THE IMPORTANCE OF CLINICAL TRIALS IN ACHIEVING HEALTH EQUITY

Mona Fouad, M.D., MPH
Associate Vice President of Diversity Equity And Inclusion, UAB
Senior Associate Dean of Diversity and Inclusion, Heersink School Of Medicine
Founding Director, Minority Health and Health Equity Research Center, UAB
Why Clinical Trials?

Clinical trials are an important step in discovering new treatments for cancer and other diseases as well as new ways to detect, diagnose, and reduce the risk of disease. Clinical trials show researchers what does and doesn't work in people.
Why Inclusive Participation in Clinical Trials Important?

➢ Absence of diverse populations participation, results of clinical trials (treatment and interventions) cannot be generalized

➢ Access to alternative/advanced treatment is not available for those in minority and diverse populations if participation in clinical trials is limited

➢ Without Inclusive participation in clinical trials, health disparities will continue to increase, and health equity will not be achieved.
Inequity in Health Care

In the United States, the reality of health disparities was clear and urgent.

Significant disparities existed in the burden of death and illness experienced by blacks and other minority groups compared with the nation’s population as a whole.
Geographic Disparities: Chronic Diseases, Social Determinants
Health-care related factors for health disparities

- Health insurance
- Health-care utilization (especially preventive care and follow up)
- Quality of care
- Physician bias
- Cultural competence
- Perceived discrimination
- Patient decision-making skills, health literacy
Health is a complex equation

World Health Organization Social Determinant of Health Conceptual Framework
World Health Organization: http://www.who.int/social_determinants/en/
Social Determinants of Health: Role in Health Care Utilization
Why Emphasize Social Determinants?

➢ Social determinants of health have a direct **impact** on health

➢ Social determinants **predict** the greatest proportion of health status variance

➢ Social determinants of health **influence** health behaviours

➢ Social determinants of health **interact** with each other to produce health outcomes
Social Factors: Where Health Disparities Begin

**Social determinants:** The social conditions in which people live, work, and play

- Education
- Income and wealth
- Employment
- Occupational prestige
- Food access, nutrition
- Housing and living conditions
- Work environment

- Neighborhood (crime, violence, segregation, access to food, open spaces)
- Social relationships (social support, social capital)
- Racism and discrimination
- Social exclusion
Minority Participation in Clinical Trials

Minorities account for fewer than 10% of patients enrolled in clinical trials, according to the National Institutes of Health (NIH) National Institute on Minority Health and Health Disparities.

➢ Recruitment: great challenge
➢ Retention: greater challenge
Recruitment Barriers

➢ Barriers related to the targeted community
➢ Barriers related to health care providers
➢ Barriers related to study design
Barriers related to the targeted community:

- Fear and mistrust
- Variability in health priorities
- Negative experiences
- Differences in health beliefs
- Economic barriers
Barriers related to health care providers:

- Loss of authority
- Legality
- Uncertainty
- Clinician vs. Scientist
- Lack of time
Barriers related to study design:

- Consent form
- Randomization
- Time commitment
- Complexity of study design
Retention and Compliance Barriers

- Loss of interest in the study
- Not assigned to desired treatment
- Older age
- Lower educational level
- Unemployment
- Transportation and child care problems
ENHANCING MINORITY PARTICIPATION IN CLINICAL TRIALS (EMPaCT) Phase II

Funding Agency: NIMHD
EMPaCT: Filling a Need

➢ Developed in response to data from UAB indicating a gap in the number of African Americans (AAs) and other underserved groups diagnosed with cancer and the number who enroll in trials

➢ AAs in UAB catchment area = 23.2%
➢ AA participants in UAB clinical trials = 11.4%
EMPaCT I
Assessment of Barriers, Impediments, and Facilitators

➢ Funded by National Institute on Minority Health and Health Disparities as RC2 MD004797

➢ Regional in focus, national in scope

➢ Consortium of five regional leaders:
  o East: Johns Hopkins University, Dr. Jean Ford
  o Southeast: University of Alabama at Birmingham, Dr. Mona Fouad
  o Midwest: University of Minnesota, Drs. Selwyn Vickers & Jasjit Ahluwalia
  o Southwest: M.D. Anderson Cancer Center, Dr. Lovell Jones
  o West: University of California Davis, Dr. Moon Chen
EMPaCT I $\rightarrow$ EMPaCT II
Strategies for Improving Minority Recruitment

**EMPaCT I Qualitative Needs Assessment**
- Outstanding minority recruitment needs
- Barriers/facilitators
- Best practices

**EMPaCT II Quantitative Needs Assessment**
- Aggregate minority recruitment data and data collection methods

**Menu of adaptable options for optimization of minority recruitment and retention**

**EMPaCT II Specific Aims**
- Web-portal
- Patient Navigation
- Clinical Trials Ombudsman
EMPaCT: Objective and Methods

Objective for EMPaCT:
➢ Develop an innovative approach to enhance minority participation in cancer trials conducted mainly at UAB CCC

Methods to accomplish the objective:
➢ Identify and train Community Health Advisors (CHAs) as patient navigators
Community Health Advisors (CHAs) Model

Individuals who are trusted and respected by community members, who are “natural helpers” and have interest in improving the health status of individuals in their communities.
Community Health Advisors Model

Role of CHAs:

- Reach “hard to reach” populations
- Spread health education information
- Encourage healthy behaviors
- Help reduce barriers to health access
- Facilitate access to needed health services
EMPaCT: Program Implementation

➢ Navigators attend weekly research team meetings and Clinical Trial Research Study meetings
  ○ Learn about new research protocols
  ○ Learn about safety issues
  ○ Provide feedback from patients (generally)
  ○ Obtain new referrals

➢ Diverse group of patients referred to EMPaCT, including:
  ○ Gastrointestinal
  ○ Gynecological Oncology
  ○ Head and Neck Cancers
  ○ Hematology Oncology
  ○ Lung
Patient Navigation Objectives

- Provide clinic-based information about trials to minority patients
- Support minority patients enrolled in clinical trials
- Logistical barriers
- Utilizing resources available within cancer center
- Referral to existing community resources
- Cultural considerations
- Emotional support
EMPaCT: Program Implementation

African American patients with cancer receive clinical trial education in the clinic waiting rooms.

Clinical research nurses contact EMPaCT navigators when there is a African American patient considering participation in a clinical trial and/or has been recruited but the patient needs support.

Navigator meets with the patients, conducts a needs assessment, and begins to provide support to patients to overcome barriers to trial participation.
EMPaCT: Program Implementation

- Clinical trial education using NCI booklets and project specific materials
- Counseling on participant’s rights
- Review of trial treatment regimens
- Trial participation calendar
EMPaCT: Program Implementation

- Community partnerships (gas cards, meal vouchers etc.)
- Identifying lodging options and making special arrangements
- Referral to appropriate service provider
- Counseling patients to be proactive
EMPaCT: Program Implementation

1. Bridging communication gaps
2. Orientation to appropriate clinical staff and resources
3. Problem solving to overcoming barriers
4. Referral to other support services
EMPaCT: Program Implementation

Direct patient advocacy
Social support
Visits in the hospital
EMPaCT: Program Outcomes

Services Provided by Clinic/Site:

<table>
<thead>
<tr>
<th>Clinic</th>
<th>Transportation</th>
<th>Lodging</th>
<th>Insurance</th>
<th>Social and Emotional Support</th>
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<tbody>
<tr>
<td>Bone Marrow Transplantation</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>43</td>
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<tr>
<td>Gastrointestinal/Genitourinary</td>
<td>62</td>
<td>3</td>
<td>0</td>
<td>348</td>
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<tr>
<td>Gynecologic Oncology</td>
<td>137</td>
<td>15</td>
<td>4</td>
<td>913</td>
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<tr>
<td>Head and Neck Hematology</td>
<td>27</td>
<td>7</td>
<td>0</td>
<td>223</td>
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<td>Hematology Oncology</td>
<td>168</td>
<td>13</td>
<td>2</td>
<td>958</td>
</tr>
<tr>
<td>Invasive Ductal Breast Carcinoma</td>
<td>394</td>
<td>10</td>
<td>1</td>
<td>1,463</td>
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<tr>
<td>Cooper Green Mercy Hospital</td>
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<td>86</td>
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<tr>
<td>Lung</td>
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<td>415</td>
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<td>191</td>
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<tr>
<td>Other</td>
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<td>0</td>
<td>0</td>
<td>21</td>
</tr>
<tr>
<td>Radiation Oncology</td>
<td>45</td>
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<td>0</td>
<td>344</td>
</tr>
<tr>
<td>Solid Tumors</td>
<td>12</td>
<td>3</td>
<td>0</td>
<td>147</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>927</strong></td>
<td><strong>71</strong></td>
<td><strong>8</strong></td>
<td><strong>5,152</strong></td>
</tr>
</tbody>
</table>
EMPaCT: Program Outcomes

Percentage of new patients referred to IMPaCT from Oncology Clinics by year:

- 5.5% in 2007
- 14.0% in 2008
- 12.0% in 2009
- 13.4% in 2010
- 12.7% in 2011
- 14.1% in 2012
- 13.8% in 2013
- 16.6% in 2014
EMPaCT: Program Outcomes

Percentage referrals for clinical trial and IMPaCT:
EMPaCT: Program Outcomes
African Americans Enrolled Pre/Post EMPaCT
EMPaCT Outcomes

Enrollment Outcomes for African American Patients Referred to the Patient Navigation Program by Year, 2006-2014.
EMPaCT Outcomes

Cancer Clinical Trial Completion Rate According to PN Program Enrollment

Retention Rate, %

<table>
<thead>
<tr>
<th></th>
<th>PN Program</th>
<th>No PN Program</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retention Rate</td>
<td>74%</td>
<td>37%</td>
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</table>
Patient Navigation As a Model to Increase Participation of African Americans in Cancer Clinical Trials

Mona N. Fouad, MD, MPH, Araac Asemgl, M6A, Sejong Bae, PhD, Andres Farero, MD, Niedro Lisovcic, PhD, Michelle Y. Martin, PhD, Gabriella R. Gottes, PhD, Edward F. Partridge, MD, and Salwy M. Vakora, MD

Abstract

Purpose
Less than 10% of patients enrolled in clinical trials are minorities. The patient navigation model has been used to improve access to medical care but has not been evaluated as a tool to increase the participation of minorities in clinical trials. Increasing Minority Participation in Clinical Trials project used patient navigators (PNs) to enhance the recruitment of African Americans for and their retention in therapeutic cancer clinical trials in a National Cancer Institute-designated comprehensive cancer center.

Methods
Lay individuals were hired and trained to serve as PNs for clinical trials. African American patients potentially eligible for clinical trials were identified through chart review or referrals by clinic nurses, physicians, and social workers. PNs provided two levels of services: education about clinical trials and referral support for patients who enrolled in clinical trials.

Results
Between 2007 and 2014, 424 African American patients with cancer were referred to the Increasing Minority Participation in Clinical Trials project. Of those eligible for a clinical trial (N = 378), 304 (80.4%) enrolled in a trial and 272 (72%) consented to receive patient navigation support. Of those receiving patient navigation support, 74.5% completed the trial, compared with 37.8% of those not receiving patient navigation support. The difference in retention rates between the two groups was statistically significant (P < 0.001). Participation of African Americans in therapeutic cancer clinical trials increased from 9% to 16%.
EMPaCT: Acknowledgements

Program Manager
- Nedra Lisovicz, PhD, MPH

Navigators
- Elise McClin
- Kimberly Robinson
- Angela Williams
- Dian Williams

Patients
Challenges of Patient Navigation Program

➢ Training Modalities

➢ Deployment of PNs is resource-intensive

➢ Patients level of needs varies

➢ PN Retention and burnout
WISDOM FOR THE JOURNEY
What Did We Learn

- Engage physicians and nurses in the process early
- Physician champion(s)
- Be prepared for iterative flow charts
- Clarify roles and responsibilities (navigators, social workers etc.)
Wisdom for the Journey

- Leverage resources within the institution and community
- Be a patient advocate
- Empower patients
- Meet with navigators weekly: debrief, inform program implementation, continuing education
QUESTIONS?