American Association of Critical-Care Nurses Testimony
for the Food and Drug Administration

Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee

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Disclosure

- I have no financial disclosures or conflicts of interest with the presented material in this presentation

Progress Made

- The FDA has begun addressing disparities in pulse oximetry accuracy based on skin pigmentation, a result of inequities in the evaluation of this technology

- The Discussion Paper for today's session describes a clinical study design that requires:
  - Inclusion of persons with different skin tones in clinical testing of pulse oximeters, based on a validated scale - Monk Skin Tone (MST) scale
  - Measurement of skin pigmentation at the sensor site by assessing the Individual Typology Angle (ITA)

- Validated tools to measure skin pigmentation may be effective in addressing clinical study design flaws

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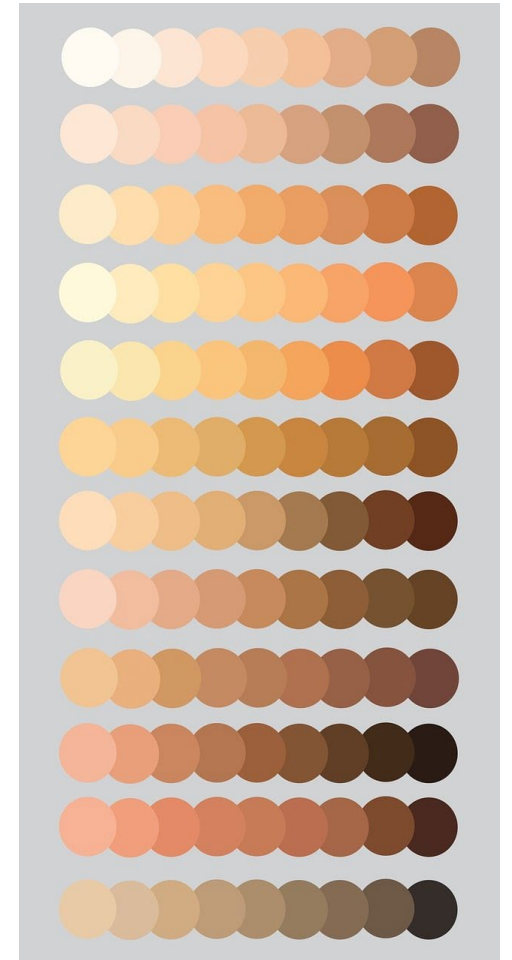
Raising Awareness: AACN Webinar

- Multiple factors interfere with pulse oximetry accuracy including: vasoconstriction, vasodilation, anemia, edema, and skin pigmentation

- Substantial evidence shows significant inaccuracy among patients who identify as Black, Asian, or Hispanic (Chelsey et al, 2022, Fawzy et al., 2022, and Andrist et al., 2022)

- While studies report differences in occult hypoxemia by race and ethnicity, it is more accurately related to the degree of skin pigmentation

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AACN Webinar: Key Points

The webinar highlighted the following implications:

- Minimize inaccuracy by using the correct sensor with the correct placement

- Be aware of limitations including the range of accuracy

- Interpret pulse oximetry in combination with other assessment data

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Key Opportunities

With pulse oximetry:

- Address risks of inaccuracy in consumer grade pulse oximeters

- Disseminate plain language content about the limitations of pulse oximetry

As a lesson forward:

- Set a precedent for improving clinical study designs across the board

- Examine clinical practices with a similar risk of disparate accuracy

- Convene professional societies and organizations that set guidelines to create and implement standards for inclusive practices

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