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October 18, 2022

Food and Drug Administration
Department of Health and Human Services
5360 Fishers Lane
Room 1061
Rockville, MD 20852

RE: FDA-2022-N-2100

Dear Commissioner Califf,

The Society of Hospital Medicine (SHM), representing the nation's hospitalists, is pleased to offer our comments on their *Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee* request for public comments.

Hospitalists are physicians whose professional focus in the general medical care of hospitalized patients. They provide care to millions of Medicare beneficiaries each year and have served their communities heroically, caring for hospitalized patients throughout the deadly COVID-19 pandemic. Hospitalists are front line users of pulse oximetry devices and rely on pulse oximetry measurements to make clinical decisions every day. As hospitalists, we have firsthand experience with the unreliability of these devices in select patient populations. We are alarmed by multiple studies the have demonstrated the inaccuracy of oxygen saturation readings in patients with darker skin pigmentation.[1,2,3,4] The inaccuracy of pulse oximetry devices contributes to racial bias and worsening health inequities. The Biden Administration has a stated goal to reduce health disparities in medicine and we believe addressing issues with pulse oximeters is an opportunity to take a step forward on this goal.

Our comments below seek to amplify comments developed by the Hospital Medicine Reengineering Network (HOMERuN), a nationwide group of hospitalists and researchers collaborating on quality, safety, and efficiency improvements in the field.

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[1] Sjoding, Michael W., Dickson, Robert P., Iwashyna, Theodore J., Gay, Steven E., Valley, Thomas S. (2020, December). Racial bias in pulse oximetry measurement. Letter to the Editor. https://www.nejm.org/doi/10.1056/NEJMc2029240

[2] Gottlieb, Eric R., Ziegler, Jennifer, Morley, Katherine, et. al. (2022). Assessment of racial and ethnic differences in oxygen supplementation among patients in the intensive care unit. *JAMA Internal Medicine.* 182 (2): 849-858. https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2794196

[3] Valbuena, Valeria S. M., Seelye, Sarah, Sjoding, Michael W., et. al. (2022). Racial bias and reproducibility in pulse oximetry among medical and surgical inpatients in general care in the Veterans Health Administration 2013-19: multicenter, retrospective cohort study. *BMJ*: 378. https://www.bmj.com/content/378/bmj-2021-069775.

[4] Fawzy, Ashraf, Wu, Tianshi David, Wang, Kunbo. (2022). Racial and ethnic discrepancy in pulse oximetry and delayed identification of treatment eligibility among patients with COVID-19. *JAMA Internal Medicine.* 182 (7): 730-738. https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2792653.

Background

Pulse oximeters, standard tools used daily throughout the hospital, assess a patient's oxygen saturation for a variety of conditions or needs. Patients with hypoxia, a condition where a patient's oxygen saturation has dropped below the normal threshold, are more likely to be admitted to the hospital from the Emergency Department, making the accuracy of these readings vital. Throughout the COVID-19 pandemic, hospitalists relied upon pulse oximetry devices because administration of many COVID-19 therapies are dependent upon oxygen saturation levels. Medicare approval for home supplemental oxygen is also based on meeting certain oxygen saturation thresholds.

The documented limitations and inaccuracies in pulse oximeters are slowing or preventing some patients with darker skin pigmentation from receiving lifesaving interventions and contributing to racial disparities in healthcare we see today. There is no practical clinical solution to address this problem. Medical devices that measure oxygen saturation must be improved to provide accurate readings for all patients, regardless of skin tone.

Recommendations

1. **Require subgroup analyses by skin pigmentation, race and ethnicity, and gender be conducted as part of the approval process for pulse oximetry devices to demonstrate equitable accuracy across a range of skin pigmentation, racial and ethnic groups, and genders.**

   Current pulse oximeter approval requirements are woefully insufficient. Existing requirements only mandate the inclusion of "2 darkly pigmented subjects or 15% of [the] subject pool, whichever is larger."[5] These requirements create little incentive for manufactures to ensure accuracy for patients with darker skin pigmentation. We call on the FDA to require equitable representation of skin pigmentation for FDA approval.

2. **Prohibit the use of "race correction factors" by manufacturers and require calibration based on objective measures of skin pigmentation, not the social construct of race.**

   Race correction factors are an insufficient solution to this problem, in part because the social construction of race does not correlate closely with the degree of skin pigmentation. Adjusting readings in this manner will remain inaccurate. Pulse oximetry devices that cannot provide reliably accurate readings on varying skin pigmentations should be deemed defective and require change.

3. **Require that device approval data include measurements from both healthy and hospitalized participants, reflecting the real-life use of these devices.**

   Current FDA approval requirements do not require testing in hospitalized patients. However, studies performed solely on healthy subjects may miss clinically significant racial biases in

[5] Pulse oximeters – premarket notification submissions [510(k)s]: guidance for industry and food and drug administration staff. (2013). *U.S. Food & Drug Administration.* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-premarket-notification-submissions-510ks-guidance-industry-and-food-and-drug.

hospitalized patients, the patients for whom accurate pulse oximetry measurements are most critical. Therefore, we believe the FDA should require *in vivo* testing of pulse oximetry devices in hospitalized patients, as well as healthy patients.

4. **Separate the approval process for medical-grade and consumer-grade pulse oximeters. Intensify approval requirements for both types of devices, especially for medical-grade devices.**

   Current FDA requirements for pulse oximeter approval are too lenient for medical-grade devices. Medical-grade devices should have more stringent approval requirements. Additionally, separating the requirements between consumer- and medical-grade devices will ensure there is not undue burden placed on manufacturers of consumer-grade devices. While it is important that consumer-grade devices also account properly for darker skin pigmentation, it is crucial that medical-grade devices used in hospitals are accurate for all hospitalized patients.

5. **Require new approval requirements for market entry and work to improve previously approved devices.**

   At a minimum, all new devices should undergo a revised approval processes that ensures this defect does not continue. Since most, if not all, pulse oximeters in use today provide inaccurate readings on darker skin pigmentations, we also believe efforts should be made to research and develop corrections on previously approved devices.

6. **Investigate other similar devices (i.e., optical devices) for the presence of racial bias.**

   The discovery of this defect in pulse oximetry devices raises concerns that other devices similarly provide inaccurate readings and analyses. We believe the FDA should update and reevaluate its approval process for all devices, ensuring that medical devices are proven to be accurate and effective on a range of skin tones.

Conclusion

SHM appreciates the opportunity to provide comments on *Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee* request for public comments. If you have any questions or require more information, please contact Josh Boswell, Director of Government Relations, at jboswell@hospitalmedicine.org.

Sincerely,

Rachel Thompson, MD, MPH, SFHM

President, Society of Hospital Medicine