Meeting the Challenge
Population Descriptors in Dermatology Research Studies

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Disclosures

- L’Oreal
- Abbvie
- Janssen
- Johnson and Johnson
- Bristol Myers Squibb
- SkinCeuticals
- Pfizer

•**Skin color** is the primary physical attribute that determines one's race.

It it is essential to note that skin pigmentation also holds significant biological considerations. Therefore, it is critical to engage dermatologists, the experts in diagnosing and treating skin diseases, in discussions to identify challenges and solutions for effectively categorizing patient populations.

Brazilian artist Angélica Dass inspires us to rethink the concept of race by showcasing the extensive diversity of human skin colors in her global photographic mosaic, **Humanae.**

Overview

1. Lack of diversity in clinical trial representation and the use of population descriptors through a dermatologic lens.
2. Pitfalls of conflating race and pigmentation, and challenges of measuring skin color
3. Lessons learned from dermatology-ongoing efforts aimed at improving how to categorize human populations best

Scope of the Problem
Need for broader representation in dermatologic clinical trials.

Results

626 published RCTs

- Adequate diversity was defined as 20% of participants identifying as minorities (African American, Hispanic, Asian/PI, and Native).
- 532 (85%) reported sex of participants
- Reported on race and ethnicity
  - 58 / 97 (59.8%) U.S. Studies
  - 52 / 626 (11.3%) International Studies
- Of the RCTs in the US that reported race, 74.4% of participants were white.

Representation varied by disease

- 30% of Psoriasis RCTs exhibited adequate diversity
- 73.9% of Acne RCTs
- 91.7% of Eczema RCTs

Clinical Review & Education

JAMA Dermatology | Review

Diversity in Dermatology Clinical Trials
A Systematic Review

Alexandra Charrow, MD, MBE; Fan Di Xia, AB; Cara Joyce, PhD; Arash Mostaghimi, MD, MPA, MPH

IMPORTANCE Though there have been significant shifts in US demographic data over the past 50 years, research cohorts lack full racial and ethnic representation. There is little data available regarding the diversity of dermatology research cohorts with respect to sex, race, and ethnicity.

OBJECTIVE To characterize and assess the representation of racial and ethnic minorities and women in randomized controlled trials across a range of dermatologic conditions.

EVIDENCE REVIEW All randomized clinical trials (RCTs) were identified between July 2010 and July 2015 within the PubMed database using the following keywords: "psoriasis," "atopic dermatitis," "acne," "vitiligo," "seborrheic dermatitis," "alopecia areata," and "lichen planus." Diverse study populations were defined as including a greater than 20% racial or ethnic minority participants based on US census data. The distributions of sex and race groups in studies were compared by journal type, disease type, and funding source.

FINDINGS Of the 626 articles reporting RCTs included in this analysis, 532 (85.0%) reported the sex of study participants. Overall, 52 of 626 international (11.3%) studies and 58 of 97 studies (59.8%) conducted exclusively within the United States reported on the racial or ethnic demographics of study participants. Across all RCTs exclusively recruited within the United States that reported race, 74.4% of study participants were white. Disease type was significantly associated with the degree of racial diversity ($P < .001$) within a study cohort: 30.0% of US-based psoriasis had more than 20% racially or ethnically diverse research participants as compared with 73.9% of acne studies and 91.7% of eczema studies.

CONCLUSION AND RELEVANCE Dermatologic clinical trials within the United States reflect the growing diversity of the US population. Reporting of both sex and racial/ethnic diversity of research cohorts is still lacking, especially among studies conducted outside of the United States.

JAMA Dermatol. 2017;153(2):193-198. doi:10.1001/jamadermatol.2016.4129

Charrow et al. *JAMA Dermatol*. 2017;153(2):193-198.

JAMA Dermatology | Brief Report

Assessment of Changes in Diversity in Dermatology Clinical Trials Between 2010-2015 and 2015-2020

A Systematic Review

Vivien Chen, BS; Shifa Akhtar, BS; Caiwei Zheng, BA; Vignesh Kumaresan, MS; Keyvan Nouri, MD, MBA

(2010 – 2015) vs. 2015 - 2020

Rates for reporting race and ethnicity in US studies have increased from

- 59.8% (2010 – 2015)
- 71.9% (2015-2020)

Dermatologic Clinical Trials

The proportion of trials that include at least 20% of non-white individuals remained stagnant.

37/97 = **38%** (2010 – 2015)

53/139 = **38%** (2015 – 2020)

Chen et al. *JAMA Dermatol.* 2022;158(3):288-292

Growing Urgency to Address Population Categories

The Reporting of Race and Ethnicity in Medical and Science Journals
Comments Invited

Annette Flanagin, RN, MA[1]; Tracy Frey, BA[2]; Stacy L. Christiansen, MA[3]; et al

≫ Author Affiliations | Article Information

JAMA. 2021;325(11):1049-1052. doi:10.1001/jama.2021.2104

Increased clarity and transparency in reporting racial labels in research studies.

Flanagin et al. *JAMA*. 2021;325(11):1049-1052.

Hidden in Plain Sight — Reconsidering the Use of Race Correction in Clinical Algorithms

Darshali A. Vyas, M.D., Leo G. Eisenstein, M.D., and David S. Jones, M.D., Ph.D.

Call to remove race from clinical care algorithms.

Vyas DA et al. N Engl J Med. 2020;383(9):874-882.

Viewpoint ONLINE FIRST

December 13, 2023

The Problematic Legacy of Skin-Thickness Measurement in Race-Based Dermatology Research

Nakisa B. Sadeghi, MD, MPH[1,2]; Adewole S. Adamson, MD, MPP[3,4]

Issues with the inappropriate use of race in dermatologic research.

Sadeghi JAMA Dermatol. Published online December 13, 2023. doi:10.1001/jamadermatol.2023.5018

JOURNAL ARTICLE

Equity in skin typing: why it is time to replace the Fitzpatrick scale Get access

U.K. Okoji, S.C. Taylor, J.B. Lipoff

British Journal of Dermatology, Volume 185, Issue 1, 1 July 2021, Pages 198–199, https://doi.org/10.1111/bjd.19932

Revision of biased, misused skin classification instruments.

Okoji UK et al. Br J Dermatol. 2021;185(1):198-199.

Race vs. Skin Pigmentation

Skin pigmentation has been correlated with race and ethnicity.

- Skin color evolved as a function of physiology, climate, and genetics, rather than race.
- Pigmentation selects for protection against UV light, which is a main determinant of skin color.

Jablonski. *Am J Phys Anthropol.* 2021;175(2):437-447.

- **Visscher et al. reported a modest correlation between melanin content and race or ethnicity.**

Visscher et al. Facial Plast Surg Clin North Am. 2017;25:119-25.

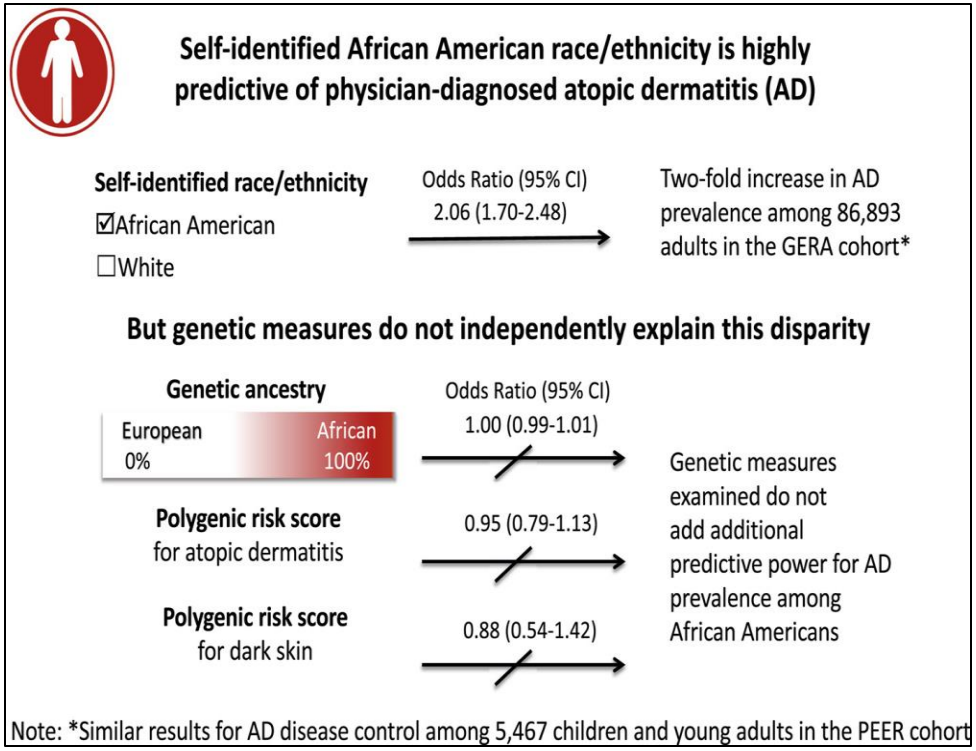
Research Implications

Correlating skin color with race can be interpreted incorrectly by **implying differences are due to** biological variations**.**

Race as a variable without considering context **can propagate ideas of immutable racial difference.**

An example is the discussion surrounding disparities in atopic dermatitis.

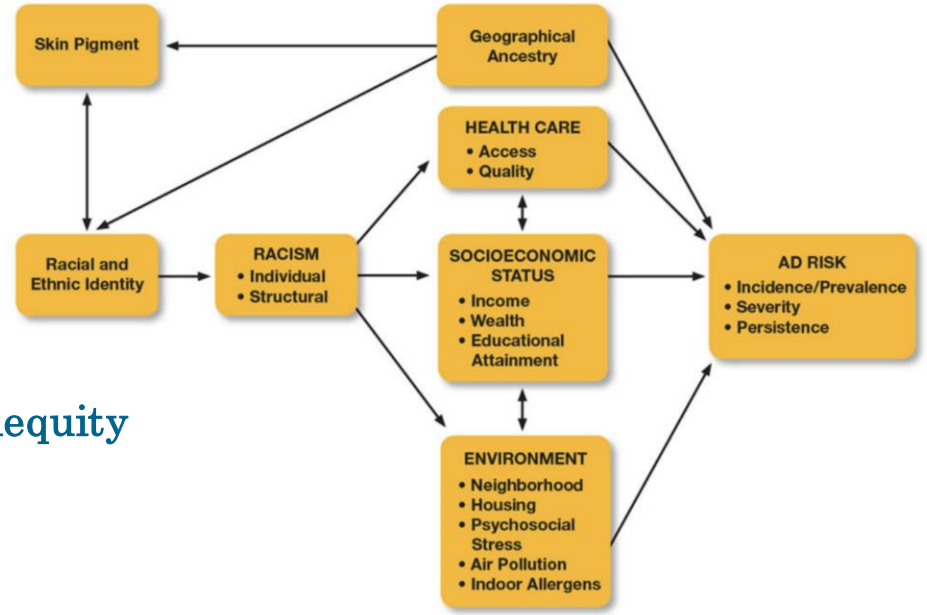
Genetic ancestry does not explain increased atopic dermatitis susceptibility or worse disease control among African American subjects in 2 large US cohorts.



Abuabara K et al. *J Allergy Clin Immunol.* 2020;145(1):192-198.e11

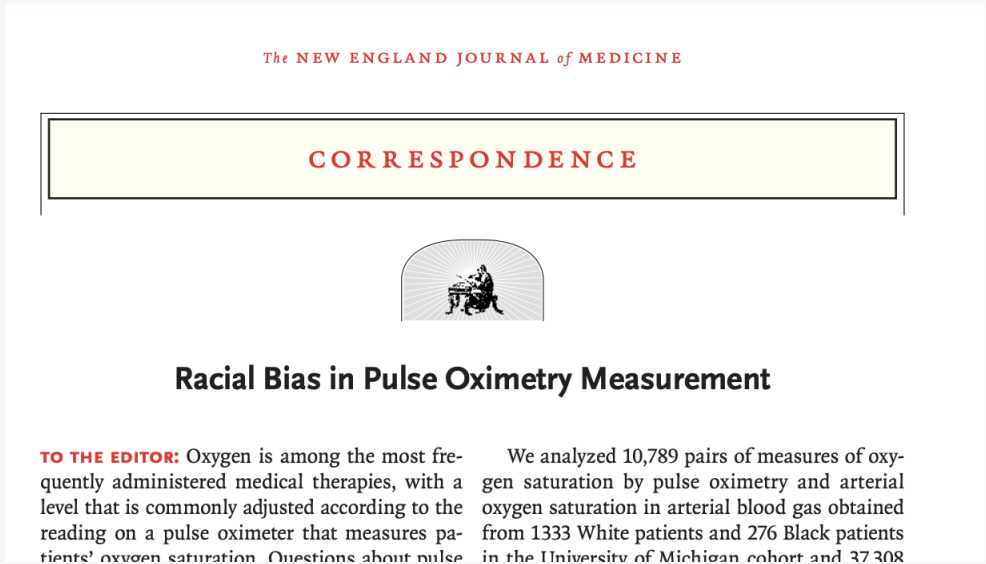
- **Skin pigment did not correlate with AD risk, provides evidence that AD is likely independent of skin pigment.**
- Differences in pigmentation between African American and White subjects do not explain the AD prevalence difference.
- **SDOH and environmental factors are likely to play an important role in AD disparities and warrant additional research.**
- Sub-analyses to detect heterogeneous treatment responses should be based on **social**, **environmental**, and **demographic** factors in addition to biomarkers or genetic polymorphisms.

Reframing racial and ethnic disparities in atopic dermatitis in Black and Latinx populations.



Driven by the more powerful sources of inequity
→ structural and individual racism.

Croce et al. *J Allergy Clin Immunol.* 2021;148(5):1104-1111



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

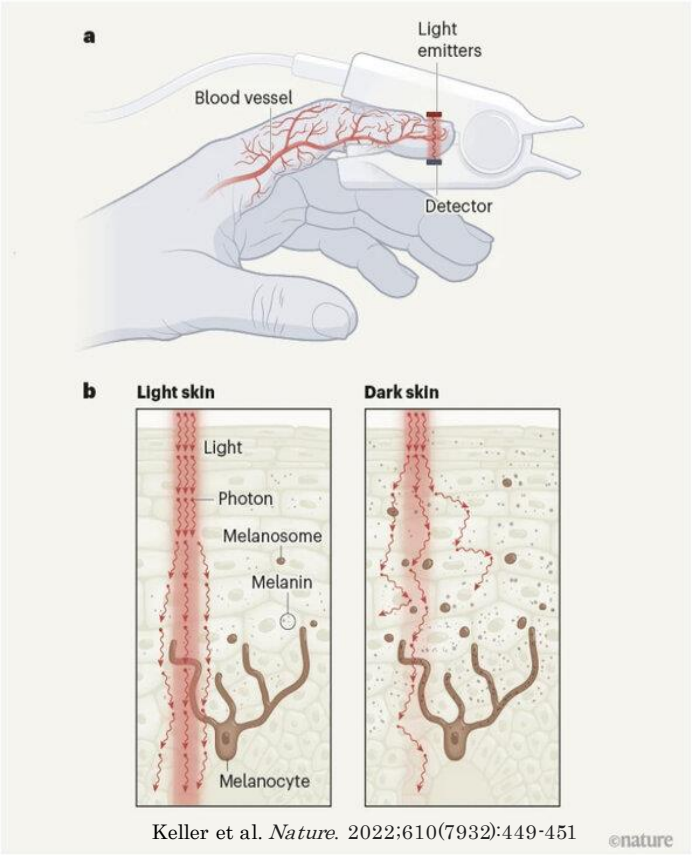
We analyzed 10,789 pairs of measures of oxygen saturation by pulse oximetry and arterial oxygen saturation in arterial blood gas obtained from 1333 White patients and 276 Black patients in the University of Michigan cohort and 37,308

Sjoding MW et al., *N Engl J Med*. 2020;383(25):2477-2478

RESULTS

- Black patients had nearly 3x the frequency of occult hypoxemia not detected by pulse oximetry, compared to White patients.

- **Implications**
  - Pulse ox measurements used as a triage mechanism can put Black patients at the risk for hypoxemia.



Keller et al. *Nature*. 2022;610(7932):449-451 ©nature

Skin colour affects the accuracy of medical oxygen sensors

Matthew D Keller, Brandon Harrison-Smith, Chetan Patil, Mohammed Shahriar Arefin

Pulse oximeters are less accurate in dark-skinned individuals at lower saturation (<80%) resulting in overestimation.

Efforts to redesign the device algorithm related to light absorption with a calibration based on SKIN COLOR are underway.

A more accurate method for classifying individuals by degree of skin pigmentation should be considered.

Classifying skin color

Classifying Skin has been Unsuccessful

Abbreviated historical snapshot	
Von Luschan	late 1800s
Fitzpatrick	1975
Martin and Massey	2003
Monk	2019
Colorimetric	2023

More than 20 scales have been created, only a small fraction are validated.

Only Fitzpatrick Skin Typing System is used widely.

Colorimetric scale, Cohen el al.

Cohen et al., *Cureus*. 2023;15(11):e48132

Fitzpatrick Skin Type: A flawed and biased Gold Standard

FST flaws

- Used beyond its intended purpose: predicting response to UV light
- Survey by Taylor et al. showed that 31% of dermatologists use FST to document race, and 47%use it to describe skin color.
- Limited response options : 40-60% of individuals could not select a FST category
- Some propose a shift to describing skin color in hues: (dark brown, medium brown, etc.).

Ware OR, Dawson JE, Shinohara MM, Taylor SC. Racial limitations of fitzpatrick skin type. Cutis. 2020;105(2):77-80.

Lessons from Dermatology

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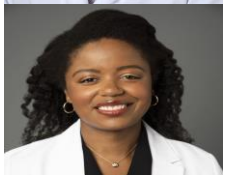

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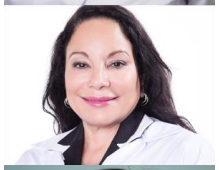

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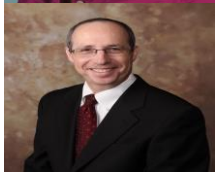

Jonathan Weiss, MD
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Analysis of the Use of Population Descriptors in Dermatology Research Studies

Virtual working group meeting

June 2022

Meeting the challenge summit- diversity in dermatology clinical trials

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Jul 2023

Findings from the 2022 Summit published in JAMA Dermatology.

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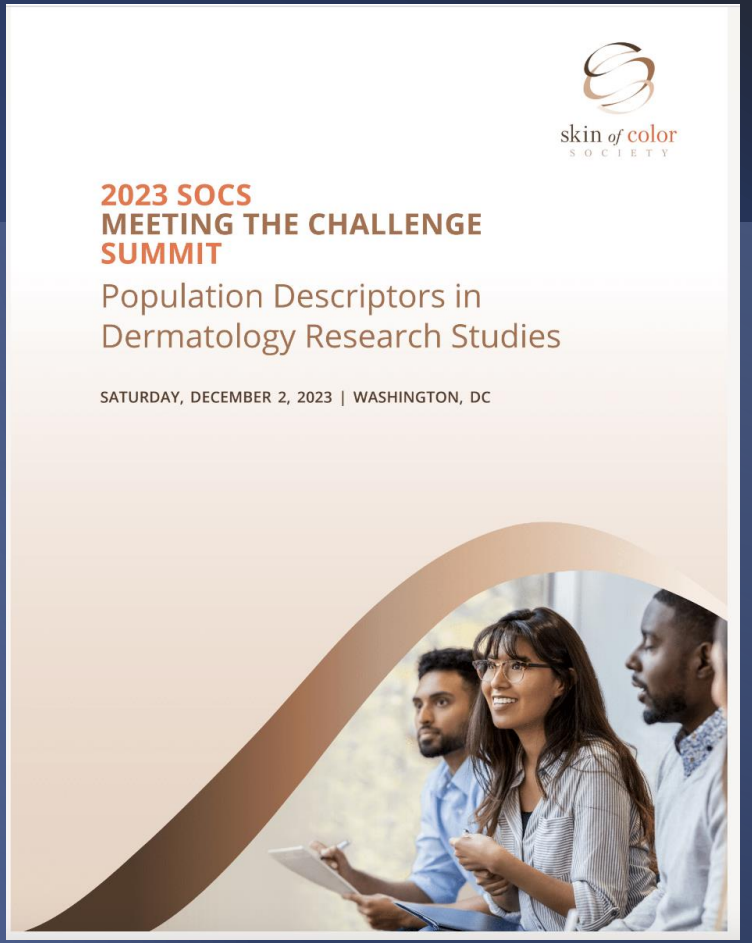
2024

Skin Scale Working Group Effort in progress.

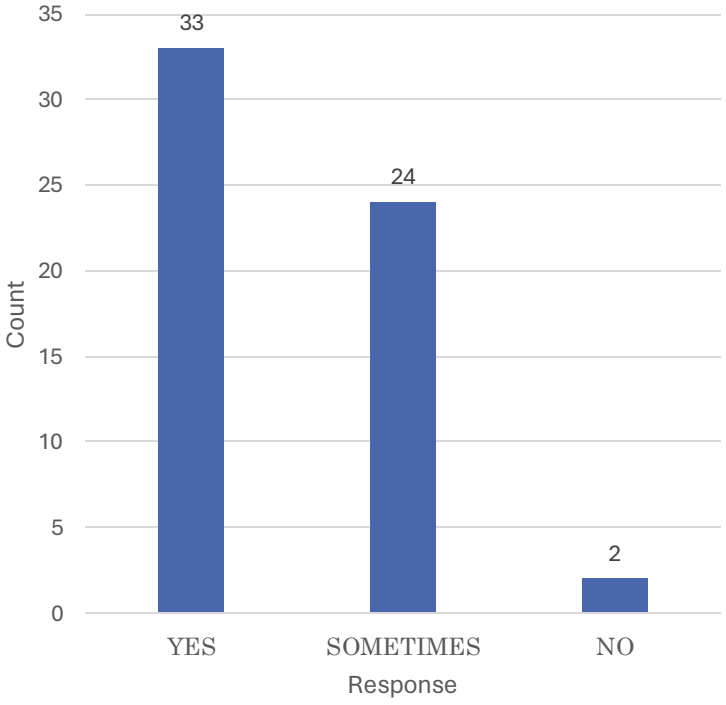
Analysis of the Use of Population Descriptors in Dermatology Research Studies



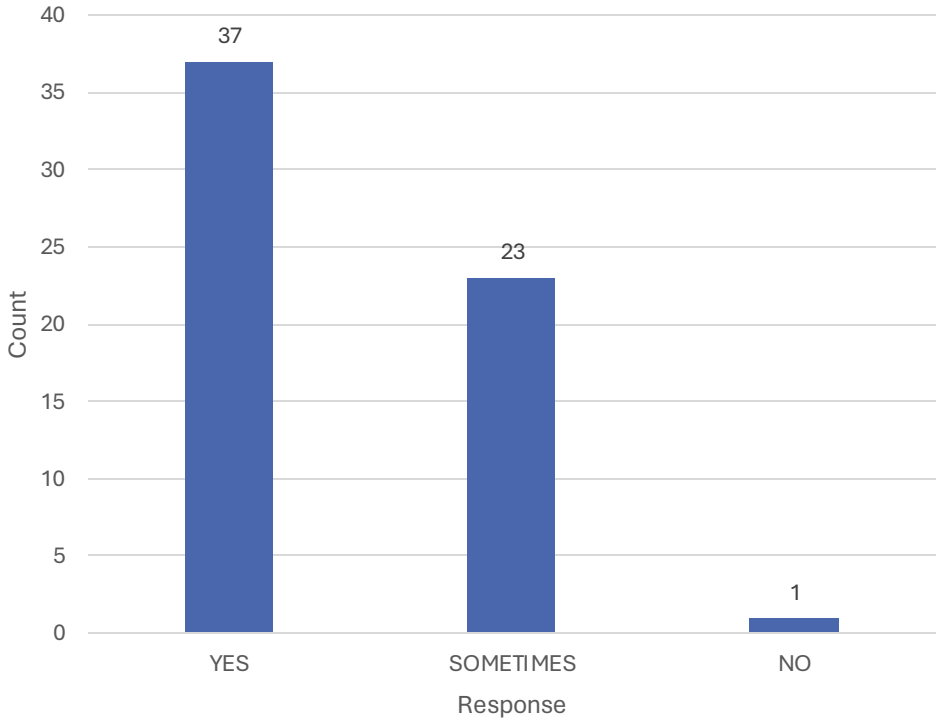
Summit Objectives

- To examine the use of demographic descriptors in dermatology and the context in which they are needed.
- To develop a framework for guidelines and recommendations on using demographic descriptors in research studies and clinical practice.
- To develop strategies for implementation and dissemination to the broader dermatologic community.

Is capturing RACE appropriate in dermatology research studies?

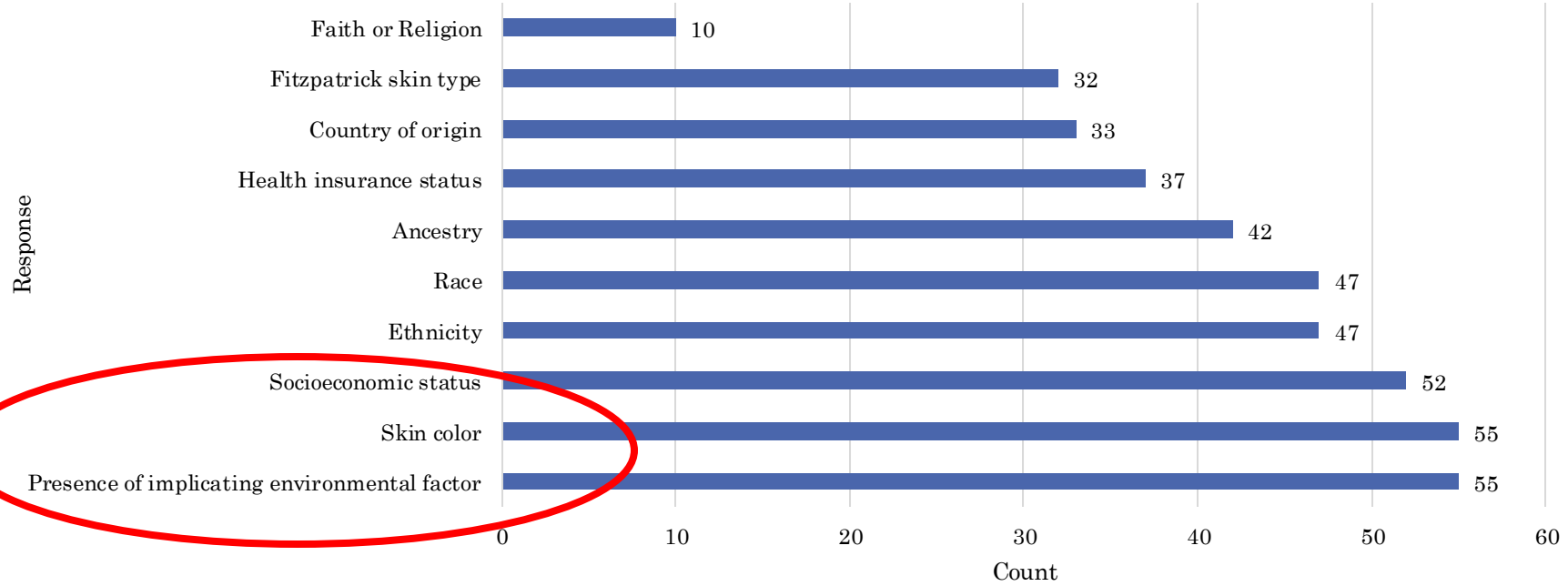


Is capturing ETHNICITY appropriate in dermatology research studies?

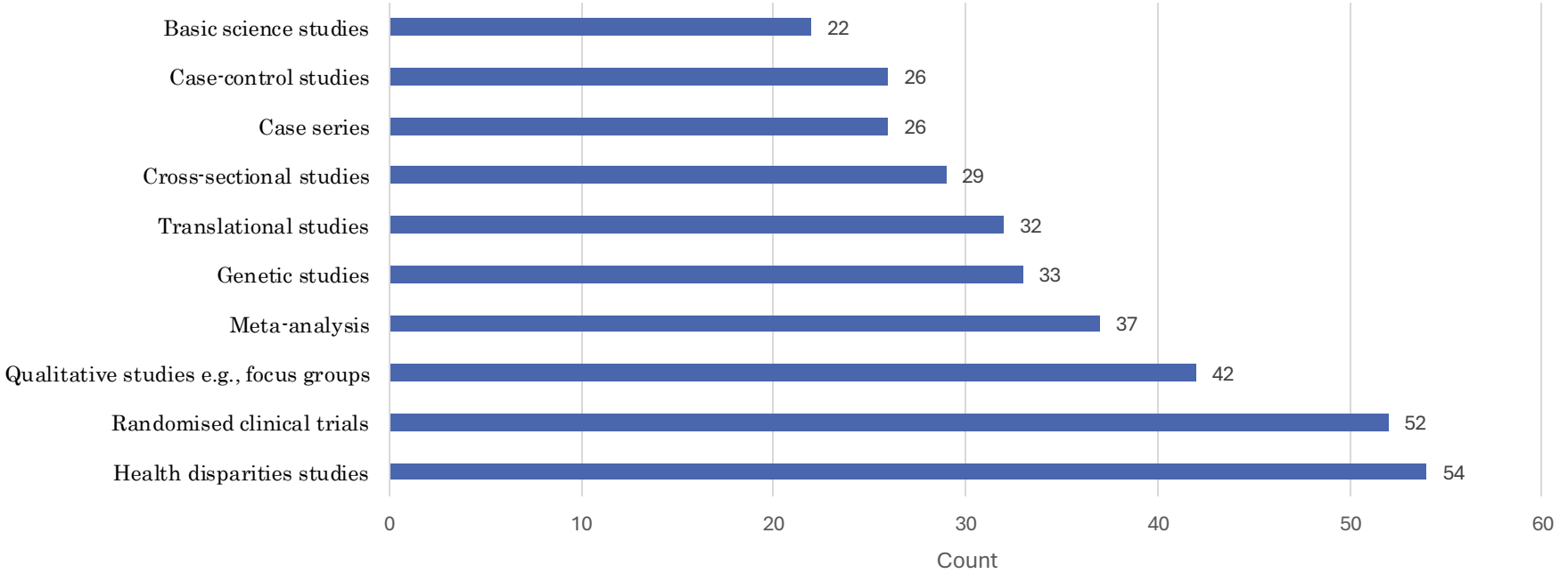


Polling questions

Which of the following population descriptors do you feel are the most important to be captured in dermatology research studies?

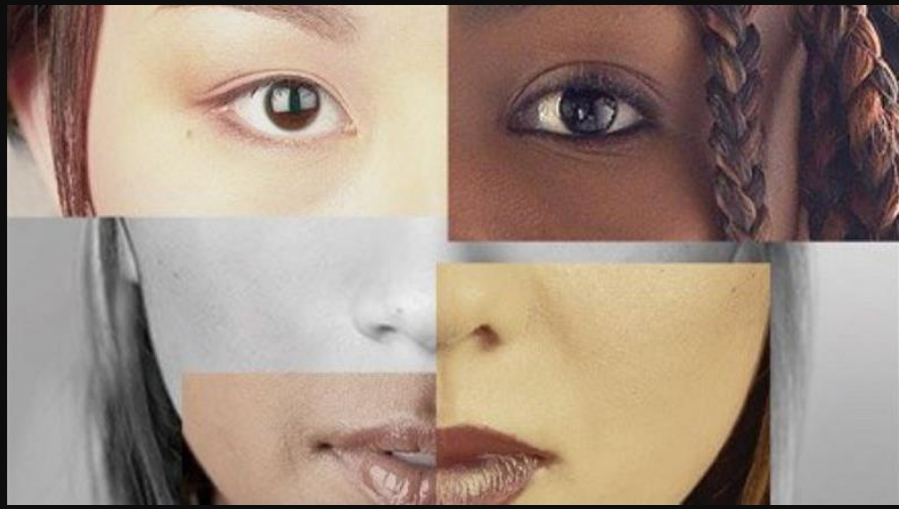


Polling Questions
In which research categories would using race and ethnicity be the most appropriate?



Meeting the Challenge
Themes and sub-themes

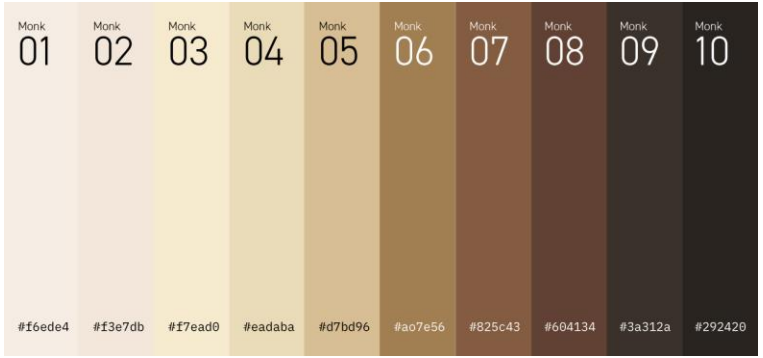
- **Importance of appreciating nuance**
  - Race is a dynamic social construct.
  - Definitions vary globally, creating inconsistencies when comparing data/research.
  - Race is more a measure of **racism**, playing an essential role in the measurement of pervasive health disparities (atopic dermatitis).
  - Descriptors should be appropriate for the specific study design or relevant to clinical outcomes.
  - Constructive/transparent use of race and ethnicity rather than elimination.



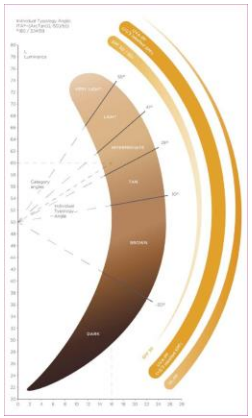
Meeting the Challenge: Themes and sub-themes

Race and ethnicity can be enhanced by including additional variables to supplement analyses, such as

- Socially determined factors
- Economic stability
- Neighborhood
- Physical Environment
- Educational status
- Community and social context
- Healthcare system factors



Colorimetric Scale



Individual Typology Angle

Monk Skin Tone Scale

Meeting the Challenge Themes and sub themes

Need for improved validated tools to measure variations in skin color.

- A preference to move away from the FST was expressed, but no accepted alternative. Challenges standardizing descriptions.
- Development of multiple tools in progress for the objective measurement of skin color
  - Eumelanin Human Skin Color Scale: 5-category scale based on skin reflectance (Melanin Index) data
  - Individual Typology Angle: 6 categories based on constitutive pigmentation as assessed by colorimetry
  - Monk Skin Tone Scale,Colorimetric scale
- Collaborative effort- top-down approach- replacement of FST will require rigorous validation studies and approval from the FDA.
- Provides value to patients, clinicians, researchers
- Emphasized the need for an instrument that is feasible (time, cost, and interpretability)

Cohen et al. Cureus, 15(11).
Osto et al. Photochem Photobiol. 2022;98(1):127-129
Monk et al. https://doi.org/10.31235/osf.io/pdf4c

Meeting the Challenge Summit Themes and sub themes

- **Challenges and Barriers to Change**
  - Constructs are deeply ingrained both in society and medical/research enteprise.
  - Creating and gaining consensus on new language for descriptors, alternatives are unclear.
  - Shifting stakeholders' perceptions and implementation of replacement/supplementary descriptors.
  - Precision must be carefully balanced with simplicity and practicality to facilitate easy implementation.
  - Their specific end-use should guide the collection of granular data. Their purpose should be to enrich scientific and health outcomes.

Meeting the Challenge
Themes and sub-themes

Importance of education and public engagement

- Dermatologists and researchers must avoid assumptions, and unsupported conclusions when using race and ethnicity. (Anticipate, avoid, and explain potentially racist interpretation of data)
- The scientific community should educate and engage the public to promote a better understanding of research involving race and ethnicity. Including the public in discussions about their perceptions of race will not only provide additional insight but will also foster public trust and support.

Analysis of the Use of Population Descriptors in Dermatology Research Studies– WHATS NEXT…..

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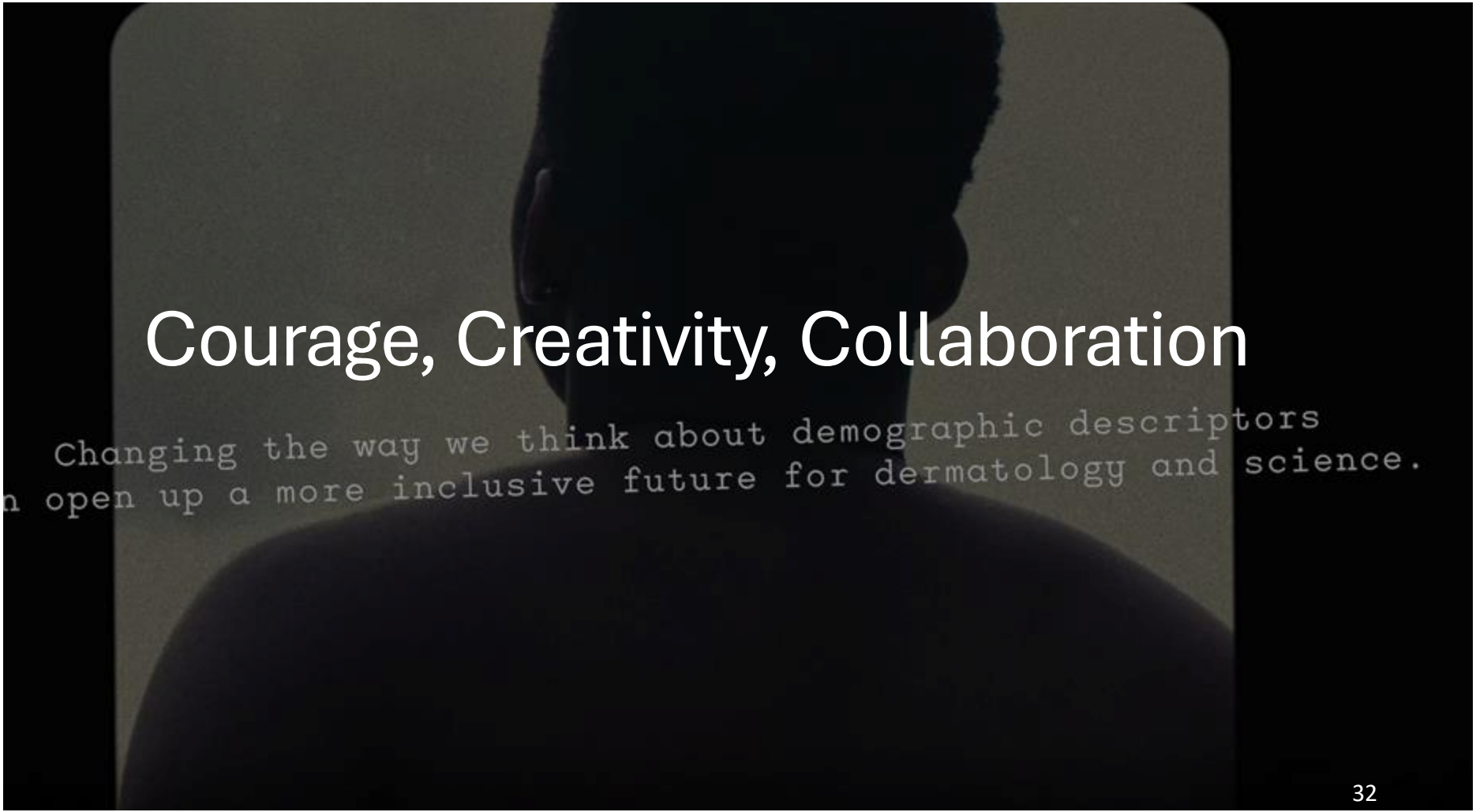
Manuscript preparation of meeting findings


Courage, Creativity, Collaboration
Changing the way we think about demographic descriptors
n open up a more inclusive future for dermatology and science.

Thank you

Do you have any questions? Valerieharvey10@gmail.com

https://deep.skinofcolorsociety.org/learn/catalog/view/7