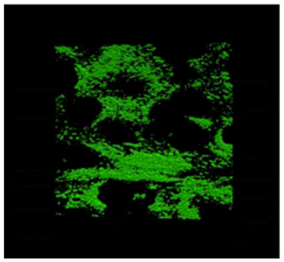
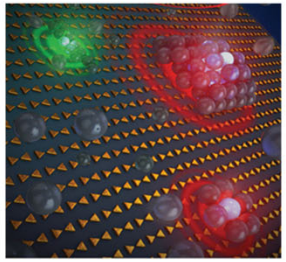
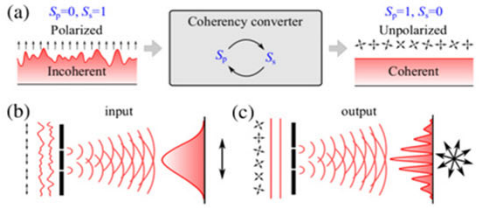
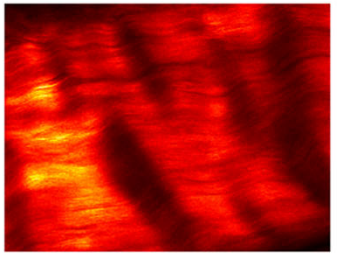






# Understanding the Challenges in Developing an Equitable Pulse Oximeter

Kimani C. Toussaint, Jr., Ph.D.

Thomas J. Watson, Sr. Professor of Science
Senior Associate Dean for Research and Strategic Initiatives,
Brown School of Engineering
Director, Brown-Lifespan Center for Digital Health

**Race and Ethnicity in Biomedical Research (January 31, 2024)**

# DISCLOSURE STATEMENT

The speakers has no disclosures.

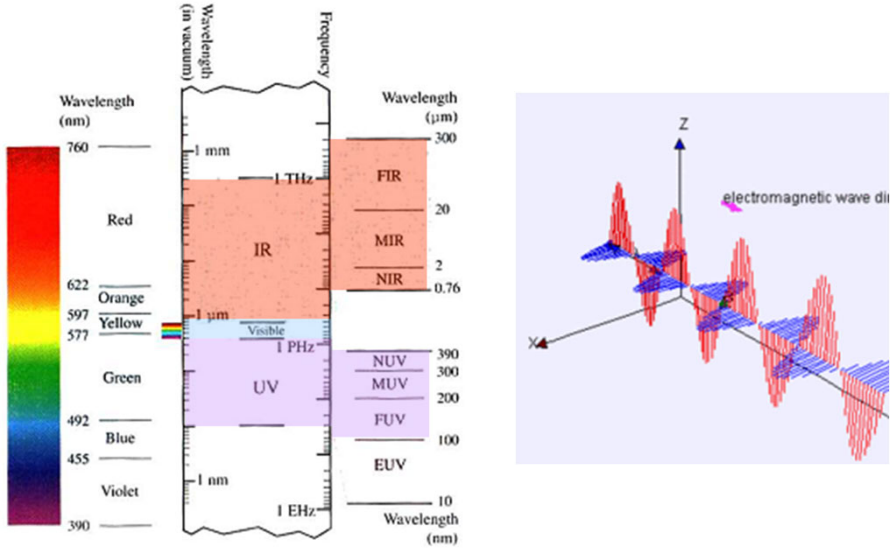
# OUTLINE OF TALK

A. Part I: Primer

B. Part II: Photoplethsymography (PPG)

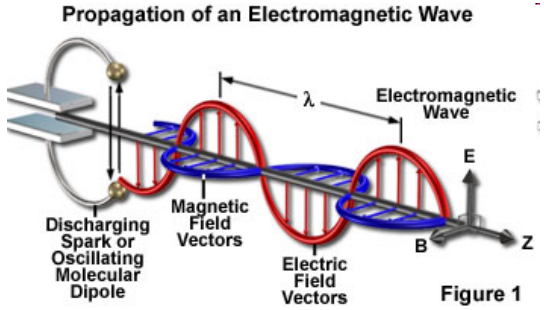
C. Part III: Bias with pulse oximetry

# LIGHT AND THE EM SPECTRUM










http://micro.magnet.fsu.edu/primer/java/polarizedlight/emwave/index.html

https://en.wikipedia.org/wiki/Electromagnetic_radiation

Image source: Fundamentals of Photonics

$$n = \frac{c_o}{c}$$

Speed of light in vacuum

Speed of light in a medium

$c_o = 3.0 \times 10^8$ m/s

Travel time

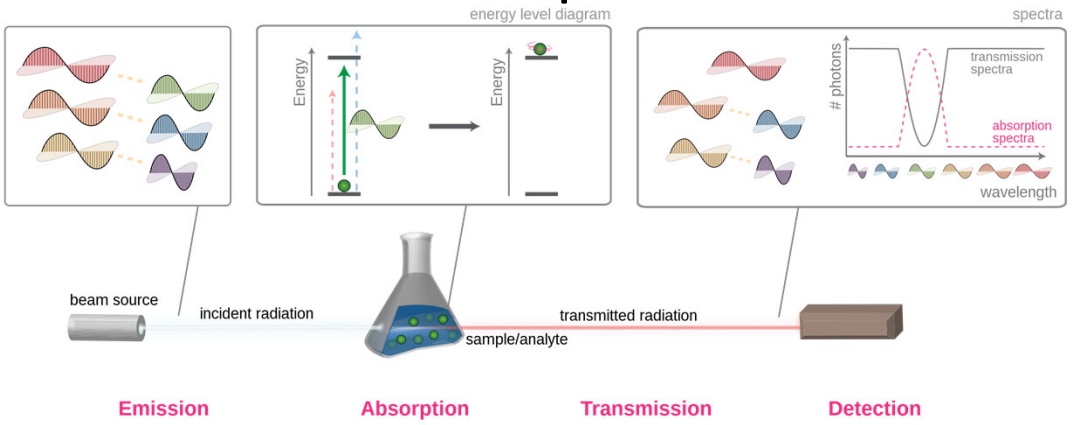
Optical pathlength

$$t = \frac{d}{c} = \frac{nd}{c_o}$$

- *n* generally will depend on $\lambda$
- *n* can depend on position in a inhomogeneous medium

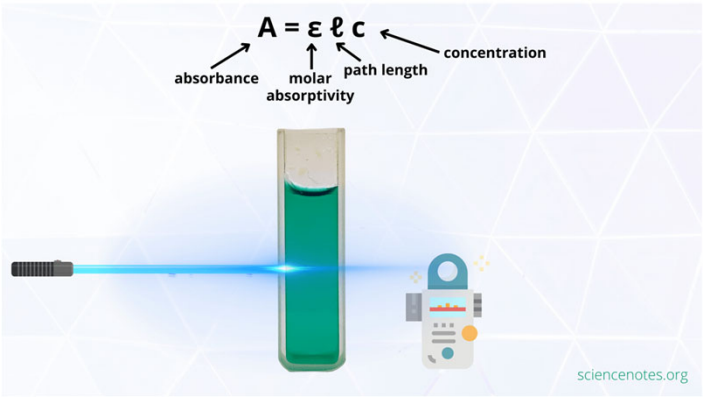
# LIGHT-MATTER INTERACTIONS

## Absorption




https://commons.wikimedia.org/wiki/File:Spectroscopy_overview.svg

Beer–Lambert law

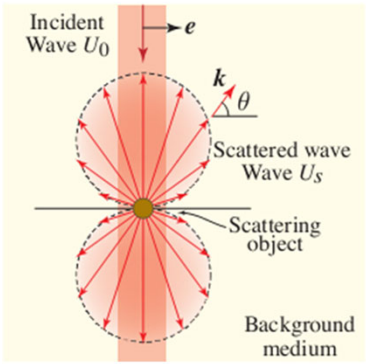



Assumptions:

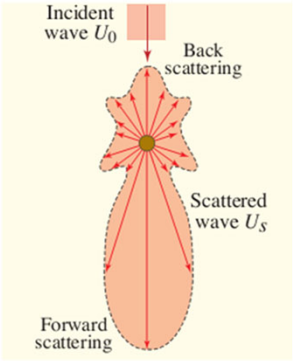
- Dilute and homogeneous
- Non-turbid
- Non-interacting species
- Parallel incoming rays

## Scattering

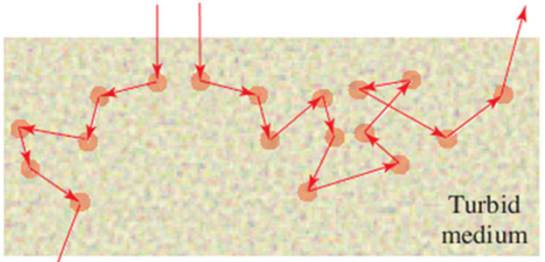
Rayleigh Scattering




Mie Scattering




Multiple Scattering



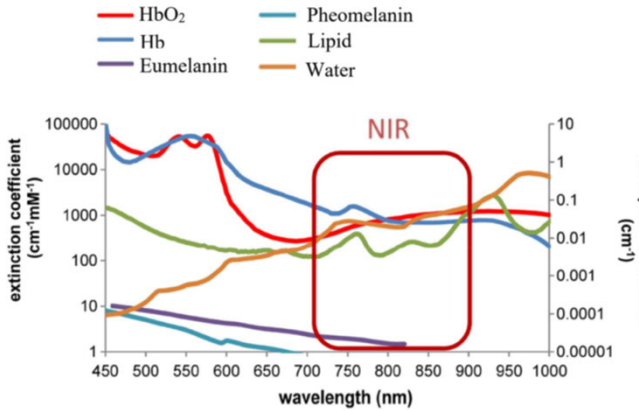

- Common in atmosphere, biological tissues, and other turbid media
- Leads to randomization and attenuation

Image source: Introduction to Subsurface Imaging

**Part I: Primer**

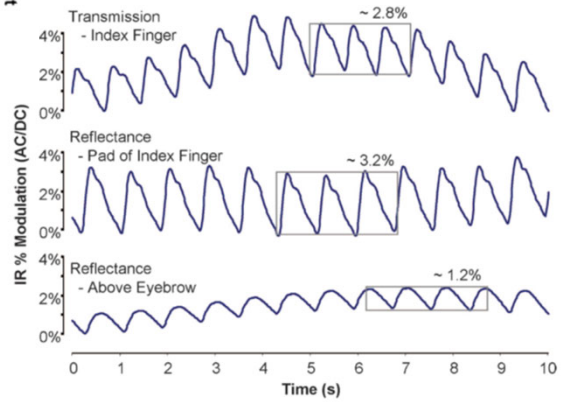
# PHOTOPLETHSYMOGRAPHY (PPG) AND PULSE OXIMETRY

- Optical technique to measure volumetric changes in blood circulation
- Enables continuous, real-time monitoring
- Basis for pulse oximetry
- Pulse oximetry synchronizes PPG signal to the cardiac cycle
- We care about fraction of $HbO_2$ relative to total hemoglobin




Lasers in Medical Science (2020) 35:1759–1764

*Signal can vary per site!*




Anesth Analg. 2007 Dec;105(6 Suppl):S10-S17.

Beer-Lambert law

$$R = \frac{R_{\lambda_1}}{R_{\lambda_2}} = \frac{AC_{\lambda_1}/DC_{\lambda_1}}{AC_{\lambda_2}/DC_{\lambda_2}}$$

$aR^2 + bR + c$

**Empirically calibrated**

$$SpO_2 = \frac{[HbO_2]}{[HbO_2] + [Hb]} \times 100\% = \frac{C_{HbO_2}}{C_{HbO_2} + C_{Hb}} \times 100\%$$

# EVIDENCE OF BIAS WITH PULSE OXIMETRY

The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

## Racial Bias in Pulse Oximetry Measurement

**TO THE EDITOR:** Oxygen is among the most frequently administered medical therapies, with a level that is commonly adjusted according to the reading on a pulse oximeter that measures patients' oxygen saturation. Questions about pulse oximeter technology have been raised, given its original development in populations that were not racially diverse.[1,2] The clinical significance of potential racial bias in pulse oximetry measurement is unknown.

Our study involved adult inpatients who were receiving supplemental oxygen at the University

We analyzed 10,789 pairs of measures of oxygen saturation by pulse oximetry and arteria oxygen saturation in arterial blood gas obtainec from 1333 White patients and 276 Black patient in the University of Michigan cohort and 37,308 pairs obtained from 7342 White patients anc 1050 Black patients in the multicenter cohort. I the University of Michigan cohort, among th patients who had an oxygen saturation of 92 t 96% on pulse oximetry, an arterial oxygen satu ration of less than 88% was found in 88 of 74 arterial blood gas measurements in Black patient

Research

JAMA Internal Medicine | Original Investigation

## Racial and Ethnic Discrepancy in Pulse Oximetry and Delayed Identification of Treatment Eligibility Among Patients With COVID-19

Ashraf Fawzy, MD, MPH; Tianshi David Wu, MD, MHS; Kunbo Wang, MS; Matthew L. Robinson, MD; Jad Farha, MD; Amanda Bradke, MD, MA; Sherita H. Golden, MD, MHS; Yanxun Xu, PhD; Brian T. Garibaldi, MD, MEHP

**IMPORTANCE** Pulse oximetry guides triage and therapy decisions for COVID-19. Whether reported racial inaccuracies in oxygen saturation measured by pulse oximetry are present in patients with COVID-19 and associated with treatment decisions is unknown.

**OBJECTIVE** To determine whether there is differential inaccuracy of pulse oximetry by race or ethnicity among patients with COVID-19 and estimate the association of such inaccuracies with time to recognition of eligibility for oxygen threshold-specific COVID-19 therapies.

**DESIGN, SETTING, AND PARTICIPANTS** This retrospective cohort study of clinical data from 5 referral centers and community hospitals in the Johns Hopkins Health System included patients with COVID-19 who self-identified as Asian, Black, Hispanic, or White.

**EXPOSURES** Concurrent measurements (within 10 minutes) of oxygen saturation levels in arterial blood ($SaO_2$) and by pulse oximetry ($SpO_2$).

**MAIN OUTCOMES AND MEASURES** For patients with concurrent $SpO_2$ and $SaO_2$ measurements, the proportion with occult hypoxemia ($SaO_2$<88% with concurrent $SpO_2$ of 92%-96%) was compared by race and ethnicity, and a covariate-adjusted linear mixed-effects model was produced to estimate the association of race and ethnicity with $SpO_2$ and $SaO_2$ difference. This model was applied to identify a separate sample of patients with predicted $SaO_2$ levels of 94% or less before an $SpO_2$ level of 94% or less or oxygen treatment initiation. Cox proportional hazards models were used to estimate differences by race and ethnicity in time to recognition of eligibility for guideline-recommended COVID-19 therapies, defined as an $SpO_2$ level of 94% or less or oxygen treatment initiation. The median delay among individuals who ultimately had recognition of eligibility was then compared.

**RESULTS** Of 7126 patients with COVID-19, 1216 patients (63 Asian [5.2%], 478 Black [39.3%], 215 Hispanic [17.7%], and 460 White [37.8%] individuals; 507 women [41.7%]) had 32 282 concurrently measured $SpO_2$ and $SaO_2$. Occult hypoxemia occurred in 19 Asian (30.2%),

Editorial

Supplemental content

THE ROOT | HOME | LATEST | THE ROOT 100 | NEWS | CULTURE | POLITICS | ENTERTAINMENT | BEAUTY/STYLE | VSB

## Black Covid Patients Were Delayed Life-Saving Care Due To Faulty Medical Device

A new study shows that false pulse oximeter readings for Black, Latino and Asian Covid patients resulted in doctors' decision to postpone treatment.

By Candace McDuffie | Friday 10:55AM | Comments (14) | Alerts

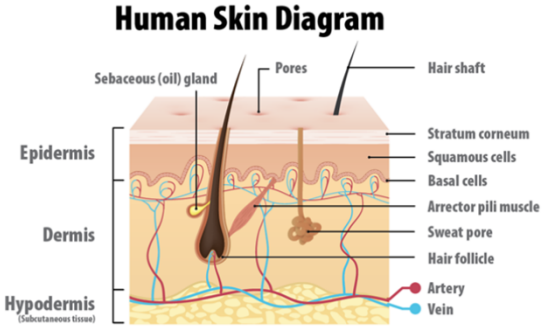
Photo: SeventyFour (Shutterstock)

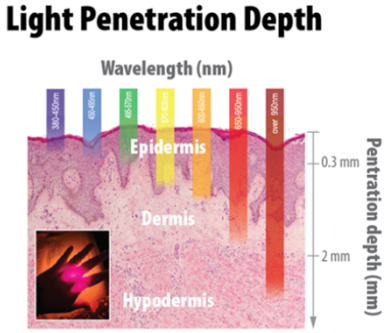
Friday 6:56PM

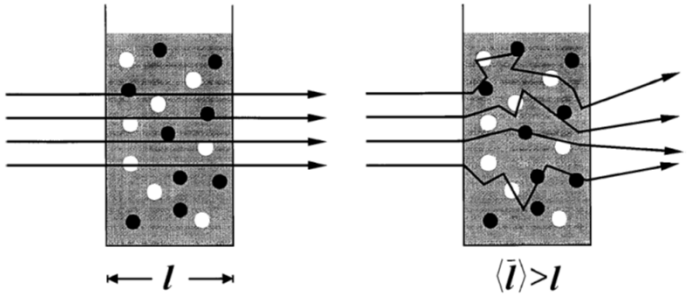
- Can overestimate SpO2 readings for Blacks, Hispanics, and Asians
- Blacks ~3X more likely to suffer from silent hypoxia
- Black patients with COVID had a median delay of 1 hr longer for treatment eligibility

**Part III: Bias with pulse oximetry**

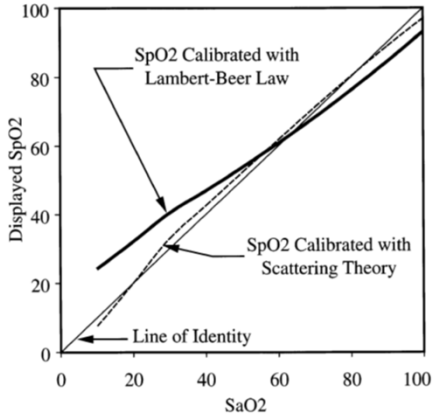
# LIGHT PROPAGATION IN TISSUE SECTION

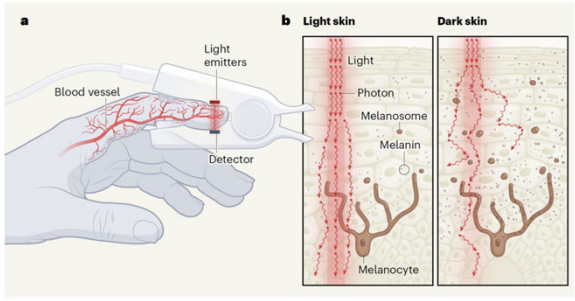



Eur J. Obstet Gynecol Reprod Biol 1997;72:S9–19




Expert insight into current research

**News & views**

Racism in science

Forum: Medical devices

**Skin colour affects oxygen-sensor accuracy**

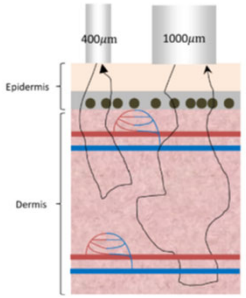
COVID-19 broadened the use of pulse oximeters for rapid blood-oxygen readings, but it also highlighted the fact that skin pigmentation alters measurements. Two groups of researchers analyse this issue, and its effects on people with dark skin.

Matthew D. Keller & Brandon Harrison-Smith
Pulse-oximetry errors affect patient outcomes

Since Sjoding and colleagues' report, several large retrospective studies have confirmed that darker-skinned people (those self-identifying as Black, Asian, Hispanic or a combination of these) are more likely than had equivalent arterial blood-gas values[1]. A more comprehensive analysis showed that, even when baseline health conditions are taken into account, people with occult hypoxaemia are prone to organ dysfunction and in-hospital mortality, and that Black people in this group have the worst organ dysfunction[2].

Although clinical reports of skin-colour bias in pulse oximetry were not widespread until the COVID-19 pandemic, evidence for this issue has been accumulating for decades[3,4]. A comparison reported in February found that pulse-oximeter readings from nine devices were consistently less accurate for darker-skinned people than for lighter-skinned people[5]. But the study also found that testing healthy individuals under carefully controlled laboratory conditions resulted in fewer cases of occult hypoxaemia than are measured in hospitals. In fact, none of the 491 people who were tested by the authors had readings consistent with occult hypoxae-






Journal of Biomedical Optics 24(12), 127001 (December 2019)

**Multidiameter single-fiber reflectance spectroscopy of heavily pigmented skin: modeling the inhomogeneous distribution of melanin**

- Cross section of human skin
- Clearly not homogenous
- Wavelength-dependent penetration depth and scattering
- Move towards a **modified Beer-Lambert law**

**Part III: Bias with pulse oximetry**

# RETHINKING SKIN-TONE SYSTEMS

## Fitpatrick


Fitzpatrick T. The validity and practicality of sun-reactive skin types I through VI. Arch Dermatol (1988);124:869–71

## Martin-Massey

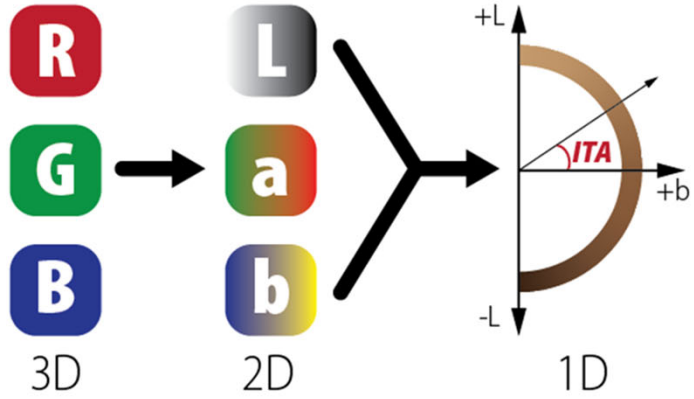

Massey, D. S., and J. A. Martin (2003), "The NIS Skin Color Scale"

Most inclusive

## Monk


Monk, Ellis. "Monk Skin Tone Scale," (2019). https://skintone.google

## Tristimulus Colorimetry




**Part III: Bias with pulse oximetry**

# WHERE DO WE GO FROM HERE?

- Recognize that equitable biomedical devices is a technological Grand Challenge!
- Include skin tone data for context for optical-based biomedical devices
- Be mindful of ethics around "race-based algorithms"→ increased disparities
- Multi-year support for new, innovative technologies that leverage a convergence of disciplines
- All impacted communities should have a seat at the table at all stages, especially for clinical trials and calibration studies

# ACKNOWLEDGEMENTS

## Thanks to NASEM Workshop Organizers!

**About PROBE Lab**

**About CDH**