

# **Disparities in Cancer Clinical Trial Participation: The Role of Opportunity**

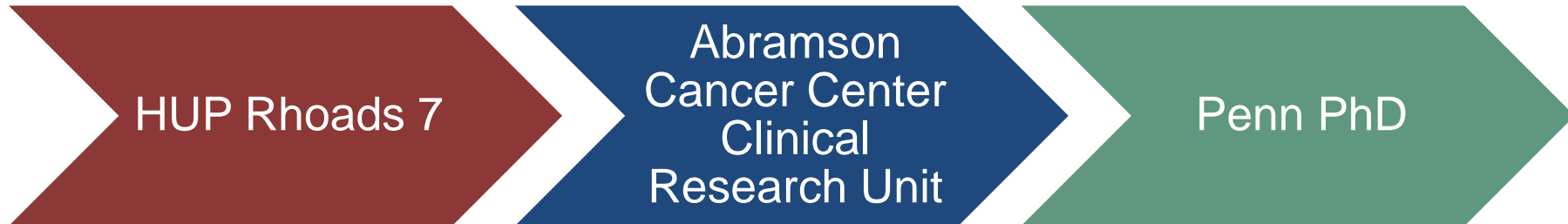


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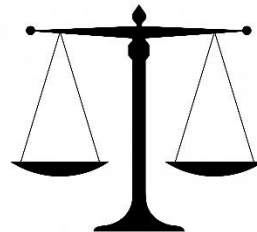
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# Using Practice to Inform Research

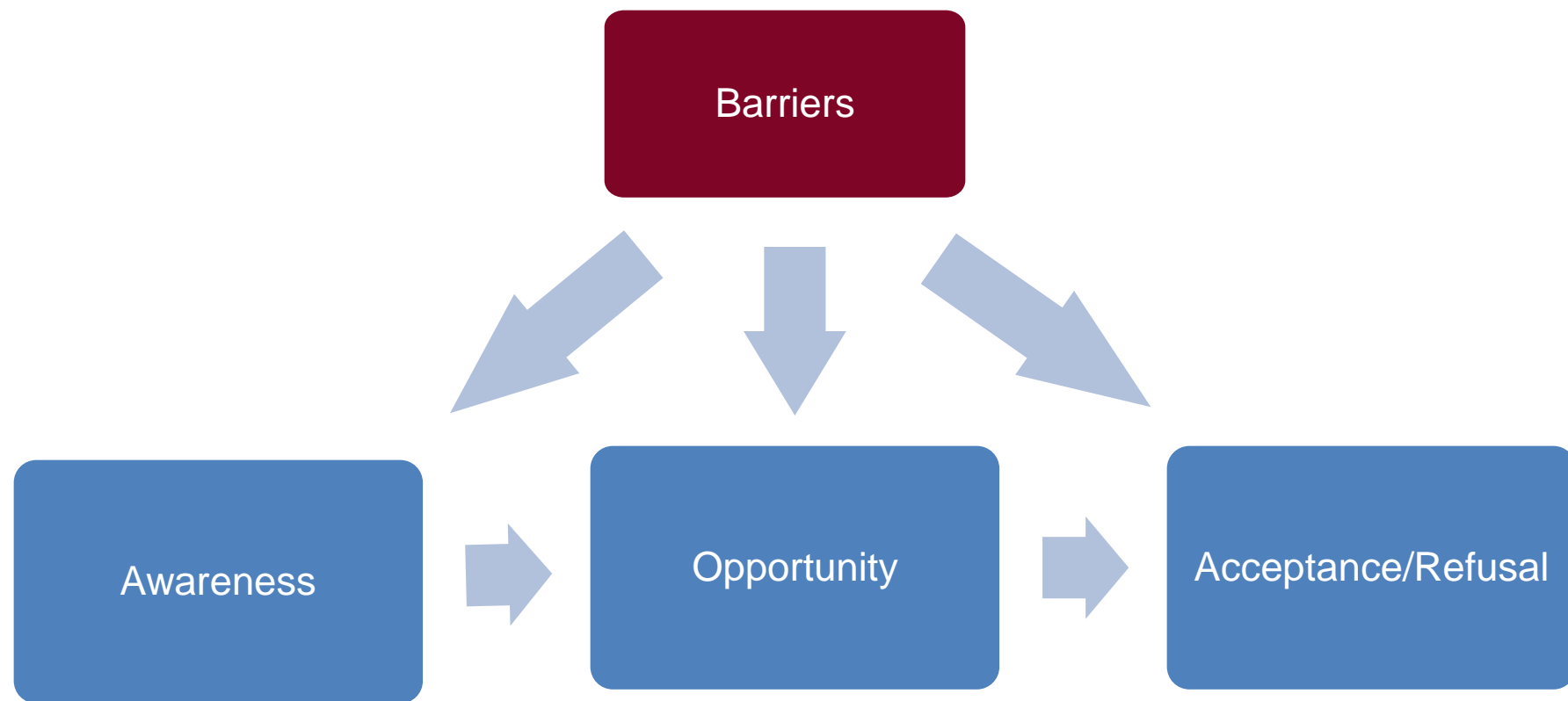


# Background/Significance

- Racial/ethnic minority populations, older adults and the economically disadvantaged are under-represented as CCT participants
- Inequitable participation in CCTs:
  - 1) decreases the generalizability of results
  - 2) diminishes the chance for under-represented groups to receive new and potentially life-saving treatments
- Recent research suggests that under-represented groups are just as willing to participate in CCTs, **but may lack the opportunity to do so**



# Examining Enrollment of Under-represented Groups to CCTs



Adapted from Ford et al., 2008

## Variables of Interest: Opportunity and Eligibility

- **Opportunity**: An offer for screening and/or enrollment in a CCT from a healthcare provider or researcher
- **Eligibility**: The key attributes/characteristics a person must have in order to participate in a CCT
  - A barrier to opportunity for under-represented groups

## Research Question

- Are there **differences in opportunity and eligibility** for CCT participation based on socio-demographic and disease characteristics?
  - Sociodemographic Characteristics: *race/ethnicity, age, sex, insurance status, income, education, primary spoken language*
  - Disease Characteristics: *cancer type, stage and performance status*

## Methods

**Design:** Cross-sectional matched study

**Setting:** Abramson Cancer Center outpatient medical oncology clinics at HUP (PCAM2, PCAM3, PCAM4)

**Sample Selection:** Using administrative data, Black or Hispanic new cancer patients matched with Non-Hispanic White new cancer patients based on cancer type and age ( $\pm$  5 years)

# Methods

## Inclusion Criteria:

- Over 21 years of age
- Completed a NPV with a medical oncologist between 1/2013 and 6/2013
- Diagnosed with one of the following cancers: breast, lung, leukemia, kidney
  - Cancer types selected due to high number of accruing Phase I-III therapeutic CCTs supported by the Clinical Research Unit



# Methods

- **Patient Questionnaire**
  - Administered verbally either via phone or in person
  - Collected socio-demographic information, cancer type and opportunity status (opportunity / no opportunity)
- **Electronic Medical Record (EMR) Review**
  - With verbal consent from participant
  - Collected cancer stage and performance status
  - Evaluated eligibility status (eligible/ ineligible)
    - Screened patients for all enrolling Phase I-III therapeutic CCTs using protocol eligibility criteria and EMR
  - Compare patient's response re: opportunity status to EMR

# Analysis

- Contingency tables constructed to examine differences in socio-demographics/disease characteristics among the following groups:
  - Opportunity/ No Opportunity
  - Eligible/Ineligible
  - Opportunity/Eligibility in tandem
- Fisher's exact tests (categorical variables)
- ANOVA or t-test (continuous variable-age)

## Final Sample (N=88)

Patient Characteristics	# (%)
Black/Hispanic	44 (50%)
Non-Hispanic White	44 (50%)
Female	76 (86%)
Private Insurance	59 (67%)
High School Education (or less)	46 (52%)
English as primary language	83 (94%)
Age range, mean (SD)	29-86, 56.2 (11.9)
Breast Cancer	57 (65%)
Early stage	36 (49%)
ECOG PS of 0	30 (41%)

## Final Sample

- Compared to Black/Hispanic participants in the sample, Non-Hispanic White participants were more likely to:
  - Have private insurance (84% vs. 52%,  $p=.002$ )
  - Have graduate level education (32% vs. 9%,  $p=.02$ )
  - Make over \$100,000/year before taxes (59% vs. 6%,  $p=.000$ )
- 73/88 patients agreed to EMR review (33 Black/Hispanic and 40 Non-Hispanic White)
- High agreement between EMR and patient report of opportunity

## Open/Enrolling Clinical Trials

- 54 Phase I-III accruing therapeutic CCTs supported by the ACC's Clinical Research Unit

Trial Characteristics	# of Trials
Phase II	17 (31%)
Phase III	16 (30%)
Leukemia	18 (33%)
Lung	14 (26%)
Pharmaceutical Sponsored	29 (54%)
Advanced disease	39 (72%)

# Results

## 1) There was limited opportunity and eligibility for CCT participation for all patients

- **Opportunity**
  - 79% (69/87) reported no opportunity for participation
- **Eligibility**
  - 84% (61/73) were ineligible for participation
- **Opportunity/Eligibility**
  - 78% (57/73) had no opportunity/were ineligible
  - 33% (4/12) of eligible patients had no opportunity

# Results

## 2) Patients with late stage cancer had increased opportunity and eligibility for participation

- **Opportunity**
  - Those **with opportunity** were **more likely** to have Stage III/IV disease (67%) vs. early stage (8%), recurrent/relapsed (8%) or other/unknown stage (17%),  $p=.001$
- **Eligibility**
  - **Eligible patients** were **more likely** to have Stage III/IV disease (75%) vs. early stage (0%), recurrent/relapsed (0%) or other/unknown stage (25%),  $p= <.001$

## Results

- **Opportunity/Eligibility**
  - Patients **with opportunity** that were **also eligible** were **more likely** to have Stage III/IV cancers (75%) vs. Stage 0/I/II (0%), relapsed/recurrent disease (0%) or others (25%),  $p < .001$



## Results

### 3) There were no significant differences in opportunity or eligibility based on race/ethnicity

- Black and Hispanic patients with cancer often share a disproportionate burden of late stage disease
- Sample and/or patient population in this setting may not be representative of the general under-represented cancer patient population locally and nationally

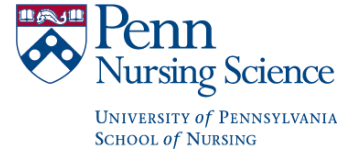
# Conclusions

- It is imperative to maximize opportunity for participation for eligible new cancer patients
- Most patients had no opportunity and were ineligible for participation, suggesting:
  - Pre-screening by healthcare providers
  - Poor fit between available trials and the new patient population
  - Stringent eligibility criteria
- More representative samples of racial/ethnic minority populations may experience different, and perhaps better, rates of opportunity and eligibility for CCT participation

# Implications for Nursing Practice

- **Nurses are integral to improving opportunity for trial participation for all patients**
  - Flagging patients for screening upon healthcare system entry
  - Facilitating timely referrals for appropriate trials
  - Advocating for equitable trial selection
    - Involving patients in the process
  - Referral of underserved populations in rural and community areas for appropriate trials
  - Community outreach/education

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