Position on Medical Devices Safety for Patients with All Skin Types

Support:

- Regulation and reclassification of medical devices used by lay people (i.e., pulse oximeter devices) to ensure safe use by patients with all skin types.
- Initiatives to educate the public on limitations of devices (i.e., pulse oximetry devices) for patients with diverse skin tones.
- Education on use of lay devices by patients with diverse skin tones, so that limitations are understood about potential false readings and when emergent care may be needed.
- Innovation of medical device technologies aimed at lay people use to be inclusive of patients with diverse skin tones with the goal to improve accuracy of performance across all skin tones.
- Additional clinical research on medical devices to include patients with diverse skin tones.

Oppose:

- Direct to consumer advertising of medical devices (i.e., pulse oximeters) without accompanying warnings for patients with diverse skin tones regarding potential for false readings.

Background:

There is empirical evidence, confirmed by FDA in November 2022, about potential inaccuracies in pulse oximeter readings, including those associated with patients' skin tones. Readings for individuals with darker skin tones may be consistently inaccurate and higher than the true underlying value due to pigment-associated attenuation of the LED light used in these devices. This creates a risk for undetected hypoxia in patients with darker skin tones. This may delay patient access to care, resulting in treatment delay and poor outcomes. Affected pulse oximetry devices include those available without a prescription for lay use, those available by prescription for home use, and those for in-office medical use by providers in outpatient or inpatient settings.

During the COVID-19 pandemic pulse oximetry acquired increased importance as a simple, widely available tool for detecting unanticipated and drastic decreases in pulmonary function and oxygenation. While the peak of the pandemic may have passed, the threat remains. Moreover, many patients with other medical conditions will also benefit from accurate pulse oximetry.

ASDSA Policy Recommendations: To address this potential problem with medical devices used by lay people (specifically pulse oximetry) and patients who have diverse skin tones, the ASDSA is recommending in the interest of patient safety and optimal patient care:

1. **There should be increased public and physician awareness of limitations of medical devices, specifically pulse oximetry, of potential erroneous readings in patients with diverse skin tones.** While improving pulse oximetry devices will take years, patients are at risk now, and that risk must be mitigated. The most direct way to reduce the impact of inaccurate readings is to advise patients, their caregivers, physicians, and the public that this a problem. Manufacturers, FDA, pharmacies/distributors, and hospitals/clinics should be among the stakeholders required to convey this information to patients and the public.

2. **Instructions for use provided with pulse oximeters should be revised and expanded so that cautions and limitations are clearly conveyed.** Pulse oximeters sold for lay use without prescription are usually packaged with extremely limited or no instructions for use. Pulse oximeters for medical use are also deficient in this regard. Clear and simple explanatory literature conveying the risk of inaccurate readings, especially in the context of darker skin tones, should be provided with both types of pulse oximeters. Additionally, the same information should be displayed also on graphical stickers that are vivid, obvious, and directly affixed to the pulse oximeters.

3. **Literature provided with oximeters should provide ranges of values that are normal, borderline, or overly concerning/emergent.** While such literature would not be intended to replace physician judgment, it would help users, particularly lay users, and their caregivers, interpret outputs and know when to seek help.

4. **Outputs on the display screens of pulse oximeters should include +/-, a range, or some other similar configuration to show that the point value that is provided is associated with an error margin.** We do not believe that the numerical value should be replaced by a less precise scale or a color scale (e.g., red, yellow, green), as decreasing the amount of information available to patients and providers is not optimal. However, the point numerical values should be displayed in such a way that it is clear to the user that these are inherently imprecise.

5. **Further research is needed to develop all medical devices, specifically pulse oximetry devices, which incorporate newer technologies to improve their performance.** The FDA should encourage manufacturers of devices (i.e., pulse oximetry devices) to undertake research and technical improvements to make their devices more accurate for all patients, and to decrease the accuracy gap between patients with lighter skin and those with darker skin tones. For instance, measurement accuracy may be improved by imbedding LEDs of more colors beyond the two that are often included. The application of other research discoveries and technological advances may also improve oximeters and other devices.

6. **FDA should require heightened minimum performance standards for pulse oximeters.** FDA can mandate that a higher level of accuracy for pulse oximeters should be implemented within 3-5 years, thereby allowing manufacturers time to improve their products. This requirement should separately require increased accuracy in patients with darker pigmented skin.

7. **FDA should reclassify and directly regulate over-the-counter pulse oximetry devices, which are currently designated as not for medical use.** Interestingly, over-the-counter pulse oximeters purchased by lay people at their neighborhood pharmacy without a prescription are currently deemed “not for medical use” by the FDA and are not regulated as medical devices. FDA should use its statutory authority to reclassify these devices as medical devices. This is not overreach but an acknowledgement of the reality that patients do not use pulse oximeters as “lifestyle” products but rather to self-screen and detect serious, life-threatening illness in themselves or their loved ones in a timely manner so that they can seek equally timely necessary medical care. Simply eliminating the over-the-counter class of pulse oximeters is not feasible as this would drastically reduce patient access to these devices; similarly, very stringent FDA standards for these oximeters may make them cost-prohibitive, again limiting access. An intermediate regulatory position, which we recommend, would be for the FDA to require a significant improvement in the performance of OTC oximeters, such that they become more precise and useful while remaining affordable.

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