COVID-19 highlights the need for action on pulse oximeter accuracy in people with dark skin

To the Editor: Recently published studies have highlighted concerns that pulse oximeter devices may underestimate hypoxia (overestimate oxygen saturation) in patients with dark skin. This occurs at levels where key decisions are made around supplemental oxygen and hospital admission (arterial oxygen saturation [SaO_2] 88–94%). Amid the coronavirus disease 2019 (COVID-19) pandemic, this important public health issue prompted the Therapeutic Goods Administration (TGA) to publish a medical device safety update.[1]

Long-standing concerns about reduced pulse oximeter accuracy in people with dark skin[2,3] have evolved into characterisation of significant racial discrepancies. A recent article compared 48 097 pairs of measurements by pulse oximetry and arterial blood gas (ABG) in adults receiving oxygen across 179 hospitals in the United States. Among patients saturating > 92% on pulse oximetry, hypoxaemia (ABG saturation < 88%) was nearly three times more common in black patients than in white patients. Graphs illustrate the median oxygen saturation bias for black patients was 3% in the 89–96% range.[4] A recent retrospective cohort study analysed registry SaO_2 data in 372 individuals (73.1% with COVID-19) about to undergo extracorporeal membrane oxygenation for respiratory failure. In patients with pulse oximeter readings of 92–96%, ABG oxygen saturation was < 88% in 21.5% of black patients and in 10.2% of white patients.[5] In these retrospective audits, patient ethnicity was based on hospital record identification, not skin colour. The oximetry devices used were not specified.

COVID-19 guidelines may incorporate pulse oximeter readings into decisions regarding hospital transfer of home-care patients. Clinicians and services should arguably have lower thresholds for hospital review and admission of patients with dark skin (including Indigenous Australians and those of African and South Asian descent) with borderline oxygen saturations, while balancing risks of increased ABG and invasive treatment rates.

Device manufacturers should develop pulse oximeters that perform accurately across more diverse populations. Further research must identify mechanisms of racial discrepancies in oxygen saturation and address them through device design. Calibration and testing processes for existing devices should be strengthened. The pre-market approval processes of the US Food and Drug Administration currently require that only 15% of a study population have darker skin, while Australia has no specified requirement.

The TGA does not regulate pulse oximeters sold directly to consumers (in stores or online) for general wellness or sporting purposes only. There are significant constraints on the scope for regulatory interventions for medical device pulse oximeters: this essential equipment cannot be excluded from the market or its supply compromised; mandating changes to instructions for use may have limited impact; differentiating between devices is hampered by evidence limitations and any consequent actions would be legally fraught; and mandating accuracy studies would be difficult to enforce.

Contemporary evidence demonstrates that dark skin is a risk factor for hypoxia being undetected by pulse oximetry. Clinicians should adjust treatments and guidelines accordingly and consider audits of devices used in their institutions. Failure to address this problem at a design and testing level compromises racial equity in health care outcomes.

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