in low- and middle-income countries. The World Health Organization defines clinically meaningful hypoxemia in children as a SpO<sub>2</sub> (peripheral oxygen saturation) < 90%. Multiple studies put this convention into question and found SpO<sub>2</sub> of 90-92% to be associated with child ALRI mortality. There is an evolving body of evidence that suggests that pulse oximeters, systematically, over-estimate oxygen saturation in individuals with dark skin tones. We conducted a narrative review of pediatric studies evaluating pulse oximeter accuracy in children without COVID-19. Four studies, one prospective, examined pulse oximeter accuracy in children of varying ages with dark skin tones. All studies had limitations that affect their generalizability. There is evidence that certain pulse oximeters may over-estimate oxygen saturation in children with dark skin tones. Further prospective research is urgently needed to identify affected populations and clinical implications. Despite recognized challenges, we strongly urge continued and expanded use of pulse oximetry as its use will save lives.

47 Globally acute lower respiratory infections (ALRI), including pneumonia and  
48 bronchiolitis, remain the number one cause of death of children under 5 years old outside of the  
49 neonatal period<sup>1</sup>. Hypoxemia is a well-recognized risk factor for ALRI mortality<sup>2</sup> that informs  
50 clinical care of severely ill patients. Pulse oximeters are portable devices that non-invasively  
51 measure the peripheral arterial oxyhemoglobin saturation (SpO<sub>2</sub>), or blood oxygen levels.  
52 Although their use is associated with reduced child pneumonia related hospital mortality<sup>3</sup>, they  
53 are inconsistently available or used within clinics and hospitals in low- and middle-income  
54 countries (LMICs).<sup>4-6</sup> A growing body of evidence suggests that pulse oximeter reported oxygen  
55 saturation (SpO<sub>2</sub>) may not precisely equate to measured arterial hemoglobin oxygen saturation  
56 (SaO<sub>2</sub>), the reference standard, with potential implications on patient outcomes. We aim to  
57 conduct a narrative review on pulse oximeter accuracy in children with dark skin tones and  
58 discuss the potential relevance in ALRI care in LMICs.

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60 *Role of Pulse Oximetry in Pediatric ALRI Care in LMICs*

61 Though pulse oximeters have not been adopted as a universal component of high quality  
62 ALRI care delivery, evidence on hypoxemia burden and the impact of oximetry on care  
63 provision and mortality indicates they should be.<sup>3</sup> A sub analysis reported in a recent metanalysis  
64 of studies exploring hypoxemia incidence in children with ALRI in LMICs estimates up to 23%  
65 of children with ALRI presenting to clinics were hypoxemic.<sup>7</sup> Hypoxemia, with a SpO<sub>2</sub> <90%,  
66 is associated with an over 5-fold increase odds for ALRI-related mortality in children under 5.<sup>2</sup>  
67 Studies from Malawi and Bangladesh suggest that a significant number of hypoxemic children  
68 would not have been referred to the hospital if clinicians relied exclusively on clinical signs for  
69 medical decision making in the absence of pulse oximetry.<sup>8,9</sup>

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70 Multiple studies report ‘moderate’ hypoxemia, defined as a SpO<sub>2</sub> of 90-92% or 90-93%,  
71 predicts pediatric ALRI-related mortality independent of severity of work of breathing, moderate  
72 or severe malnutrition, or tachypnea.<sup>2, 9-12</sup> Anemia, poor pulmonary reserve or chronic lung  
73 disease, altered affinity between hemoglobin and oxygen due to fever or acidosis, mild  
74 malnutrition, or other host or environmental factors could be unmeasured contributors to this  
75 association. The association between ‘moderate’ hypoxemia and death could also in part be  
76 explained by systematic over-estimation of SaO<sub>2</sub> by pulse oximeter measured SpO<sub>2</sub> in children  
77 with dark skin tones.

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### 79 *Pulse Oximetry Accuracy in Adults with Dark Skin Tones*

80 Pulse oximeters calculate a SpO<sub>2</sub> using proprietary algorithms that interpret changes in  
81 light diffusion as it passes through the nail, tissues, and skin of the measurement location, which  
82 is usually a finger or toe. Movement, moderate-severe anemia, nail polish, dirt, ambient light,  
83 and digit thickness can affect pulse oximeter accuracy.<sup>13</sup> Manufacturers report SpO<sub>2</sub> accuracy  
84 within +/- 2% of the reference SaO<sub>2</sub>. Triggered by discordance between pulse oximeter measured  
85 hypoxemia and clinical outcomes during the COVID-19 pandemic, several retrospective studies  
86 conducted in adults report that US Food and Drug Administration (FDA) approved pulse  
87 oximeters may systematically produce SpO<sub>2</sub> results that over-estimate SaO<sub>2</sub> in Black patients.<sup>14-</sup>  
88 <sup>17</sup>

89 Although the WHO defines hypoxemia as a SpO<sub>2</sub> <90%, studies that assess SpO<sub>2</sub> over-  
90 estimation of SaO<sub>2</sub> define occult hypoxemia as a SaO<sub>2</sub> <88% when the SpO<sub>2</sub> is >92%, however  
91 this is less stringent than FDA accuracy requirements. The first large retrospective study of  
92 adults reported an occult hypoxemia prevalence of 11.4% (95% CI 7.6-15.2%) in Black patients

93 compared to 3.6% (95% CI 2.5-4.6%) in White patients.<sup>16</sup> The study paired SpO<sub>2</sub> and SaO<sub>2</sub>  
94 measurements collected up to 10 minutes apart even though these indices change minute to  
95 minute, severely limiting the strength of these findings. A subsequent, retrospective study  
96 simultaneously paired SpO<sub>2</sub>-SaO<sub>2</sub> measurements demonstrated a more modest occult hypoxemia  
97 prevalence of 6.2% (95% CI 5.1-7.6%) amongst Black adults and a 3.6% prevalence (95% CI  
98 3.4–3.8%) amongst White adults.<sup>14</sup> This study uniquely identified associations between occult  
99 hypoxemia and longer hospital stays in surgical patients (2.5 days) and increased odds for  
100 mortality amongst surgical [adjusted odds ratio (aOR) of 2.96, 95% CI 1.20-7.28] and intensive  
101 care unit (aOR 1.36, 95% CI 1.03-1.80) patients.<sup>14</sup> A recent meta-analysis reported that measured  
102 SpO<sub>2</sub> over-estimates SaO<sub>2</sub> by 1.1% in people with darker skin pigmentation.<sup>17</sup> Based on  
103 limitations in existing studies, the FDA highlighted the need to further explore if this over-  
104 estimation occurs in people with dark skin tones and exacerbates racial health disparities.<sup>18</sup> In  
105 contrast, a meta-analysis of 32 studies reported an acceptable pooled mean SpO<sub>2</sub>-SaO<sub>2</sub> difference  
106 of (1.52%; 95% CI 0.95 to 2.09%) amongst electronic medical record (EMR) reported  
107 Black/African American patients, and the overall root mean squared error was <4%, also within  
108 acceptable limits, amongst all racial groups.<sup>17</sup> Notably, studies have not attempted to distinguish  
109 if different pulse oximeter manufacturers or probe types are more accurate than others.

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#### 111 *Pulse Oximetry Accuracy in Children with Dark Skin Tones*

112 We searched PubMed using these search terms: “pediatric, pulse oximeter, accuracy,  
113 bias.” We included only non-COVID 19 specific studies, to assure this narrative review is  
114 generalizable, that compared SpO<sub>2</sub> to arterial blood gas SaO<sub>2</sub>. Pediatric studies examining pulse  
115 oximeter performance with respect to dark skin tones are sparse, mostly retrospective, and also

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116 inconsistent (Table 1).<sup>19-22</sup> An exception was a single prospective study in infants with cyanotic  
117 congenital heart disease that classified skin hue using the Munsell Soil Color chart, an  
118 unvalidated means of skin tone classification.<sup>21</sup> It found no skin tone differences in pulse  
119 oximetry performance,<sup>21</sup> but these patients had cyanotic congenital heart disease and pulse  
120 oximeters are known to be inaccurate at a SpO<sub>2</sub> <80%.<sup>18</sup> The first large retrospective pediatric  
121 study in patients hospitalized in intensive care units [N=1061 (17.2% Black), 9023 SpO<sub>2</sub>-SaO<sub>2</sub>  
122 pairs] reported Black children had a 2.16 adjusted odds (aOR) of occult hypoxemia (defined as a  
123 SaO<sub>2</sub> <88% with a SpO<sub>2</sub> ≥92%) compared to White children.<sup>20</sup> Notably SpO<sub>2</sub>-SaO<sub>2</sub>  
124 measurements were paired within 10 minutes, rather than concurrently, and the authors did not  
125 extrapolate the effect on clinical outcomes. Another retrospective study in children undergoing  
126 cardiac catheterization reported an unadjusted difference between SpO<sub>2</sub> and SaO<sub>2</sub> of 2.58 (95%  
127 CI 2.15-3.00) in Black children compared with that of 0.89 (95% CI 0.64-1.15) in White  
128 patients.<sup>19</sup> And finally a retrospective study in preterm neonates under 32 weeks gestational age  
129 reported that there was no difference in the frequency of occult hypoxemia in Black vs White  
130 neonates.<sup>22</sup> No study to date has attempted to prospectively investigate the impact of skin tone on  
131 pulse oximeter performance or if discrepant matched SpO<sub>2</sub>-SaO<sub>2</sub> measurements impact clinical  
132 outcomes in pediatric patients.

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<b>Table 1: Pediatric Pulse Oximetry Racial and Dark Skin Tone Bias Studies (excluded COVID19 related)</b>				
Author	Ruppel <sup>19</sup>	Andrist <sup>20</sup>	Vesoulis <sup>22</sup>	Foglia <sup>21</sup>
Population	1-17 years old undergoing cardiac catheterization; frequently with CHD*	Children 17 years old or younger hospitalized in an intensive care unit	Neonates < 32 weeks gestational age <1500 grams	Infants with CHD* and baseline SpO <sub>2</sub> < 90%
Design	Retrospective Cross-sectional EMR <sup>^</sup> 2016-2021	Retrospective Cross-sectional EMR <sup>^</sup> 2015-2020	Retrospective Cross-sectional EMR <sup>^</sup> 2012-2019	Prospective Cross-sectional 2013-2015
Sample Size	774 patients (26% Black)	9023 measurements from 1061 patients (17.2% Black)	4387 measurements from 294 patients (42% Black)	36 infants (39% with dark skin tone)
Occult Hypoxemia Definition	SaO <sub>2</sub> < 88% and SpO <sub>2</sub> ≥ 92% collected within 1 minute	SaO <sub>2</sub> < 88% and SpO <sub>2</sub> ≥ 92% collected within 10 minutes	SaO <sub>2</sub> <85% and SpO <sub>2</sub> ≥ 90% collected within 1 minute	Did not report occult hypoxemia; collected simultaneously
Gas Sample Collection Site	Descending aorta, femoral artery, or systemic ventricle	Not documented	Not documented, likely included umbilical artery	Not documented
Occult Hypoxemia Frequency	5% (7/139) in Black and 1% (4/407) in White patients.	9.6% (95% CI 6.3-14.5%) in Black and 5.8% (95% CI 4.6-7.3%) in White patients.	9.2% in Black and 7.7% (p=0.08) in White patients.	Did not report occult hypoxemia
Pulse Oximeter Bias	2.58 (95% CI 2.15-3.00) in Black vs 0.89 (95% CI 0.64-1.15) White Children	3.5 (5.0) in White vs 4.3 (5.0) in Black patients (P<0.001)	1.73 in Black vs 0.72 in White infants p<0.01	Masimo Radical 7: 1.6 (4.8) in Dark vs 0.2 (3.8) in Fair infants Nellcor Oximax: 5.4 (5.1) in Dark vs 3.0 (5.0) in Fair infants

\*CHD: congenital heart disease, ^EMR: electronic medical record

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### 137 *Challenges in Interpreting Existing Studies*

138           Although compelling, retrospective studies characterizing differences in paired SpO<sub>2</sub> and  
139 SaO<sub>2</sub> measurements have limited generalizability. First, pulse oximeters may save continuous  
140 SpO<sub>2</sub> measurements, but few record plethysmography waveforms to confirm measurement  
141 accuracy making it difficult to confirm if EMR extracted SpO<sub>2</sub> measurements were accurate.  
142 Second, the time stamp of an ABG may not be precise, limiting the ability to truly pair SpO<sub>2</sub>-  
143 SaO<sub>2</sub> measurements. Many studies paired measurements collected within 5-10 minutes, which  
144 could account for the apparent discrepancies. Third, most published studies relied on race data

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145 extracted from the EMR; however there may be discordance between patient reported and EMR  
146 documented race.<sup>23</sup> Finally, the hypothesis of studies assessing SpO<sub>2</sub> over-estimation of SaO<sub>2</sub> is  
147 that skin tone, not the social construct of race, affects pulse oximeter accuracy. Race may not  
148 accurately reflect a subject's skin tone and skin tone may differ in different areas of the body. To  
149 test the hypothesis that pulse oximeter accuracy is affected by patient skin tone, subject skin tone  
150 must be measured, including at the site of measurement, and SpO<sub>2</sub>-SaO<sub>2</sub> measurements must be  
151 near simultaneously paired.

152 All of the aforementioned SpO<sub>2</sub> accuracy studies were conducted in high-income  
153 contexts, and it is notable that 90% of children who succumb to ALRI live in LMICs.<sup>24</sup> Pulse  
154 oximeters effectively designed for LMICs should be less expensive, more portable, run on  
155 batteries, have reusable probes, withstand environments with more heat and dust, and still  
156 perform accurately.<sup>25-27</sup> Pulse oximeters that don't meet these specifications may not perform  
157 well in LMIC environments. To date, no published studies have evaluated if the measured SpO<sub>2</sub>  
158 of pulse oximeters designed for LMICs is within regulatory standard accuracy (+/- 2%) of SaO<sub>2</sub>  
159 in children or when used clinically. Additionally, it is unclear how SpO<sub>2</sub> relative to SaO<sub>2</sub> may  
160 differ between different types of pulse oximeter probes and manufacturers. The COVID-19  
161 pandemic brought a rush of respiratory care supplies, including pulse oximeters, into LMICs. As  
162 the pandemic subsides these pulse oximeters presumably are being integrated into child ALRI  
163 care pathways, but it is critical that this is done judiciously. A large inaccuracy in pulse  
164 oximeters more commonly used in LMICs, particularly if healthcare workers inappropriately use  
165 hypoxemia as the sole clinical indication for hospital referral or escalation of hospital based care,  
166 could result in delayed ALRI treatment of children.

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168 Conclusions

169 Pulse oximeters, based on limited low quality data, may be inaccurate in children with dark  
170 skin tones like what has been reported in adult populations. While other explanations are  
171 plausible, an over-estimation of SaO<sub>2</sub> may be contributing to the association between a SpO<sub>2</sub> of  
172 90-93% and ALRI mortality in children living in LMICs.<sup>2, 9-12</sup> Given the different types of  
173 oxygen saturation probes available and manufacturer specific light wavelength interpretation  
174 algorithms, some oximeters are likely to be more inaccurate and biased than others. We need to  
175 understand the full magnitude and clinical implications of these inaccuracies, determine if they  
176 are across all or specific manufacturers of pulse oximeters and probes, define affected  
177 populations, and determine how other co-morbidities that affect systemic oxygen carrying  
178 capacity affect device accuracy. If a discrepancy truly exists, we must understand how it impacts  
179 individual patient outcomes in order to thoughtfully address this bias at a population level. These  
180 questions must be answered systematically and through collaborative multi-country research  
181 with studies in LMICs. To date no published studies have occurred outside of high income  
182 countries. In order to reduce further ALRI deaths it is critical that studies occur in LMICs as  
183 these countries have the greatest population of children with dark skin tones and bear the greatest  
184 child ALRI mortality burden.

185 Despite recognized challenges, we strongly urge continued and expanded use of pulse  
186 oximetry in child ALRI care as its use will save lives.<sup>28</sup> This is particularly important as the  
187 WHO Integrated Management of Childhood Illness guidance, when implemented without pulse  
188 oximetry, may not identify all hypoxemic or children at risk for ALRI related mortality as  
189 needing hospital referral. With this knowledge in hand, in the interim, health systems should  
190 continue to integrate pulse oximetry into child ALRI care while emphasizing to clinicians that

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191 hypoxemia is one of several clinical findings associated with mortality. Pulse oximeters should  
192 be used alongside other clinical information. Clinicians should interpret SpO<sub>2</sub> measurements  
193 conservatively by weighing the risk profile of patients (i.e., age, immune and nutritional status,  
194 vaccination history, co-morbidities) alongside existing hypoxemia evidence when deciding on  
195 patient management. Children with an overall clinical picture suggestive of severe pneumonia,  
196 even if their SpO<sub>2</sub> seems normal, should still be referred to care. Further, it is critically important  
197 that health systems continue to allocate resources to support incorporation of pulse-oximeters in  
198 LMICs.

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