

**Article:**

Heather M Stieglitz, Nichole L Korpi-Steiner.

Pulse Oximeter Performance across Populations with Diverse Skin Tones.

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Guest: Dr. Heather Stieglitz from the Ohio State University Wexner Medical Center in Columbus, Ohio.

Bob Barrett:

This is a podcast from *Clinical Chemistry*, a production of the Association for Diagnostics & Laboratory Medicine. I'm Bob Barrett. Hospital and clinic patients with a variety of illnesses are often evaluated using pulse oximeters--non-invasive devices placed on a finger that estimate oxygen saturation using light absorption. Pulse oximetry is ubiquitous due to its simple, continuous, pain-free approach. But a 2020 study in the *New England Journal of Medicine* showed pulse oximetry overestimated oxygen saturation more frequently in patients with darker skin tones.

In fact, self-identified Black patients were approximately three times more likely than White patients to have hypoxemia that was missed by pulse oximetry. In response to this finding, the FDA has asked pulse oximeter manufacturers to eliminate disparities in instrument performance. While reducing disparities is clearly a desirable goal, some have pointed out that this guidance may actually have a negative effect if it results in some devices being removed from the market, reducing access and increasing costs.

A News & Views article, appearing in the July 2025 issue of *Clinical Chemistry*, discusses the impact of skin tone on pulse oximetry measurements and suggests ways for laboratorians to help reduce disparities while maintaining access for all patients.

In this podcast, we welcome the editorial's author. Dr. Heather Stieglitz is a Clinical Associate Professor and Co-Division Director of Clinical Chemistry and Toxicology at the Ohio State University Wexner Medical Center in Columbus, Ohio. And Doctor Stieglitz, pulse oximeters are readily used in healthcare just about everywhere. Let's get basic. Can you expand on just what pulse oximeters are and how they are used in clinical care?

Heather Stieglitz:

Yeah. So, pulse oximeters are really neat and technologically advanced small devices that attach to an external body site such as like a fingertip. So, these devices contain a light source and a detector, and they can rapidly measure pulse rays and arterial oxygen saturation by shining a light on the

skin and measuring the absorbance of hemoglobin. So, specifically, pulse oximeters are designed to measure arterial oxygenated and reduced hemoglobin. They use these measurements to estimate the percent of functional hemoglobin that is bound to oxygen, which is a term also called hemoglobin oxygen saturation.

So, these measurements are basically an indirect way to determine the partial pressure of oxygen in the blood, which is used clinically to evaluate and monitor patients for adequate oxygen status as well as for heart and lung function. And so, pulse oximeters specifically are often used because they're quick, they're easy, and they are less invasive than a direct arterial oxygen saturation measurement obtained by an arterial blood collection and analysis by a blood gas analyzer. However, while there are a lot of advantages to using these, they do have some limitations.

Bob Barrett: Well, let's get into that. What are some of the limitations of using pulse oximeters?

Heather Stieglitz: Yeah, so since they're commonly used on tissues like a fingertip or an ear, any condition that's associated with poor perfusion can cause unstable readings, and those can lead to inaccurate results. Also, since pulse oximeters measure the percent of functional hemoglobin that is oxygenated, the results could be misleading in the presence of hemoglobin like carboxyhemoglobin or methemoglobin that can present in burn patients or other patient populations. And so, ruling out the presence of this hemoglobin is prudent when using pulse oximeters.

But the limitation that we want to focus on today is the bias that's been observed in oxygen saturation readings among patients with different skin tones, especially at low oxygen levels. This bias can be very dangerous when it leads to an inaccurate evaluation of oxygen status. This problem first came to light through the publication of several case reports, some as old as nearly 40 years ago. But this issue hasn't only been noted in case reports.

So, for example, one study that evaluated two large cohorts of paired oxygen saturation readings from pulse oximeters and blood gas analyzers among self-identified Black and White participants found that there was a three times higher frequency of missed hypoxemia by pulse oximeter readings for Black patients compared to White patients. And this study came out during the COVID-19 pandemic when pulse oximeters were constantly in use. And data was coming to light that showed that poor pulse oximeter performance was linked to health disparities in patients with darker skin tones.

So, while this issue has been known for a while, and the Food and Drug Administration had previously attempted to address it with a guidance document in 2013, it really prompted the FDA to sort of reevaluate and come out with some improved guidance, which they did in January of this year when they released a new draft guidance document.

Bob Barrett: Well, Dr. Stieglitz, in your article you highlight the recent release of that draft Food and Drug Administration guidance document regarding pulse oximeters. Can you please share a few of the recommendations that were put forward by the FDA?

Heather Stieglitz: Sure, the FDA's draft guidance provides several recommendations for in vitro diagnostic manufacturers either aiming to gain approval or clearance of a new pulse oximeter device, as well as those manufacturers who already have devices that are currently marketed.

The overall aim of this guidance document is to encourage manufacturers to really evaluate the racial bias of pulse oximeters by conducting controlled studies that evaluate the performance of pulse oximeters on people with a variety of skin tones. So, more specifically, the guidance document outlines what scales and metrics should be used to evaluate pigmentation level in study participants. They also recommend a certain number of total study participants, as well as the number of participants of each pigmentation level that should be included. They also provided recommendations for what results would be considered successful in demonstrating non-disparate performance across different skin tones.

And so, furthermore, the FDA recommends that pulse oximeters that do demonstrate non-disparate performance be labeled accordingly so that clinicians and consumers are aware of this when they're using these devices. And then as an extra effort to help educate the public, they also mentioned in that guidance document that they intend to include on their website a list of those pulse oximeters that are labeled as having demonstrated non-disparate performance to help guide device selection.

Bob Barrett: Well, finally, Dr. Stieglitz, given these findings and recommendations, what should clinical laboratorians do? Are there approaches for clinical laboratorians to help mitigate this potential racial disparity with pulse oximeters?

Heather Stieglitz: So, I think the major takeaway for clinical laboratorians is first to be aware that there are these limitations with pulse oximeter oxygen saturation readings, including the potential for disparate performance across skin tones. And more specifically, one of the major risks is not detecting hypoxemia

in Black patients. So, laboratorians should also consider familiarizing themselves with these devices that have demonstrated non-disparate performance, which they can again find on that FDA website, so that they could potentially provide guidance to clinicians and stakeholders when they're trying to choose between what pulse oximeters they should purchase.

Bob Barrett:

That was Dr. Heather Stieglitz from the Ohio State University Wexner Medical Center in Columbus, Ohio. She wrote a News & Views article in the July 2025 issue of *Clinical Chemistry* discussing the impact of skin tone on pulse oximeter measurements and she has been our guest in this podcast on that topic. I'm Bob Barrett. Thanks for listening.