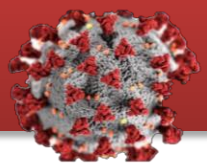
NEQCA
New England Quality Care Alliance
Affiliated with Tufts Medical Center

COVID-19 BRIEFING

UPDATED: February 26, 2021



PULSE OXIMETRY IMPORTANT CAUTIONS

Potentially dangerous inaccuracies in pulse oximetry results related to skin pigmentation

A recent publication in the NEJM noted that darker skin pigmentation can lead to the failure to diagnose occult hypoxemia in black patients via pulse oximetry. In this series, clinically important occult hypoxemia was missed by standard clinical pulse oximeters three time more often in black patients (11.6% of the readings) compared with white patients (3.6%).

Non-clinical (direct to consumer, over the counter) pulse oximeters and smartphone apps

A variety of non-clinical grade pulse oximetry devices and smartphone apps are sold directly to consumer. These include inexpensive stand-alone fingertip oximeters, similar in form factor to typical clinical oximeters. They also include sensors which plug into a smartphone and apps to collect the data. Finally, some inventors have used the smartphone camera directly as the sensor, with the only required additional purchase being the app to collect the data.

The available data on the accuracy of these devices is quite scanty. What is published, however, is by and large not very encouraging. Thus, we do not recommend these devices for clinical use by health professionals or consumers, even in the current emergency.

The FDA published an advisory ON February 19, 2021, which spoke to the above points:

> "**Over-the-counter (OTC) oximeters** are sold directly to consumers in stores or online and include smart phone apps developed for the purpose of estimating oxygen saturation. Use of OTC oximeters has increased as a result of the COVID-19 pandemic. These products are sold as either general wellness or sporting/aviation products that are not intended for medical purposes, so they do not undergo FDA review. OTC oximeters are not cleared by the FDA and should not be used for medical purposes."

References

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