Advancing equity by addressing racial bias in medical devices: Lessons and recommendations from the FAS Forum on Bias in Pulse Oximetry on November 2, 2022

By Jasper Cooper and Grace Wickerson, Federation of American Scientists

Background and Summary:
Pulse oximeters, devices that estimate oxygen saturation, were used widely to assess the severity of COVID-19. Racial bias in these critical tools, first documented over thirty years ago, created potentially life-threatening delays to medical care for thousands of darker-skinned Americans during the pandemic. Reducing this bias requires long-term action to design and disseminate better devices, as well as parallel steps to improve standards of care using existing technologies now.

On November 2, 2022—timed to coincide with the Food and Drug Administration’s (FDA) advisory committee meeting on bias in pulse oximetry—the Federation of American Scientists (FAS) convened a forum to chart a path toward equitable oximetry. Eight experts from medicine, engineering, sociology, and anthropology shared insights with an audience of 60 participants from academia, the private sector, and federal government.

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<th>Key Findings</th>
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<td>● Existing evidence suggests reducing bias in pulse oximetry requires replacing devices with less-biased ones. This will take time as new devices are developed and will be a significant cost.</td>
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<td>● The crux of the problem is a comprehensive standard for quantifying the full range of skin pigmentation. This is vital to understanding how pulse oximeter accuracy varies by melanin content.</td>
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<td>● Near-term solutions will require changes to the clinical care standards. More evidence is required to identify the best approaches to equitable care with existing devices. This evidence gathering process should be initiated over the next year.</td>
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<td>● Once the care standards are changed, there is a need for system-wide efforts to communicate these to clinicians nationwide, inform procurement across federal hospitals, and re-evaluate insurance reimbursement standards.</td>
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<td>● Identification of bias in medical devices has been piecemeal rather than the outcome of proactive, deliberative efforts. Further efforts to address bias in medical devices should engage diverse stakeholders to establish best practices for ensuring equity in medical devices.</td>
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Forum at-a-glance:
Through discussions with experts during the forum, three key themes rose to the surface:

1. **Racial bias in pulse oximetry cannot be fixed by focusing on “race” alone.** The racial bias in pulse oximeter readings arises because melanin interferes with light absorbance, leading to over-estimates of darker-skinned patients’ oxygen saturation. Racial categories, which are historical constructs, serve as limited proxies for these skin tone differences. Today, people identified as “Black” have a wider variation of melanin content compared to people racialized as white, which in turn produces more spread in the estimates of oxygen saturation for those individuals compared to people racialized as white. It may be tempting to “correct” for bias by changing diagnostic thresholds for Black patients. However, such a correction could increase false diagnosis of hypoxemia—low oxygen content in the blood—among light-skinned Black patients. Bias in pulse oximeters must be fixed through devices that are better calibrated for all skin tones.

2. **Better calibration for skin tone is vital, but measurement is complicated.** There is no scientific consensus on the best strategy for measuring skin pigmentation. Existing skin pigmentation scales can either fail to capture the full diversity of skin pigmentation or have so many color categories that they are difficult for clinicians to use. At the FDA’s meeting, several members of the advisory committee called for more objective measures of skin pigmentation. Yet objective measurements of skin tone through colorimeters or spectrophotometers do not account for variation in pigment distribution throughout the body. For example, there is less pigment on the palm of the hand than on the top of the hand where pulse oximeter readings are usually drawn. There are also important technical confounds to overcome, such as the sensitivity of skin tone measurement to skin redness (erythema). More research is needed to assess skin pigmentation effectively in the clinical setting.

3. **Proactively identifying and addressing bias in medical devices will require system-wide efforts.** It took a pandemic and the concerted attention of researchers outside the mainstream of medical science and engineering to mobilize stakeholders around the problem of racial bias in pulse oximetry, despite identification of this bias more than thirty years prior. More generally, identification of bias in medical devices has not been the outcome of proactive, deliberative efforts, but rather has been piecemeal and slow-moving. This need not be the case. The creation of large, linked datasets such as EPIC’s Cosmos, a HIPAA limited data set combining the electronic health record (EHR) data of over 122 million patients, has paved the way for systemic and ongoing audits for bias in medical devices. Engineering education can integrate the social scientific study of structural racism into design practice. Equity can be incorporated alongside performance as a key metric for engineering and computer science.
Equity in care: Reducing racial bias in pulse oximetry now:
Resolving the problem of bias in pulse oximeter devices will likely take several years. But in the meantime, this issue will continue negatively impacting patients. Thus, we need to think about actions that can be initiated this next year that will advance more equitable care with existing pulse oximeters. Key stakeholders can work together to advance equity in standards of care by:

1. **Gathering evidence on existing pulse oximeter devices and their use in care [ASAP, start early 2023].** Our Forum and the FDA's advisory committee meeting identified several...
questions that need to be answered to safely utilize the existing pulse oximeters in clinical care, detailed in Figure 1: Gathering Evidence. The National Institutes of Health (NIH), Food and Drug Administration (FDA), and external funders should invest in research that answers these questions. These questions include:

- How accurate are the existing, “most popular” pulse oximeter devices?
- Can we ensure that existing pulse oximeter devices are effective at diagnosing hypoxemia?
- What interventions can be developed to correct for “misses” of hypoxemia in dark-skinned patients?
- What are the best strategies for assessing skin pigmentation in clinical care?

There is an urgent need for a comprehensive audit of the clinical performance of existing pulse oximeters on the market, such as diagnostic accuracy for hypoxemia. The NIH and others should fund independent assessments of the most common pulse oximeters, through both prospective trials in real-world clinical settings and retrospective evaluations that link electronic health record data and procurement information from large hospital systems. The FDA should work with industry stakeholders to share testing data with procurement officers within hospital systems to inform purchasing decisions.

Funding should go to research that can identify potential strategies to address diagnostic “misses” of hypoxemia caused by factors like skin pigmentation. Well-researched correction factors may be a short-term solution that can be integrated into clinical care guidelines. For example, recent studies comparing oxygen saturation measurements from arterial blood gasses with measurements from pulse oximeters find overestimation of oxygen saturation ranging between 1-3 percentage points.

Finally, looking ahead towards needed advancements in regulatory standards, research funding should go towards strategies to assess the broad range of human pigmentation. Rigorous, evidence-based comparisons of subjective and objective evaluations of skin pigmentation can identify best strategies for different settings. These recommended standards can be used for regulatory evaluation of devices, integrated into clinical care decision-making, and included within correction factors.

2. Establishing consensus to advance the standard of care [start early 2024]. After growing the body of evidence, there will be a need to convene around key conclusions derived from the evidence.

The NIH and the Agency for Healthcare Research and Quality (AHRQ) can create comprehensive reviews to inform new standards of care for use of existing pulse oximeter devices. This could involve setting a higher threshold for hypoxemia in darker-skinned patients to counter overestimation of oxygen saturation.
Clinical care societies and The Joint Commission, which accredits hospitals, should use these reviews to **rapidly craft new care guidelines and standards** for effective use of the pulse oximeter.

Finally, a **list of “less-biased” devices could be curated** based on audits in the real-world clinical setting.

3. **Taking action to ensure equitable care nationwide [2024 onwards]**. Implementing a new standard of care for existing pulse oximeter devices will require significant investment in **raising awareness** among clinicians about existing bias, in **training clinicians on improved care practices**, and in **overhauling device infrastructure**.

Systematic audits of pulse oximeter device performance across representative populations (outlined above under evidence gathering), can **inform the federal government’s procurement** of new devices for the hospitals and health centers that it runs—including Veterans Affairs hospitals, the Indian Health Service, and Federally Qualified Health Centers, which collectively serve 45 million Americans.

The federal government could also **fund replacement of existing pulse oximeter devices with less biased devices**, if identified, for healthcare organizations working in low-resourced areas.

Finally, the Centers for Medicare and Medicaid Services **need to re-evaluate insurance requirements** that set a certain pulse oximeter value to receive care benefits, **such as for home oxygen**.

**Make equity actionable:**
This is a start to a roadmap to achieving equity in pulse oximetry. Investment in gathering evidence, establishing consensus, and taking action to combat bias in pulse oximetry will take substantial resources. But these initial investments will pioneer a model that can be readily applied to combatting biases across the medical device ecosystem. Looking ahead, we support **further investigations** into the **issue of existing biases in medical devices**, following a model such as the United Kingdom’s [Equity in Medical Devices Independent Review](https://www.gov.uk/government/publications/health-and-social-care-equity-review). Through a systematic approach, stakeholders can work to close racial disparities in the near-term and advance health equity.

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*A recording of the FAS Forum on Bias in Pulse Oximetry can be accessed* [here](https://www.fas.org/editorial/bias_in_pulse_oximeter)
Appendix:

Event Agenda

9:30–9:40  
*Welcome and Opening Remarks*
- Grace Wickerson, Science Policy Fellow, Federation of American Scientists

9:40–9:45  
*Keynote Address*
- “Open Oximetry: Designing a Better Pulse Oximeter”: Gregory Leeb, Fellow, Center for Health Equity in Surgery & Anesthesia, University of California, San Francisco (UCSF)

**Part 1: Understanding the Consequences of Bias**

9:45–10:00  
*Ideation Talks*
- “Small Biases Can Translate Into Large Differences: An Example From COVID-19”: Tianshi David Wu, Assistant Professor, Baylor College of Medicine
- “Racial Disparities in Pulse Oximetry Cannot Be Fixed With Race-Based Correction”: Neal Patwari, Professor of Electrical and Systems Engineering, Washington University

10:00–10:10  
*Interactive Reflection*

**Part 2: How to Build an Evidence Base for Bias-Free Pulse Oximetry**

10:10–10:25  
*Ideation Talks*
- “Using Big Data Sets to Assess Medical Technologies”: Jackie Gerhart, Vice President of Clinical Informatics, Epic and Sam Butler, SVP of Clinical Informatics, Epic
- “Understanding Skin Tone Bias in Pulse Oximetry: The Roles of Measurement and Regulatory Standards”: Ellis Monk, Associate Professor of Sociology, Harvard University

10:25–10:45  
*Ideation Talks*
- “Futures of Equitable Design”: Amy Moran-Thomas, Associate Professor of Anthropology, Massachusetts Institute of Technology (MIT)
- “Equitable Optics: the UCLA Pulse Oximeter and Plethysmograph”: Achuta Kadambi, Assistant Professor of Electrical and Computer Engineering, University of California, Los Angeles (UCLA)
- “Tracking Bias in Pulse Oximetry Through a Complex Healthcare System”: Harriet Nembhard, Dean of Engineering, University of Iowa
10:45–10:55  Interactive Reflection

10:55–11:00  Closing Remarks
  ●  Grace Wickerson, Science Policy Fellow, Federation of American Scientists

11:00–11:10  Break

11:10–12:00  Focused Conversation: The Path Forward for Equitable Progress in Pulse Oximetry

12:00–12:45  Lunch