Anesthesiology Advisory Committee meeting on Pulse Oximeters, November 1, 2022

Panel Questions

1. Please discuss the clinical evidence from the scientific literature about the accuracy of pulse oximetry among patients with darker skin pigmentation. In your deliberations consider the strengths and limitations of the studies, including study design, outcome definitions, and potential confounding factors that can impact interpretation of the evidence. Specifically, please address the following:

    a. Does the currently available clinical evidence demonstrate disparate performance in patients with darker skin pigmentation? If so, do you believe such disparate performance may lead to increased risks? Please include prescription use and OTC pulse oximeters (when used for medical purposes) in your deliberations.

    b. Do you believe the reported disparate performance or increased risks may be explained by factors other than darker skin pigmentation such as perfusion index, motion artifacts?

2. There are several tools to assess skin pigmentation, including but not limited to, colorimetry, spectrophotometer, melanosome volume fraction, and skin color scales (e.g., Fitzpatrick scale, von Luschan color scale). Please provide recommendations for studies evaluating pulse oximeters, for the following:

    a. Standardization of skin pigmentation assessment.

    b. Categorization and reporting of skin pigmentation data.

3. FDA currently recommends assessment of the effectiveness of pulse oximeters using Arms [Root mean square of pooled data pairs], and adherence to the currently recognized ISO 80601-2-61:2017 standard. For this variable (Arms), currently, pulse oximeters are expected to have accuracy within 1 standard deviation (SD) (66% of the time), and within 2 SD (95% of the time). Please address the following:

    a. Please discuss how accurate pulse oximeters should be for clinical use. In your discussion, please address whether the accuracy varies based on: (i) the clinical setting or (ii) the levels of SaO_2.

    b. Please discuss your recommendations for pulse oximeters performance across sub-groups of subjects with different skin pigmentation.

    c. Please discuss if Arms is an appropriate measure of device effectiveness for clinicians and users. If you do not believe Arms is appropriate, please discuss alternative methods to assess the accuracy of a pulse oximeter.

4. Current labeling for prescription use pulse oximeters is intended for clinicians and generally it does not address inaccuracies that may be associated with skin pigmentation. In your deliberations, please discuss:

    a. Labeling modifications to address inaccuracies that may be associated with skin pigmentation.

    b. Recommendations for the content of labeling for lay users who may use pulse oximeters at home.