

Pulse oximetry and racial bias:

Recommendations for national healthcare, regulatory and research bodies

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Summary

Pulse oximetry is a simple, cheap, and non-invasive means of testing the level of oxygen in a person's blood. In simple terms, it works by attaching a small device to a person's finger, toe, or earlobe, which then sends a beam of light through that part of the body and registers the differences between oxygenated and deoxygenated blood. Its simplicity has transformed healthcare by providing a painless way of monitoring conditions such as pneumonia, lung cancer, and anaemia; and providing an effective tool in detecting the early stages of hypoxia. The device is considered simple enough that patients have been able to self-administer the test at home during the Covid-19 pandemic.

There is a growing body of evidence, however, that pulse oximetry is less accurate in darker skinned patients.¹ Given the increased mortality amongst ethnic minority patients during the Covid-19 pandemic, it is possible that the differential accuracy of pulse oximetry is a contributing factor to this health inequality.²

This raises issues about the test itself, and more generally about the tendency for such medical devices to be developed and calibrated based on lighter skin. This rapid review examines the evidence on the accuracy of pulse oximetry in patients with pigmented skin and provides both strategic and practical recommendations to help narrow any potential health inequalities between different ethnic groups.

Background

On its introduction, the pulse oximeter was a significant development, providing a non-invasive, inexpensive means to measure oxygen saturations and enable the early detection of hypoxia. The pulse oximeter uses light to detect the amount of oxygen in the arterial blood circulating peripherally by measuring the differences in light absorption between oxygenated and deoxygenated blood. This is a less invasive measure than measuring oxygen saturation through arterial blood analysis but provides a less accurate reading. Where the pulse oximeter relies on light to produce a reading, arterial blood analysis directly measures the amount of oxygen and carbon dioxide in the blood. Where oxygen saturation is measured using a pulse oximeter, it produces an SpO₂ reading. Where it is measured through blood analysis, it produces an SaO₂ reading.

Over the years, healthcare professionals have become increasingly reliant on the pulse oximeter to inform clinical decision making when adjusting supplemental oxygen levels and to triage patients. Pulse oximeters are widely accessible and demonstrate a great ease of use. This has resulted in an increased use of pulse oximeters by members of the public during the Covid-19 pandemic in order to self-monitor their condition.

What does the evidence suggest?

There is a growing body of evidence, going back three decades, that suggest there may be drawbacks when using pulse oximetry on darker skinned patients. In as early as 1990, a study revealed discrepancies in the reliability of a target SpO₂ of 92% when comparing white and black patients receiving mechanical ventilation.³ Whilst a 92% target was suitable for white patients (n=25), a higher target of 95% was required in order to prevent significant hypoxaemia associated with this target in black patients (n=29). In addition, inaccurate pulse oximetry readings were more than two times more common in black patients than white patients.

Further trials revealed significant skin pigment-related differences when testing three different models of pulse oximeters (Nellcor Inc., Novamatrix Inc. and Nonin Inc.) and consistently identified overestimated SpO₂ during hypoxia in dark-skinned individuals (n=11).^{4,5}

A more recent study conducted in 2020, at the University of Michigan Hospital compared measures of oxygen saturation by pulse oximetry and arterial blood gas samples from adult inpatients receiving supplemental oxygen.⁶ The sample consisted of white patients (n=1333) and black patients (n=276) and revealed that of the patients who had an SpO₂ reading between 92% and 96%, black patients were three times more likely (11.7%) to have an arterial oxygen saturation of less than 88% than white patients (3.6%).

Whilst the above-mentioned element of the study has great relevance to the Covid-19 pandemic, the study also collated and analysed retrospective data on a much larger scale, drawing data from 178 hospitals in the United States and assessing the consistency between pulse oximetry and arterial blood gas samples between the years of 2014 to 2015 from patients in intensive care units. The analyses revealed similar findings, with arterial blood

gas oxygen saturations of less than 88% and pulse oximeter readings between 92% and 96% in 17.0% of black patients and 6.2% of white patients. This is suggestive of a more long-term issue.

A smaller trial conducted in Singapore in 1993 explored the effect of ethnicity on the accuracy of pulse oximetry in multi-ethnic Singaporean patients admitted to intensive care.⁷ Three ethnic groups were studied: Chinese (n=22), Malay (n=6) and Indian (n=5). The study found that Indian patients showed the greatest difference between SpO₂ and SaO₂ readings and with increasingly hypoxic conditions, Indian, Chinese and Malay groups of patients showed greater differences in SpO₂ and SaO₂ readings.

The mechanism by which skin pigmentation affects pulse oximetry is unclear; however, a further study did reveal greater variation in pulse oximetry signal quality among darker skinned patients.⁸ A few studies which explored the effect of skin pigmentation on the precision of pulse oximetry have found that the degree of skin pigmentation does not affect the accuracy of pulse oximetry in infants and darkly pigmented critically ill adult patients in South Africa.^{9,10,11}

More focused research is required to determine the degree to which there is a link between pulse oximetry racial bias and Covid-19.

Implications

With the increased use of pulse oximetry amongst members of the public, the overestimation of SpO₂ in hypoxic patients with darker skin could have serious clinical implications. Current guidance, issued by NHS England and Improvement on the use of the pulse oximeter at home, suggests that patients should seek medical attention if the SpO₂ reading is below 94%.¹² With evidence showing black patients are at an increased risk of hypoxaemia due to the inaccuracy of pulse oximeter SpO₂ readings, this may result in delays when presenting for medical care and inadequate supplemental oxygen therapy being provided in secondary care settings.

Pulse oximetry is used to frequently monitor oxygen saturations and guide clinical management. In light of the Covid-19 pandemic, patients who are seriously unwell risk premature step-down treatment from intensive care. Another study assessed the agreement between pulse oximetry and arterial blood gas in Covid-19 ICU patients (n=30) who were considered suitable to be stepped down. The study found that pulse oximetry readings were suboptimal in comparison to the arterial blood gas analysis.¹³

Within this study, 67% of patients in this sample were from ethnic minority groups. Pulse oximeters have been found to not overestimate SpO₂ in light-skinned individuals, suggesting that the large majority of devices utilised data based on calibration studies with light-skinned individuals, and that skin pigmentation had not been taken into consideration when calibrating the devices.

Recommendations

Whilst the picture on racial bias in pulse oximetry is still mixed, as a worst-case scenario, the application of this intervention can potentially have negative outcomes for patients with more pigmentation in their skin. To help counter potential health inequalities in this area, we outline a number of recommendations for healthcare, regulatory and research bodies.

RECOMMENDATION 1:

There should be an urgent review of pulse oximetry medical products used in the United Kingdom

An urgent review of pulse oximetry medical products should be conducted by the UK Medical and Healthcare Products Regulatory Agency (MHRA) in order to assess the accuracy of pulse oximeter SpO2 readings in ethnic minority patient groups.¹⁴ Pulse oximetry products used in clinical settings, and those which are more widely available for purchase by members of the public, should be reviewed. Products which are approved for use must be suitable for ethnic minority patients as well as the majority population.

The outcome of such a review may have implications for medical training and for public awareness regarding the use of pulse oximeter devices.

RECOMMENDATION 2:

Identification of suitable parameters to identify hypoxia need to be verified

It is possible for patients to present with severe hypoxaemia in the absence of dyspnoea – what is known as “silent hypoxaemia”.¹⁵ As a result of the increased use of pulse oximetry for self-monitoring in Covid-19 patients managed outside of the hospital, patient education is key to allow other clinical signs to be used when assessing the need to seek further medical attention. The appropriateness of clinical signs for ethnic minority patients should be reviewed by critical care and respiratory academic groups and NHS England and NHS Improvement; language such as “going blue” may not be appropriate when assessing for cyanosis. This may require readjustment of thresholds for seeking care for ethnic minority groups and inform future guidance and treatment pathways.

RECOMMENDATION 3:

Review of all medical equipment and devices

This review has highlighted the need to ensure healthcare equipment and devices are culturally competent and sensitive so that they meet the needs of diverse populations. All medical equipment and devices should therefore be assessed for suitability of use with ethnic minority patients, as well as with the majority population. This should be sufficiently evidenced by manufacturers before devices receive market approval.

RECOMMENDATION 4:

Further research

Further research in this area, with larger and more diverse populations, is recommended as a priority for research bodies such as the National Institute for Health Research (NIHR) to consider.¹⁶ Research will help determine the extent of racial bias in pulse oximetry and will help to inform long-term developments of pulse oximetry devices. Data derived from specific ethnic groups could be used to generate calibration curves or enable the use of correction factors that would result in built-in-user optional adjustments in future pulse oximeters.

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