

Feedback to FDA on Proposed Clinical Study Design for Pulse Oximetry

January 15, 2024

Conflict of Interest Statement

I have NO financial disclosure or conflicts of interest with the presented material in this presentation

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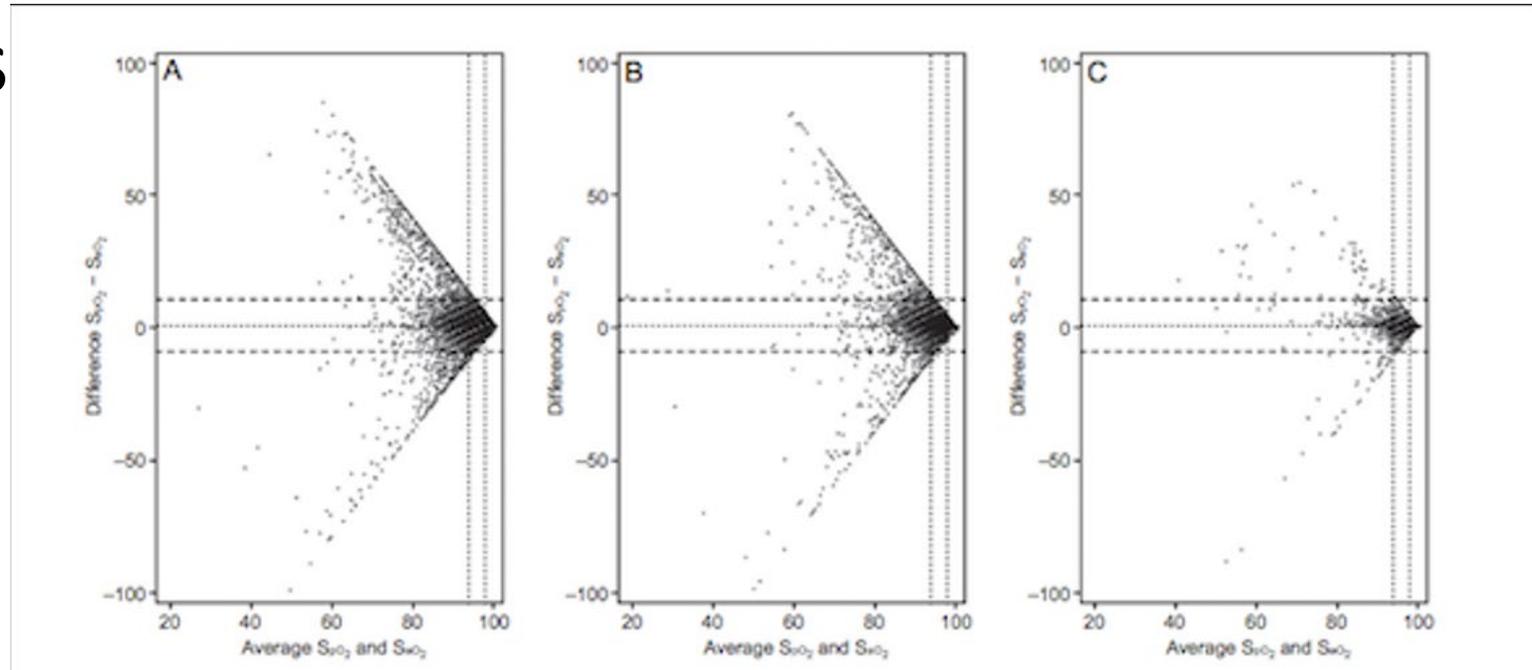
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Major Recommendations

- Agree with stratified design for Monk Skin Tone scale
- Test in simulated hypoperfusion
- Recruit to resolve racial question

Simulate Hypo-perfusion Conditions

- SpO₂-SaO₂ correlations are dynamic
- Test across all ranges to ensure robustness



Sample to Resolve Racial Question

- Greater mechanistic insight

- Restore public confidence

The New York Times

Pulse Oximeters May Be Less Accurate for Black People. Should You Use One?

The Washington Post
Democracy Dies in Darkness



🕒 This article was published more than 3 years ago

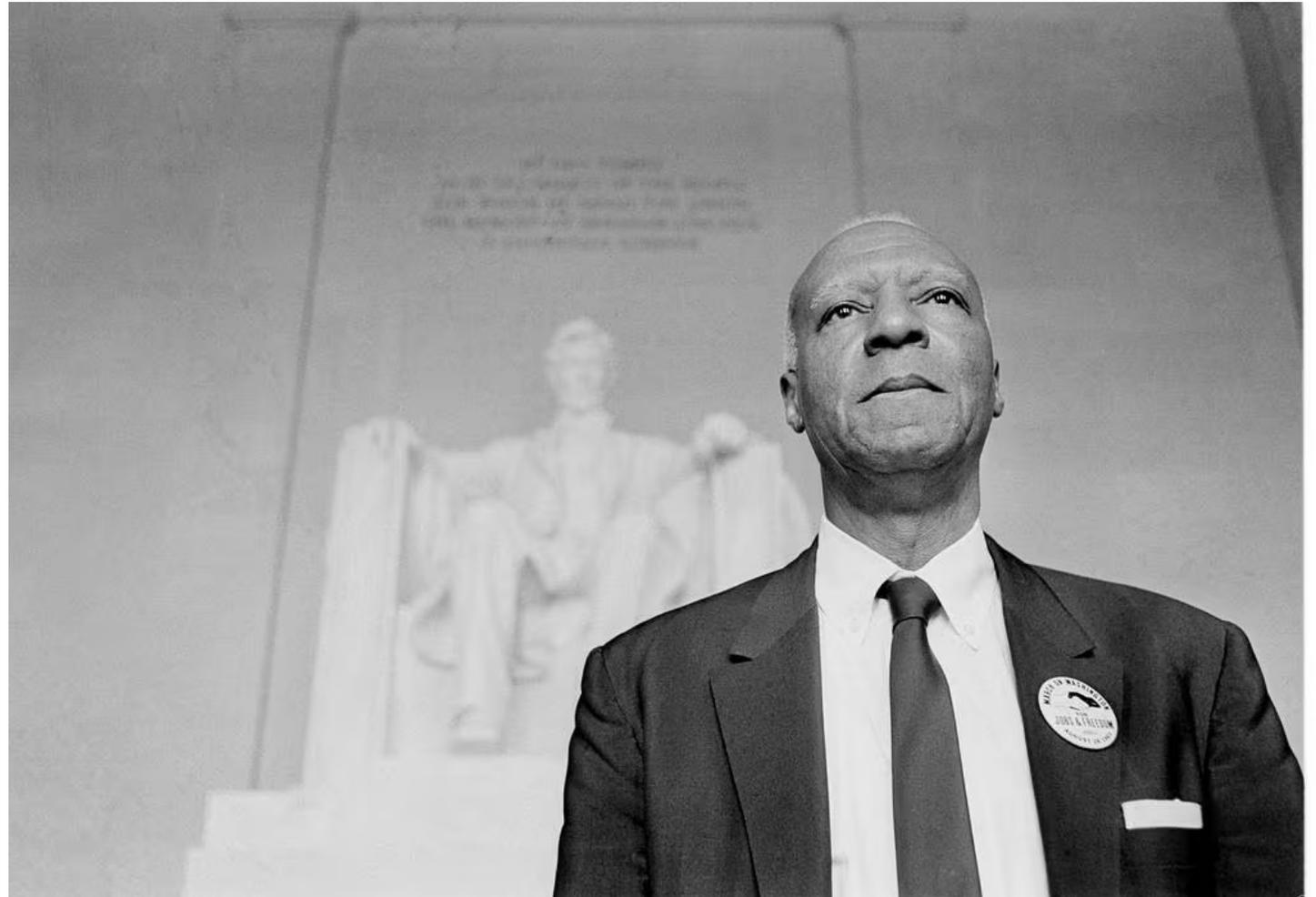
HEALTH Health Care Medical Mysteries Science Well+Being

Oxygen-monitoring devices may be less reliable in Black patients, researchers say

January 5, 2021 at 12:02 a.m. EST

A. Philip Randolph

- Founder, Brotherhood of Sleep Car Porters
- Proposed March on Washington
- Pressed for desegregation of defense industry (Executive Order 8802)



Summary Recommendations

- Agree with stratified design for Monk Skin Tone scale
- Test in simulated hypoperfusion conditions
- Recruit to resolve racial question