Video commentary for the Anesthesiology Devices Panel of the FDA Medical Devices Advisory Committee

Pulse oximetry and skin pigmentation

February 2, 2024

Presenter and disclosures

This video represents the views of the Anesthesia Patient Safety Foundation (APSF). It was prepared by Dr. Meghan Lane-Fall, Vice President of the APSF.

Dr. Lane-Fall discloses the following **conflicts or possible perceived conflicts** relevant to the topic of this presentation:

- Grants: Co-investigator, "Evaluating the relationship between skin color and pulse oximeter accuracy in children", NIH, PIs Halley Ruppel and Michael O'Byrne
- Speaking fees: Medtronic, "Health Equity and the Pulse Oximeter Paradox"

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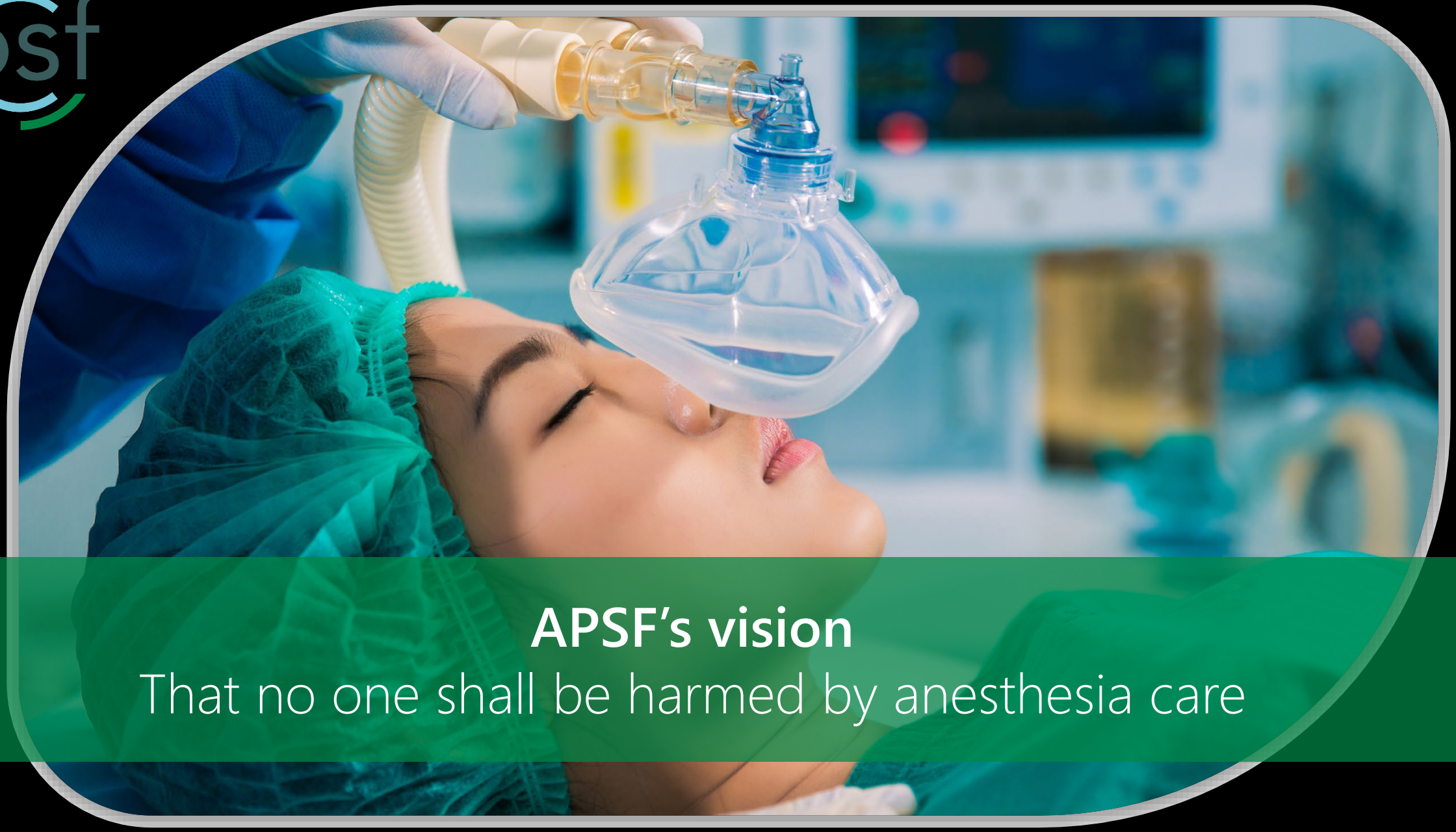
APSF was founded in 1985

Oldest national patient safety foundation in the United States



APSF's vision

That no one shall be harmed by anesthesia care

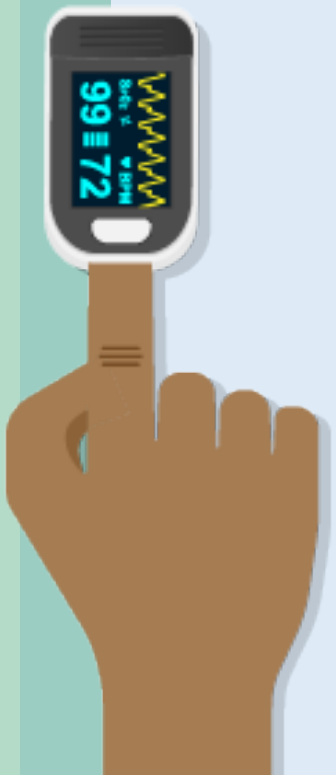
APSF includes all anesthesia and perioperative professionals

Anesthesiologists, CRNAs, AAs, nurses, surgeons

APSF builds partnerships and coalitions

Partners with industry, academia, regulatory agencies and others

The pulse oximeter is a key tool in the anesthesia professional's toolbox



Pulse oximetry allows close monitoring of blood oxygenation at important times in the perioperative journey:

- Pre-operative evaluation
- During surgery
- During recovery from surgery
- During pain procedures
- In the intensive care unit

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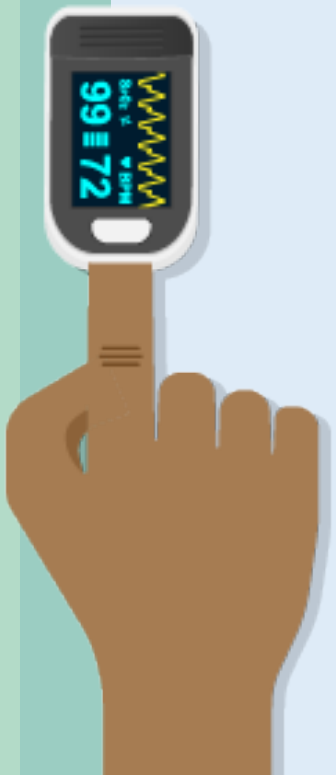
The pulse oximeter influences clinical decision making



Pulse oximeter values influence many decisions during the perioperative care continuum:

- Decision to proceed with surgery
- Decision to provide supplemental oxygen
- Oxygen modality and F_iO_2
- Decision to intubate or extubate
- PEEP titration
- Admission decisions (e.g., ICU, hospital)

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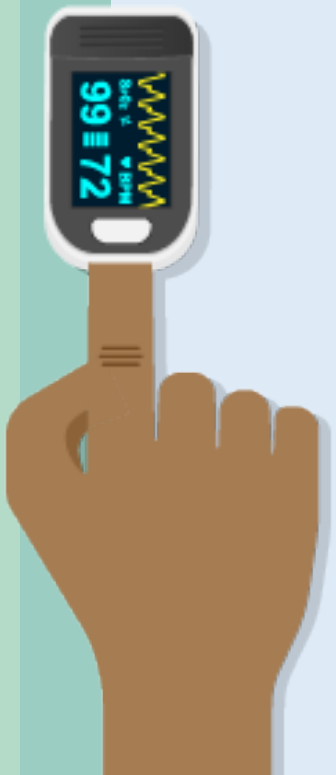
Bias in pulse oximetry threatens the ability to provide equitable care



- It is imperative that pulse oximeters exhibit minimal bias across clinically relevant SpO_2 ranges (85-100%)
- Bias in pulse oximetry is related to skin pigmentation; device testing requirements should focus on a range of skin pigments
- Other factors known to affect pulse oximeter accuracy (e.g., perfusion) must be considered alongside skin pigmentation

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