



SYMPOSIUM

**BLACK
WO(MEN)
SPEAK**



Session 1

How Healthcare Provider
Communication Can Impact
Clinical Trial Enrollment





KEYNOTE SPEAKER

Oluwadamilola "Lola" Fayanju, MD, MA, MPHS, FACS

Moving the Needle on
Disparities in Breast Cancer

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**BLACK
WOMEN
SPEAK**

2022 Black Wo(men) Speak Symposium

**Moving the Needle on Disparities in Breast Cancer:
The Critical Role of Clinical Trials**

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Disclosures

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My goal....

To elevate care for all women with breast cancer to a level that is universally equitable, effective, and efficient

Definitions

Disparity

Equity

Health Disparity

An observed inter-group difference in health screening, outcomes, and/or treatment

- Rooted in Inequity
- Can Be Avoided



Hebert PL, et al. Health Affairs 2008;27:374-82.

Health Equity

- distribution of health according to clinical need
- equal opportunities to use health care resources

Do we share a common view of justice?



Rathore SS, Krumholz HM. Ann Intern Med 2004; 141(8):635-8.
Hebert PL, et al. Health Affairs 2008;27:374-82.

Breast Cancer

- Most common non-skin cancer in US women
- 1 in 8 women will be diagnosed in her lifetime
- 270,000 new cases of invasive breast cancer and 60,000 cases of noninvasive breast cancer are diagnosed in US women each year
- Leading risk factor is simply being a woman

Siegel RL, et al. Cancer statistics, 2019. *CA: a cancer journal for clinicians*. 2019;69(1):7-34.



Breast Cancer

- But men can get breast cancer, too
 - 2700 new cases/yr
 - Indication for genetic testing! – Ex. Mathew Knowles, BRCA2
- Most women (~80%) dx'd with breast cancer have no family hx
- 1st-degree relative with breast cancer → 2x ↑ risk
- About 5-10% breast cancers are genetic
- 5-year overall survival for early-stage breast cancer >95%



Siegel RL, et al. Cancer statistics, 2019. *CA: a cancer journal for clinicians*. 2019;69(1):7-34.

Breast Cancer

- Non-Hispanic White women have higher incidence, but
 - Black women more likely to be dx'd <40 and to die at every age & stage
 - Latinas more likely to be dx'd with +LNs and have longer time to surgery
 - 9% of Blacks vs 6% of Whites and Latinas present with de novo Stage 4

Reproductive Health	Lifestyle	Family/Genetics/Breast
Menarche <12 Menopause >55	Poor energy balance, i.e., obesity, ↓exercise	Mutations in BRCA1/2, PALB2, PTEN, ATM, p53, CHEK2
Not breastfeeding	Alcohol	1 st & 2 nd -degree relatives
Nulliparity 1 st birth after 35	Smoking	Dense breasts Previous BENIGN biopsies

Disparities in Breast Cancer

Focus on static/immutable characteristics

Race

Education
Level

Neighborhood

Parity

Family History

Ethnicity

Sexual
Orientation

Income

More limited, less successful translation of knowledge into outcomes-oriented action

Causes of Breast Cancer Disparities

► Biology

- Subtype frequency by race/ethnicity

► Access

- Screening
 - Imaging
 - Genetic testing
- Diagnosis
- Treatment
- Surveillance
- Clinical trials

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Clinical Trial Disparities

US Congress NIH Revitalization Act (1993)

Goal: *Encourage participation of women & minority patients in NIH-sponsored research*

Is there something special about breast cancer?

- 2017 review of oncology clinical trial enrollment
 - racial/ethnic minorities remains disproportionately low across most disease sites but...
 - ...near equal participation in breast cancer
 - Excluded surgical oncology trials



Freedman LS, et al. *Controlled Clinical Trials*. 1995;16(5):277-285.
Duma N, et al. *Journal of Oncology Practice*. 2018 Jan;14(1):e1-e10.

A Case-Control Study Examining Disparities in Clinical Trial Participation Among Breast Surgical Oncology Patients

Oluwadamilola M. Fayanju, MD, MA, MPHS; Yi Ren, MS; Samantha M. Thomas, MS; Rachel A. Greenup, MD, MPH; Terry Hyslop, PhD; E. Shelley Hwang, MD, MPH; John H. Stewart IV, MD, MBA

Objective: How has trial participation for breast surg onc pts changed over time (2000-2012)?

Cohort: 792,719 trial-eligible patients (NCDB) vs 17,125 trial participants (CTEP)

Outcomes:

- Factors associated with trial participation
- Race-specific trial participation rates over time

Results:

- Participation declined across all racial/ethnic groups over time.
- Black (OR 0.80, 95% CI 0.75-0.85) & Hispanic (OR 0.84, 95% CI 0.77-0.92) pts less likely to participate than White pts BUT there were significant interactions b/w income & race/ethnicity.
- High-income Black pts were ~50% less likely to participate than lower-income Black pts.

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Conclusions:

- ▶ Differences in trial participation // complex interactions b/w race/ethnicity and SES
- ▶ Diverse array of interventions needed to facilitate equitable trial participation
- ▶ Future trials will be increasingly biology-driven, subtype-specific, clinician-informed
 - Ex: Must prioritize recruitment and inclusion of racial/ethnic minority patients who are disproportionately affected by aggressive subtypes of breast cancer

Who is at the table when these decisions are made?

Health Disparities and Research

Is there a problem?

Clinical trials

African-Americans = 13% US but only 5% in clinical trials

Hispanic/Latinx = 15-20% US but only 7-8% in clinical trials

AND...

What does consent process look like by phase?

- Exploitation of therapeutic misconception
- Failure to convey goals of Phase I studies
- Enrollment bias in Phase III studies

*Underrepresentation happens even in cancers with higher prevalence in people of color
AA and Latinx are overrepresented in Phase I & underrepresented in Phase III Trials
AA pts more likely to participate in trials that do not require informed consent*

A Framework for Better Science


Redressing Disparities in Trial Participation

Change the Players

- Diversity at design, deployment, and dissemination
 - Who are your collaborators, and how do you complement each other?
 - Who is your statistician, and what are her priorities?
 - Who does your recruiting and counseling? Who are your gatekeepers?
 - How are you incentivizing participants?
 - Are you in danger of conflating race and genetic ancestry in your study?
 - Who represents the future of your research, and where are they now?

Changing the Players...a work in progress

Despite diversity initiatives, several groups remain underrepresented in medicine (URiM).



Cureus. 2021 Jan; 13(1): e12838. PMID: PMC7899283
Published online 2021 Jan 21. doi: [10.7759/cureus.12838](https://doi.org/10.7759/cureus.12838) PMID: [33633878](https://pubmed.ncbi.nlm.nih.gov/33633878/)

Gender, Geographic, and Socioeconomic Representation in Medical Student Journals: A Cross-Sectional Analysis

Monitoring Editor: Alexander Muacevic and John R Adler

Ibrahim S Al-Busaidi,¹ Kareem Sharif,² and Ahmad Hassan³



FULL LENGTH ARTICLE | VOLUME 258, P179-186, FEBRUARY 01, 2021

Equity, Diversity, and Inclusion in Academic American Surgery Faculty: An Elusive Dream

Kai Zhu, BSc • Priya Das, PhD • Ahmer Karimuddin, MD, FRCSC • Sabeen Tiwana, DMD, BDS • Javed Siddiqi, MD, DPhil (Oxon) • Faisal Khosa, MD, MBA, FFRCRCSI, FRCPC

Published: October 01, 2020 • DOI: <https://doi.org/10.1016/j.jss.2020.08.069> Check for updates

Aim: We examined trends in racial/ethnic and gender representation among medical students and surgical faculty in the United States from 2011 - 2020

Results

↑URiM faculty in a program was associated with...

↑ Female medical students

(estimate= +6.2% students for every 100% increase in faculty)

↑ URiM medical students

(estimate= +70.1% students for every 100% increase in faculty)

↑Female faculty did not have these associations

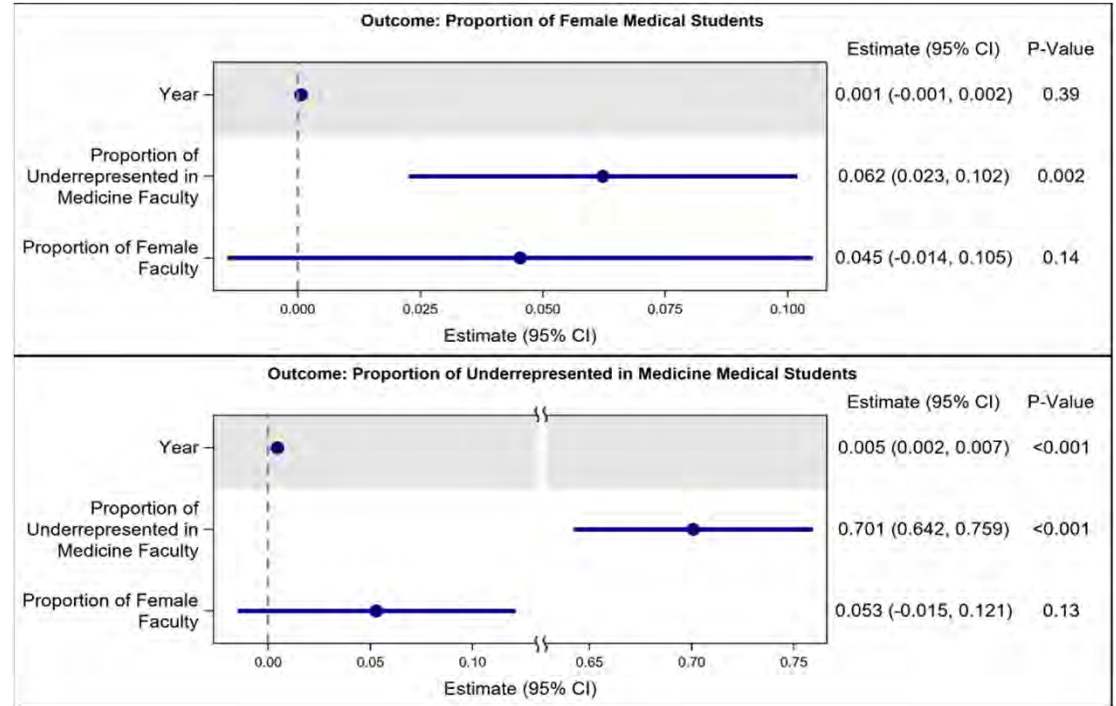


Figure 3: Linear regression models demonstrating the association of time and surgical faculty diversity with student diversity, AAMC programs, 2011-2020

Conclusion

Having **more racially and ethnically diverse surgical faculty** was associated with **greater racial/ethnic *and* gender diversity among students.**

Stagnant proportions of URiM surgical faculty from 2011 – 2020  need for **improved recruitment and retention of diverse faculty.**

Redressing Disparities in Trial Participation

Change the Game

Bench-to-Bedside Model → Discovery-to-Delivery Disconnect?

Community-to-Clinic

Cyclical, not Unidirectional (e.g., Open Science)

Patient-centered (e.g., clinical trial navigators)

Community-based (e.g., lay educators)

Builds trust(worthiness) – the burden lies with us!

Redressing Disparities in Trial Participation

Community-to-Clinic Model for Clinical Trial Development

- Patient-centered and community-based
 - 2014-2018: Community outreach and engagement program at Penn
 1. Culturally tailored marketing strategies for cancer clinical trials
 2. Plans for each protocol to facilitate Black participant enrollment
 3. New partnerships with faith-based organizations serving Black communities to conduct educational events about clinical trials
 4. Pilot programs with Lyft and Ride Health to address transportation barriers
 5. Patient education by nurse navigators regarding cancer and clinical trials
 6. Improved informed consent process

Redressing Disparities in Trial Participation

Community-to-Clinic Model for Clinical Trial Development

- Patient-centered and community-based **Just Ask!**
 - ↑ Black patients treated (11.1% → 16.5%) and enrolled in trials

	Therapeutic	Non-therapeutic Interventional	Non-interventional
2014	12.2%	8.3%	13.0%
2018	23.9%	33.1%	22.5%

Conclusion

Next steps...

Redressing disparities in clinical trial participation requires

- Acknowledging and rectifying past and current wrongs in the creation, dissemination, & application of research
 - The Henrietta Lacks Enhancing Cancer Research Act
- Recognizing diversity both within and across groups in order to develop effective education materials and recruitment strategies (e.g., **Nat'l Pan-Hellenic Council**)
- Providing opportunities for patients to hear about trials (e.g., **Duke's Just Ask program**), tell us what they need, and provide input on how we can respectfully respond

Thank you!

Penn Division of Breast Surgery



Lola Fayanju



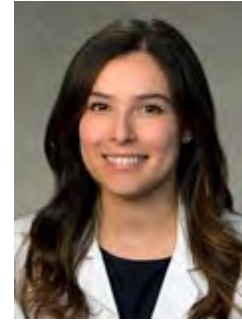
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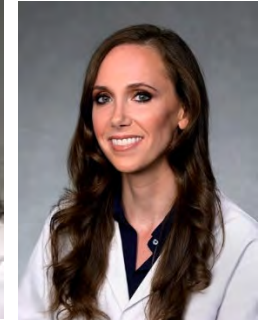
Ari Brooks



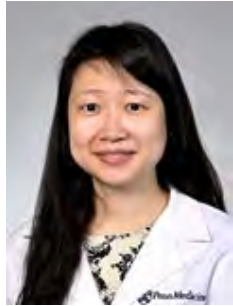
Alina Mateo



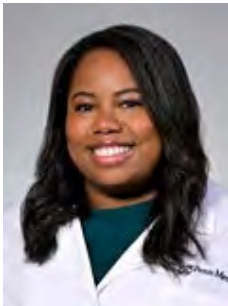
Rebecca Fishman



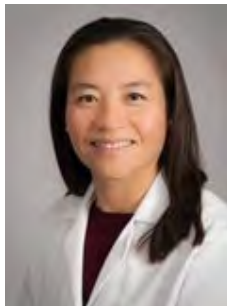
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