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Technology has a Role in Driving Better, More Equitable Care

Pulse oximetry measures blood oxygen levels, one of many important vital signs that helps clinicians provide timely care. Pulse oximeters work by sending light through a patient's finger and measuring its absorption. Darker skin pigmentation can absorb more light, skewing the results and potentially impacting care. There are nuances in how different pulse oximeters function, calling for a further review of the technology. Therefore, it is important that the medical device industry works to advance pulse oximetry to help ensure equitable care for all.

Before the invention of pulse oximetry, anesthesiologists relied on clinical observation, manual pulse, and arterial blood draws to confirm safe management of patients during anesthesia. Pulse oximetry created a more stable way to monitor a patient's oxygen level and pulse rate. The reassuring beep tones indicating stable levels drove non-invasive LED-light based pulse oximetry to be widely adopted and included in required monitoring guidelines only three years after it became commercially available.[1] Pulse oximetry is now considered the fifth vital sign across all areas of care.

However, these devices can have blind spots. Melanin, for example, can impact light absorption – specifically the red LED light used in a pulse oximeter – leading to unrecognized hypoxemia in patients with darker skin pigmentation.[2-5] This became a major concern during the COVID-19 pandemic when pulse oximetry was used to determine which patients would be treated for respiratory distress. During the pandemic, research showed that Asian, Black, and non-Black Hispanic patients were more likely to experience undetected low oxygen levels than White patients, contributing to significantly delayed or unrecognized eligibility to receive therapies and worse outcomes among Black and Hispanic patients.[2] These studies prompted a review of this 40-year-old vital sign through the lens of a more equitable technology.

Boosting Pulse Oximetry Performance

In November 2022, an FDA panel recommended the industry standardize and improve how it evaluates skin pigmentation in clinical studies.[6] Through public discussion, it was clear that there was lack of awareness and standardization to control device assessment. The FDA guided companies to update labels for prescription and over-the-counter pulse oximeters and explored additional assessments to help clinicians understand the factors that can impact device accuracy. There was agreement that a consistent and validated skin tone scale would be needed to ensure equal representation in each device evaluation and increase the sample size and statistical assessments. The FDA launched real-world studies to determine what key factors contribute to the differences in performance that were seen in the numerous real-world studies compared to the controlled studies included in device submissions.

In 2024, the FDA made updating the pulse oximetry guidance a key priority and published a discussion paper on the agency's current perspective. Key changes under consideration include:

1. Ensuring studies meet required representation by replacing the Fitzpatrick Scale, a skin type scale for how skin reacts to sun exposure, with two additional measures: the subjective 10-level Monk Skin Tone (MST) Scale, which was the first scale created for representation using a sociological approach, and the objective Individual Typology Angle (ITA) spectrophotometric measurement.
2. More than doubling the required study sample size.
3. Not only assessing accuracy but also statistical comparisons of accuracy between skin tone levels.

Questions remain about how to apply the guidelines, which are still in development. A draft is anticipated by the end of 2024.[7]

Not All Pulse Oximeters Work the Same Way

Medtronic manufactures the Nellcor™ pulse oximetry system, which was the first widely used pulse oximeter and continues to be used commonly in hospitals across the globe. The Medtronic Nellcor™ technology takes a unique approach to assessing patient oxygen saturation by using a form of artificial intelligence called pattern-matching neural network to precisely recognize and track each patient's unique pulse. As a result, when low perfusion or dark skin pigmentation reduce the signal strength picked up by the device, it can rely on the patient's consistent pulse to manage poor signal quality. This particular pulse oximeter also uses a calibration system that is specific to each sensor in order to enable low saturation accuracy, which is crucial in critical care.

This approach matters as there are three fundamentals that drive pulse oximetry functionality, and each one has a corresponding challenging clinical situation that can impact performance.

1. Low perfusion: Pulse oximeters read periodic increases in light absorbance that happen when there is an increase in blood volume during the arterial pulse. This helps the device know when to take an oxygen reading. However, when a patient has low perfusion, this makes it challenging for the device to confirm the arterial pulse and know when to read the oxygen.
2. Low light levels: Pulse oximetry sensors detect the red and infrared LED light absorbance that shifts in the presence of oxygenated and deoxygenated hemoglobin. However, when tissue is thick or the skin has dark pigmentation, less light penetrates through, making it harder to read oxygen level.
3. Low saturation: Calibration curves used by a pulse oximeter help translate the electrical and light signals into saturation percentages. Careful selection of the right calibration curve matters most during low saturation because the curves are farther apart at those low levels.

Some low-cost sensors do not include the higher-grade shielding required to maintain signal quality from the patient sensor to the processor inside the monitor. These components particularly help protect signal quality during low signal events such as low perfusion. There are also differences in how pulse oximetry technologies process light signals into SpO_2. For example, Masimo SET® uses signal extraction technology, a saturation-based approach that prioritizes light absorption, whereas the Medtronic Nellcor™ pulse-based technology first locks onto each patient's unique pulse. When faced with challenging signals during critical situations, differences in how technologies process signals can lead to differences in performance.

Rigorous Study

An independent prospective study, led by Philip Bickler, M.D., Ph.D., professor and director of the Hypoxia Research Laboratory at the University of California at San Francisco (UCSF), evaluated the leading pulse oximeters – from Medtronic and Masimo – for their ability to read blood oxygen in patients with dark skin pigmentation and low perfusion. In an article published in the journal Anesthesia & Analgesia, the UCSF team showed that the Medtronic Nellcor™ system more accurately identified hypoxemia in patients with dark skin pigmentation and low perfusion.

In the study, the researchers assessed oxygen saturation, skin pigmentation, and perfusion to assess device bias. The cohort included 146 healthy subjects, including 25 with light pigmentation, 78 with medium and 43 with dark. The team analyzed 9,763 readings, comparing Medtronic Nellcor™ SpO_2 and Masimo SpO_2 devices, matching pulse oximetry and arterial oxygen saturation results.

The Bickler team determined that darker skin pigmentation, low perfusion, and low oxygen saturation reduced pulse oximeter accuracy. The Medtronic devices missed 8% of occult hypoxemic events, while Masimo devices missed 30%.

In addition, the Masimo devices had relatively low concordance between their readings and other blood oxygen tests. In some cases, Masimo pulse oximeters measured 93% oxygen saturation while blood tests put the levels closer to 75%.[4]

These are major distinctions in a clinical setting where an artificially high pulse oximeter reading could potentially delay clinical intervention.

The Medtronic Commitment

Recent industry research found that only 25% of nurses are aware of equity concerns related to medical devices such as pulse oximetry.[8] Medtronic is working to help close this gap through education, ensuring confident use of pulse oximetry with the goal of protecting at-risk patients. Medtronic has also opened a new Clinical Physiology Lab in Denver, Colorado, which is investigating pulse oximetry devices in a diverse patient population. The lab was set up to expand clinical research, develop real-world evidence, and bring innovative pulse oximetry and other technologies to patients sooner.

While Medtronic Nellcor™ pulse oximeters are leading the way clinically for patient monitoring, Medtronic believes there is room to do more. The company is focused on reducing disparities in care through advancing technology, building lasting partnerships, and sharing its learnings with those on the front lines of care.

References

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