The FDA Weighs in (Again) on Biased Pulse Oximeters

The medical devices don’t work as well on dark skin. Will federal guidance released last month improve accuracy?

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Pulse oximeter is a small sensor that can be clipped to a person’s fingertip, earlobe, or toe in order to measure oxygen levels in the blood. The device may provide crucial information for medical decision-making: Over time, low blood-oxygen levels will damage a person’s tissues and organs. When a patient’s levels drop, a physician may recommend supplemental oxygen, which is typically delivered through tubes that connect to a person’s nostrils.

Since the 1990s, studies have shown that pulse oximeters can produce misleading readings in people with dark skin. The pandemic put a spotlight on the issue. In 2020, researchers at the University of Michigan found that fingertip pulse oximeters showed inaccurate results for some Black patients, many of whom suffered from Covid-19. In fact, the devices missed three times as many cases of low-oxygen levels in Black patients as in White patients. These inaccurate readings may influence care decisions, physicians and researchers have noted. For example, one study showed that Black patients with Covid-19 had a lower chance of getting prescribed dexamethasone — a potentially lifesaving treatment — than White patients.

Owing in part to problems that came to light during the pandemic, the Food and Drug Administration has been reevaluating the situation. In January, the agency released new draft guidance. It aims to improve the accuracy and performance of pulse oximeters by recommending that manufacturers increase the minimum size of their testing pools from 10 to 150 people. It also states that at least 25 percent of test subjects should fall in each of three groups — light, medium, and dark skin tones — and that 50 percent of subjects in the dark-skin tone category include individuals with very dark skin. Furthermore, the FDA recommends that companies use an objective, scientifically-based process called colorimetry, which measures skin tone using reflective light.

Some experts have characterized the guidance as a step in the right direction, though it largely applies to devices used in hospitals and clinics. This is a significant limitation, given the growing market for devices sold over the counter to consumers at risk of experiencing low-blood oxygen levels due to acute or chronic heart and lung conditions. Most OTC devices are not FDA-cleared and not intended for medical purposes.

In the lead-up to the revised draft guidance, researchers published a letter showing modest, but more frequent inclusion of discussions of performance testing in people with a range of skin tones after the agency issued its first guidelines in 2013. However, pulse oximeters still appear to be mostly tested and calibrated on participants with light skin. It's the manufacturers of these products that the FDA guidance is primarily targeting.

The FDA says it expects some currently marketed pulse oximeters may meet the updated criteria without the need for substantial modifications. In these cases, a manufacturer can submit performance data, which the agency intends to review within 30 days. It also recommends that manufacturers include a labeling statement on the pulse oximeter, indicating that the device has demonstrated its accuracy across a range of skin tones, and proposes publishing a list of all pulse oximeters that have undergone this review online.

There will now be 60 days of public comments on the draft guidance, followed by work on a final version. (Some researchers who study how the devices work with different skin tones worry their funding could be in jeopardy due to President Donald Trump's crackdown on diversity, equity, and inclusion.)

While the draft guidance applies to pulse oximeters intended for medical purposes, it doesn't apply to devices that are sold as general wellness products or sporting and aviation products, which are not FDA-cleared. Such products are often sold over the counter in stores or online. They're not supposed to be used in clinical decision-making or determining whether to seek medical intervention.

Hospitals and other health care facilities were the biggest players in the market for pulse oximeters in 2020, accounting for a revenue share of 82 percent, but home users — who often purchase OTC products — are the fastest-growing segment. Overall, forecasters project a robust average 8.8 percent annual growth rate for all types of devices through 2026, driven by high rates of chronic obstructive pulmonary disease, asthma, and pneumonia, among other respiratory diseases, and the awareness of the importance of monitoring of oxygen levels.

The omission of the majority of OTC products from the FDA's draft guidance is concerning, said Carmel Shachar, faculty director of the Health Law and Policy Clinic at Harvard Law School. "Many people purchased OTC pulse oximeters, especially during the start of the Covid-19 pandemic," she wrote in an email to Undark. "So it is possible, for example, that during this flu and respiratory illness season, that some people will use their OTC pulse oximeters to determine if to seek medical care, unaware that these devices may not perform well on their skin tone."

Recently, a small number of OTC pulse oximeters were cleared by the FDA for medical purposes. The manufacturer Masimo's MightySat Medical became the first FDA-cleared medical fingertip pulse oximeter available OTC product in February 2024. And since late last year, there's another FDA-approved product made by Nonin Medical called the TruO2 that, according to company data, also provides reliable readings across skin tones.

Overall, certain devices evaluated by experts appear to provide more accurate measures than

others. Device manufacturer Medtronic say they're "working to close the inequity gaps." Based on an independent study, the company claims that one of its products, Nellcor N-595, performs better in people with dark pigmentation than one of its competitor products, Masimo's Radical 7.

Achieving equitable diagnostic care in oximetry requires ensuring all medical devices serve everyone. To help consumers and health care providers make better choices, perhaps the FDA should consider providing a list of devices that haven't been thoroughly evaluated for accuracy across skin tones.

Still, in a December viewpoint published in the Journal of the American Medical Association, Shachar and her colleagues argued that no single actor, including the FDA, can solve the racial and ethnic bias in pulse oximetry. What the authors call a "wicked" problem is complex and multifaceted. To solve it will require coordinated action among device manufacturers, clinicians, regulators, and policymakers. The authors write that by combining market incentives, stronger regulatory frameworks, and requirements that healthcare providers adopt improved devices, the medical community can achieve more equitable care for all patients.

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