Eliminating racial bias in medicine is an obligation we all share

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The recent focus on the fact that pulse oximetry devices routinely convey inaccurate measurements of blood oxygen levels in patients with darker skin pigmentation should surprise no one, as researchers documented this concern more than 30 years ago.

Pulse oximeters are widely used to inform medical decision-making and to make critical decisions in acute care settings, so it is essential that these devices are accurate and reliable in all people. The risk posed by inaccurate readings is typically an overestimate of oxygen levels in patients with darker skin pigmentation, resulting in these patients being less likely to receive supplemental oxygen and life-saving treatment.

The Food and Drug Administration (FDA) issued a safety communication in February 2021 to inform patients and health care professionals that pulse oximeters have limitations and may deliver inaccurate results under certain circumstances, included due to skin pigmentation.

Only more recently has the FDA begun reevaluating the performance of pulse oximeters in measuring blood oxygen saturation in patients of color, with an eye toward updating their clinical use guidelines. Last month, the AMA House of Delegates called on the FDA to ensure the accuracy and reliability of pulse oximeter readings for patients with varying degrees of skin pigmentation, and make certain that health care personnel and the public are educated on the limitations of pulse oximeter technology so they can account for measurement error.

It should be noted that two types of pulse oximeters exist. Prescription pulse oximeters are reviewed by the FDA, receive 510(k) clearance, and can only be obtained by prescription. These are used in hospitals, physician’s offices and similar clinical settings. The second type, over-the-counter pulse oximeters, are sold online and at retail locations and should not be relied upon for medical purposes. Over-the-counter pulse oximeters are not reviewed by the FDA.
Device development

The first pulse oximeters were developed to prevent World War II pilots from losing consciousness due to hypoxia during high-altitude missions, and were worn on the earlobe. The technology was largely dormant until the 1970s, however, when Takuo Aoyagi, a Japanese electrical engineer whom I knew personally, refined the method of measuring arterial blood saturation using red and infrared light.

His advancement, and the commercial development and production of finger-worn pulse oximeters that began in the 1980s, led to an immediate and dramatic decline in anesthesia-related fatalities through faster and more accurate monitoring of blood oxygen saturation. The devices quickly became a standard of care in a wide range of medical settings, and many clinicians treat the measurement of arterial oxygen saturation as a fifth vital sign along with body temperature, pulse rate, respiratory rate and blood pressure.

Racial and ethnic bias

One of the drawbacks of pulse oximeters manufactured in the 1980s, as well as those on the market today, lies with the unreliable readings they provide from patients of color.

Calibration is the underlying problem here. When pulse oximeters were developed in Japan, calibration data was not gathered from a diverse pool of volunteers. And even though the FDA has long since required that medical technology be evaluated on patients from multiple demographic groups, problems persist. A study conducted by University of Michigan researchers showed that Black patients were three times more likely than their white counterparts to have below-normal blood oxygen levels that pulse oximeters failed to identify.

The role that pulse oximetry discrepancies played in triage and treatment decisions for Black and non-Black Hispanic patients with COVID-19 infections is documented in an original investigation published in *JAMA Internal Medicine* in May 2022. The authors concluded that greater occult hypoxemia in those patients may have contributed to poorer outcomes due to “significantly delayed or unrecognized eligibility for COVID-19 therapies.”

FDA action

The FDA’s recent review of differences in pulse oximeter accuracy is a welcome development that builds upon its February 2021 recommendations for patients and caregivers, which noted the issues
that darker skin pigmentation can present. Additional factors that can trigger inaccurate readings include skin thickness, tobacco use, and poor circulation, among others.

We hope the FDA will take additional action going forward, including requiring quantitative data on device performance across a range of skin pigmentation in clinical studies, particularly for devices with color-sensing technology. Studies illuminating the varying medical treatment responses based on skin color warrant the design of regulatory pulse oximetry accuracy standards, which we urge the FDA to pursue.

Pulse oximeters shown to reproduce racial bias, particularly those with FDA approval, should bear a warning label noting the risk of inaccurate readings. The FDA should also require additional collection of real-world evidence and increased post-market surveillance to ensure appropriate performance of these devices.

The medical community can also play a role in mitigating the impact of bias in these devices by ensuring that physicians and other health care professionals know about the limitations of current pulse oximeter technology. Those who direct patient care using these devices should be trained to account for systemic measurement errors when developing diagnoses and treatment plans.

**Advancing equity in medicine**

Eliminating bias and addressing inequities in the design and manufacture of digital tools such as pulse oximeters and other medical devices is a key part of the AMA’s broader strategy to advance racial justice and equity in medicine. The AMA Center for Health Equity this year launched the In Full Health initiative, which will help meet these challenges by giving physicians a better understanding of how structural racism, sexism and bias impact health innovation, and by investing in new digital tools from and for historically marginalized communities.

One troubling question remains unanswered, however: How is it acceptable that, more than three decades after skin pigmentation discrepancies were first brought to light, pulse oximeter manufacturers have not acted to eliminate them? I would suggest that the lack of corrective action points to the larger issue of implicit bias in medicine that helps create and sustain barriers that prevent historically marginalized communities from accessing the care they need.