AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 915
(I-22)

Introduced by: Washington

Subject: Pulse Oximetry in Patients with Pigmented Skin

Referred to: Reference Committee K

Whereas, Awareness of concerns on the accuracy of pulse oximetry in pigmented skin has been noted since the 1970s and the Hewlett Packard Model 47021A Oximeter was designed in that era specifically with the ability to calibrate for various degrees of skin pigmentation; and

Whereas, The Journal of the American Medical Association (JAMA) has reported an increased incidence of hidden hypoxemia (SaO2 <88% despite SpO2 ≥88%) in racial and ethnic minority groups – specifically Black, Hispanic, and Asian groups – with an associated increase in major organ dysfunction at 24 hours in otherwise matched groups and increased in-hospital mortality; and

Whereas, The British Medical Journal has reported that in general care inpatient settings across the Veterans Health Administration paired readings of arterial blood gas and pulse oximetry were obtained, black patients had higher odds than white patients of having occult hypoxemia noted on arterial blood gas but not detected by pulse oximetry; and

Whereas, JAMA Internal Medicine has reported that greater occult hypoxemia in Asian, Black, and non-Black Hispanic patients with COVID-19, which was associated with significantly delayed or unrecognized eligibility for COVID-19 therapies among Black and Hispanic patients; and

Whereas, The Critical Care Societies Collaborative has urged the FDA to direct pulse oximeter manufacturers to conduct the tests needed to ensure that their devices provide accurate and reliable readings for patients with diverse degrees of skin pigmentation; and

Whereas, The FDA has acknowledged that skin pigmentation can affect the accuracy of pulse oximetry readings and is planning to convene a public meeting of the Medical Devices Advisory Committee later this year to discuss available evidence about the accuracy of pulse oximeters, recommendations for patients and health care providers, the amount and type of data that should be provided by manufacturers to assess pulse oximeter accuracy, and to guide other regulatory actions as needed; therefore be it

RESOLVED, That our American Medical Association make recommendations to the US Food and Drug Administration that will ensure pulse oximeters provide accurate and reliable readings for patients with diverse degrees of skin pigmentation. (Directive to Take Action)

Fiscal Note: Not yet determined

Received: 10/10/22
REFERENCES:

5. https://ccsconline.org/other/inaccuracy-of-pulse-oximeters