San Antonio Breast Cancer Symposium – December 9-12, 2025

Geographic Barriers Drive Breast Cancer Clinical Trial Disparities: A National Cancer Database Analysis

Ana Sandoval-Leon, Yolcar Chamorro, Muni Rubens, Mukesh Roy, Naomi Dempsey, Lauren Carcas, Leanne Dumeny, Manmeet Ahluwalia, Reshma Mahtani

Baptist Health South Florida. Miami Cancer Institute, Miami, FL, USA

Miami Cancer Institute
BAPTIST HEALTH SOUTH FLORIDA

PS4-09-10

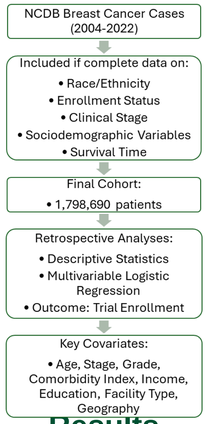
Background

- Clinical trials are essential for advancing cancer diagnostics, treatments, and patient outcomes. However, racial minorities continue to be underrepresented, limiting the generalizability of trial results.
- Several barriers contribute to this disparity in trial participation, including inadequate healthcare access, distance, financial constraints, insufficient information, and cultural mistrust [1].
- Despite initiatives to address these issues, Black (B) and Hispanic (H) enrollment remains low, with recent reports indicating that most trial participants are still predominantly White (W) [1,2].

Objective

- We aim to understand disparities and barriers that lead to differences in breast cancer clinical trial enrollments.

Methods



Results

- Cohort Overview
  - Total N= 1,798,690 breast cancer patients
  - Median age: 62 years
- Of this total:
  - 79.7% were White, 10.9% were Black, 4.9% were Hispanic, and 4.6% identified as Other.

Only 1,645 (< 1%) of patients enrolled in clinical trials.

Table 1: Patient Characteristics

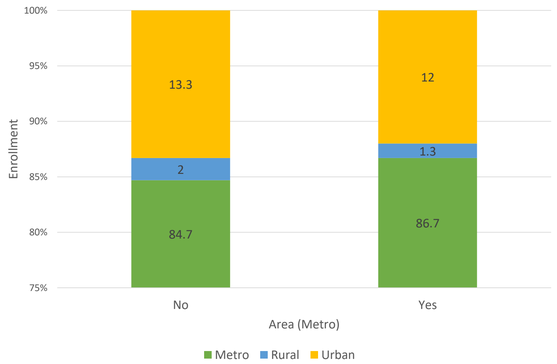
Characteristics	Enrollment No (n=1,788,045)	Enrollment Yes (n=1645)	P-value
Age, Mean (SD)	62.5 (12.25)	56.7 (9.98)	**<0.001**
Distance, n (%)			**<0.001**
Less than 50 miles	5.8%	11.1%	
More than 50 miles	94.2%	88.9%	
Facility Type, n (%)			**<0.001**
Academic	7.6%	5.2%	
Non-Academic	92.4%	94.8%	
Facility Location			**<0.001**
East North Central	16.3%	18.6%	
East South Central	6.0%	8.3%	
Middle Atlantic	15.0%	22.2%	
Mountain	4.4%	2.9%	
New England	6.5%	3.1%	
Pacific	14.7%	14.0%	
South Atlantic	22.7%	11.1%	
West North Central	7.1%	13.3%	
West South Central	7.3%	6.6%	
Area (Metro), n (%)			**0.026**
Metro	84.7%	86.7%	
Rural	2.0%	1.3%	
Urban	13.3%	12.0%	
Stage, n (%)			**<0.001**
Stage 0	17.1%	7.4%	
Stage I	45.0%	29.9%	
Stage II	26.1%	37.3%	
Stage III	8.4%	17.0%	
Stage IV	3.3%	8.3%	
Race/Ethnicity, n (%)			0.325
Black	10.9%	10.0%	
Hispanic	4.9%	5.6%	
Other	4.6%	4.2%	
White	79.7%	80.2%	
Income, n (%)			0.199
Quartile 1	14.3%	14.4%	
Quartile 2	20.9%	22.1%	
Quartile 3	26.9%	24.7%	
Quartile 4	37.9%	38.8%	
Education, n (%)			0.659
Quartile 1	14.0%	13.7%	
Quartile 2	20.5%	20.2%	
Quartile 3	23.1%	22.2%	
Quartile 4	42.4%	43.9%	

* Income and education were estimated by matching zip code of residence against files from the Census data or the American Community Survey depending on the year.

Table 2: Factors Independently Associated with Lower Odds of Clinical Trial Enrollment

Characteristic	OR (95% CI)	P-value
Distance		
Distance More than 50 miles vs. Less than 50 miles	0.436 (0.366-0.519)	**<0.0001**
Facility Type		
Non-Academic vs. Academic	1.438 (1.153-1.792)	**0.0012**
Area (Metro)		
Rural vs. Metro	0.381 (0.244-0.596)	**<0.0001**
Urban vs. Metro	0.649 (0.547-0.771)	**<0.0001**
Race/Ethnicity		
Black vs. White	0.848 (0.714-1.008)	0.0614
Hispanic vs. Black	1.108 (0.890-1.379)	0.3574
Other vs. Hispanic	0.875 (0.684-1.120)	0.2888
Income		
Quartile 1 vs. Quartile 4	0.994 (0.842-1.174)	0.9449
Quartile 2 vs. Quartile 4	1.046 (0.911-1.202)	0.5213
Quartile 3 vs. Quartile 4	0.89 (0.784-1.01)	0.0718
Education		
Quartile 1 vs. Quartile 4	0.899 (0.731-1.105)	0.3123
Quartile 2 vs. Quartile 4	0.937 (0.799-1.100)	0.4279
Quartile 3 vs. Quartile 4	0.893 (0.776-1.028)	0.1145

Figure 1: Enrollment Percentage based on Area*



*Total Overview: Metro: 84.7% , Urban: 13.3% , and Rural: 2.0%

Conclusion

- Clinical trial enrollment remained extremely low, with <1% of pts documented as participants.
- Rural residence, and the need to travel more than 50 miles were significantly associated with lower odds of trial enrollment, pointing to structural and geographic barriers as key determinants.
- Unexpectedly, treatment at a non-academic center was associated with higher odds of clinical trial enrollment compared to academic centers.
- Race, income, and education were not independent predictors of clinical trial enrollment, suggesting that access drives much of the disparity.

Limitations

- A key limitation of this study is the use of the NCDB, which may significantly underreport clinical trial participation, including underreporting at academic sites, as this database is not specifically designed to capture detailed trial enrollment data.
- There could be other social determinates of health or comorbidities which could account for the difference seen.

Future Directions

- The small number of patients shown as enrolled highlights the need for improved data collection methods to reflect participation and guide equity-focused interventions more accurately.

Acknowledgement

- The data used in the study are derived from a de-identified NCDB file. The American College of Surgeons and the Commission on Cancer have not verified and are not responsible for the analytic or statistical methodology employed, or the conclusions drawn from these data by the investigator.

References

1. Fairley R, Lillard JW, Jr., Berk A, Cornew S, Gaspero J, Gillespie J, Horne LL, Kidane S, Munro SB, Parsons M et al: Increasing Clinical Trial Participation of Black Women Diagnosed with Breast Cancer. J Racial Ethn Health Disparities 2024, 11(3):1701-1717.
2. Loree JM, Anand S, Dasari A, Unger JM, Gothwal A, Ellis LM, Varadhachary G, Kopetz S, Overman MJ, Raghav K: Disparity of Race Reporting and Representation in Clinical Trials Leading to Cancer Drug Approvals From 2008 to 2018. JAMA Oncol 2019, 5(10):e191870.

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