Enrollment Rate Of African Americans In A Colon Cancer Screening Trial At A Historically Black College And University Is Similar To Other Patient Populations

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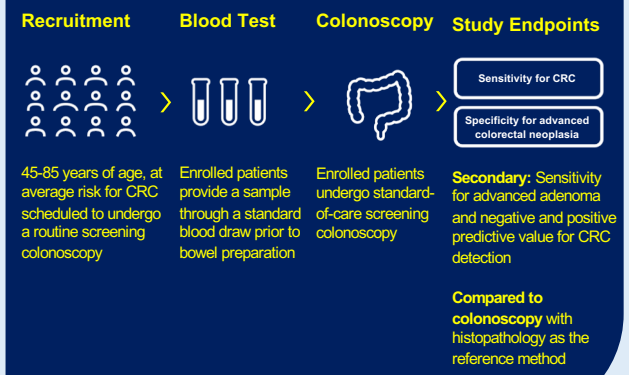
Background

- Clinical trials often have low enrollment of minorities, particularly African-Americans (AAs)[1]
- Barriers to recruitment[2]:
  - Mistrust due to historical abuses
  - Communication issues with providers
  - Socio-economic factors
  - Lack of access to clinical trials
- Morehouse School of Medicine is a Historically Black College and University (HBCU) serving primarily AA patient population
- Freenome has developed a multiomics blood test for colorectal cancer (CRC) screening
- A large, prospective, multi-center clinical trial (PREEMPT-CRC®) to validate this blood-based test for early detection of CRC was initiated at Morehouse.



Methods

- To maximize study recruitment:
  - Racially congruent recruitment staff
  - Synchronized timing of consent/study procedures
  - Detailed information for all eligible subjects was recorded
- Demographic and socio-economic data including census information for eligible subjects that enrolled vs those not enrolling were compared.
- We evaluated the enrollment of eligible patients for a colorectal cancer (CRC) screening clinical trial. This was compared to enrollment rates for a subset of sites (26 of the 180 total sites) where pre-screening logs were available.

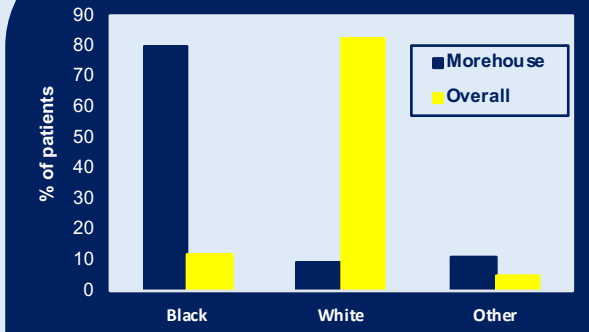
Results

- The enrollment rate at the HBCU was 55% (44 out of 80 eligible patients; 95% CI 43.5-66.2%), compared to 49.8% (258 out of 518 eligible patients; 95% CI 45.4- 54.2%) for the subset of 26 study sites.
- The main difference was race: at the HBCU the study participants were 80.0% AAs and 9.0% Caucasians, while at the other sites the participants were% 11.5% AAs and 82.8% Caucasians (p< 0.001)
- At the HBCU, the demographic characteristics and socio-demographic data including income, marital status, insurance status / type, and census tract median household income of the 44 enrolled and 36 not-enrolled subjects were similar (Table 1).

Table 1. Demographics of patients

	Not Enrolled (N=36)	Enrolled (N=44)	p-value
Female	20 (55.6%)	23 (52.3%)	0.77
Age	57.4 ± 8.3	60.7 ± 7.3	0.06
Race			0.15
African American	32 (88.9%)	35 (79.5%)	
American Indian	1 (2.8 %)	0 (0.0 %)	
Asian	0 (0.0 %)	4 (9.1 %)	
Caucasian	2 (5.6 %)	4 (9.1 %)	
Hispanic	0 (0.0 %)	1 (2.3 %)	
Unknown	1 (2.8 %)	0 (0.0 %)	
BMI	30.8 ± 11.3	31.0 ± 8.1	0.93
Marital Status			
Divorced/Separated	11 (30.6%)	13 (29.5%)	0.51
Married	6 (16.7%)	10 (22.7%)	
Single	18 (50.0%)	16 (36.4%)	
Unknown	0 (0.0 %)	1 (2.3 %)	
Widowed	1 (2.8 %)	4 (9.1 %)	
Religion (Christian)	28 (77.8%)	34 (77.3%)	0.96
Insurance Status			0.72
Medicare	12 (33.3%)	11 (25.0%)	
Medicaid	5 (13.9%)	6 (13.6%)	
Private	10 (27.8%)	11 (25.0%)	
None	9 (25.0%)	16 (36.4%)	
Census Tract Median Household Income	$53,000	$48,000	0.29

Figure 1. Race of trial participants



Discussion

- The PREEMPT CRC study will likely be the largest prospective, multi-center registrational validation study of a multiomics blood test for average-risk CRC screening.
- By providing access to clinical trials to Black patients in a HBCU, patient enrollment is similar to Caucasian-predominant study populations.
- Future trials should consider including HBCU sites to attain adequate AA enrollment to improve the generalizability of research findings.

References

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2. Barrett NJ, Ingraham KL, Hawkins TV, Moorman PG. Engaging African Americans in research: the recruiter's perspective. Ethnicity & disease. 2017;27(4):453.