

# 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?

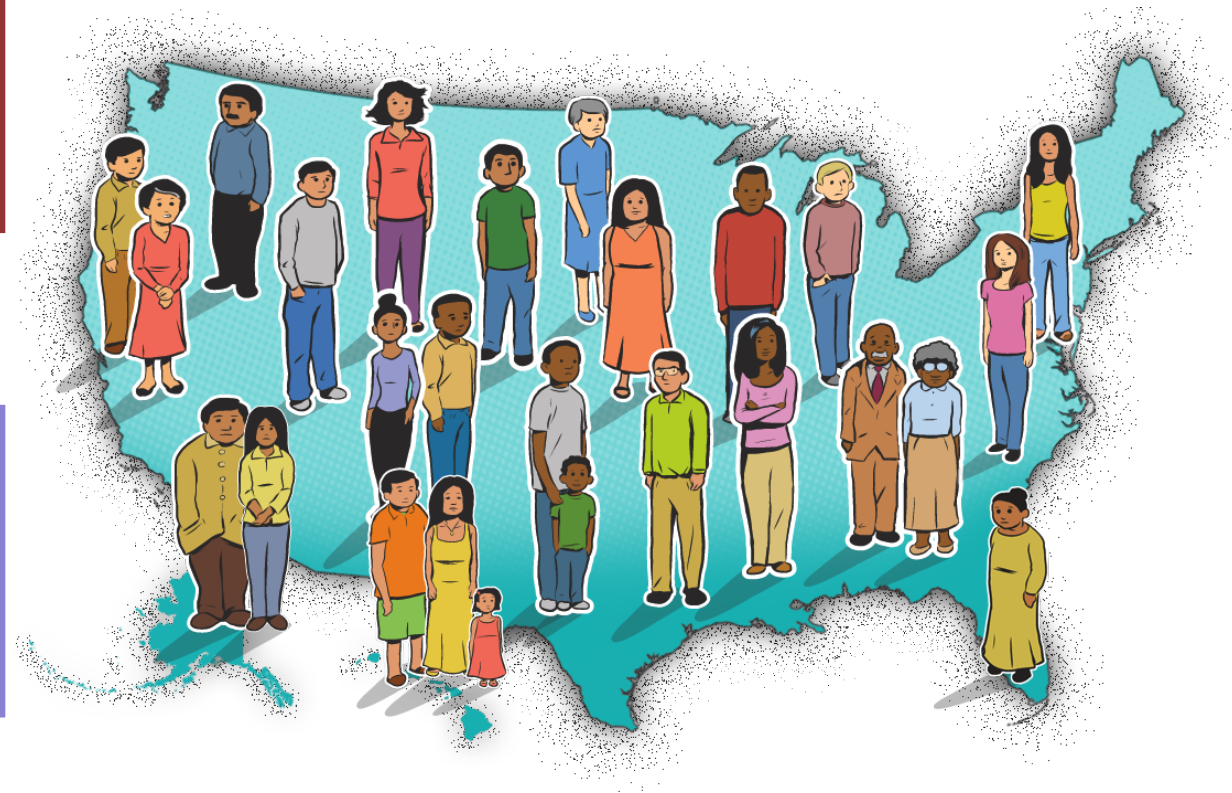
- Absence of diverse populations participation, results of clinical trials (treatment and interventions) cannot be generalized
- Access to alternative/advanced treatment is not available for those in minority and diverse populations if participation in clinical trials is limited
- Without Inclusive participation in clinical trials, health disparities will continue to increase, and health equity will not be achieved.



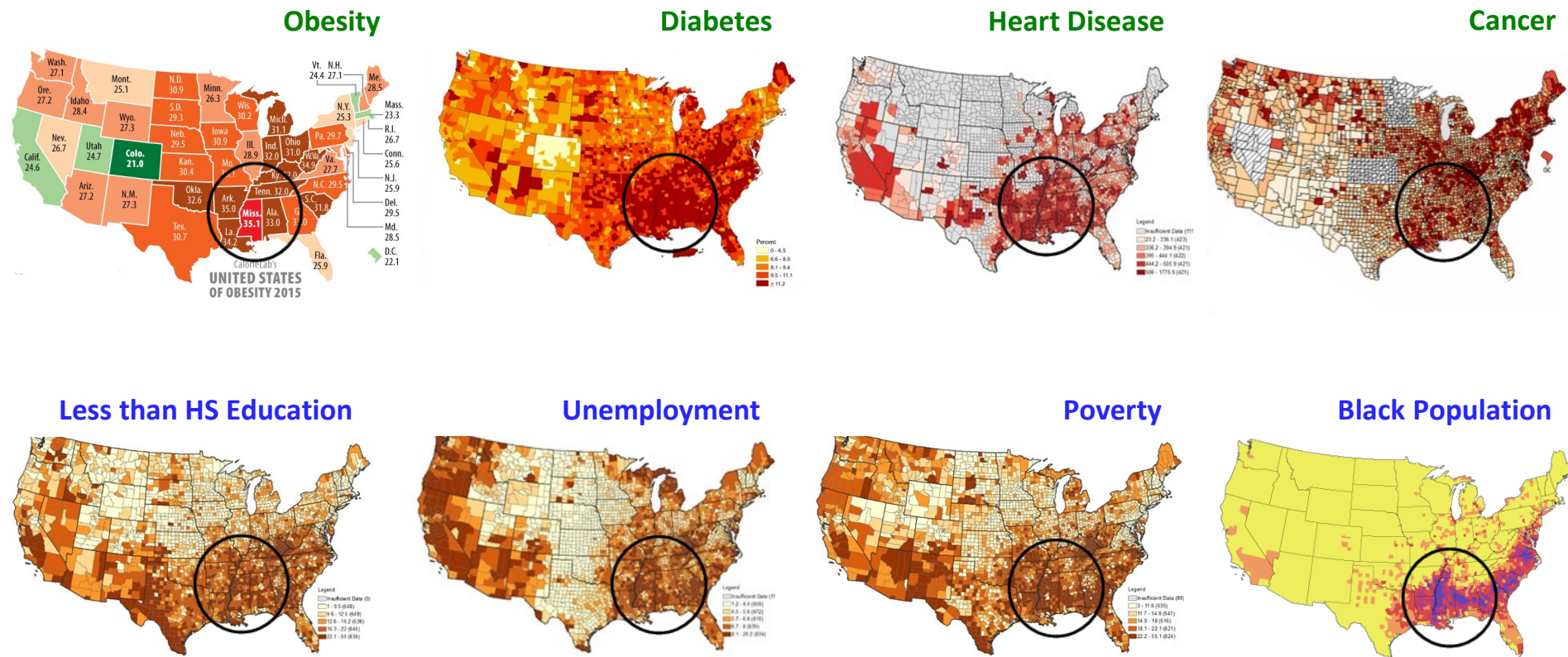
# Inequity in Health Care

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



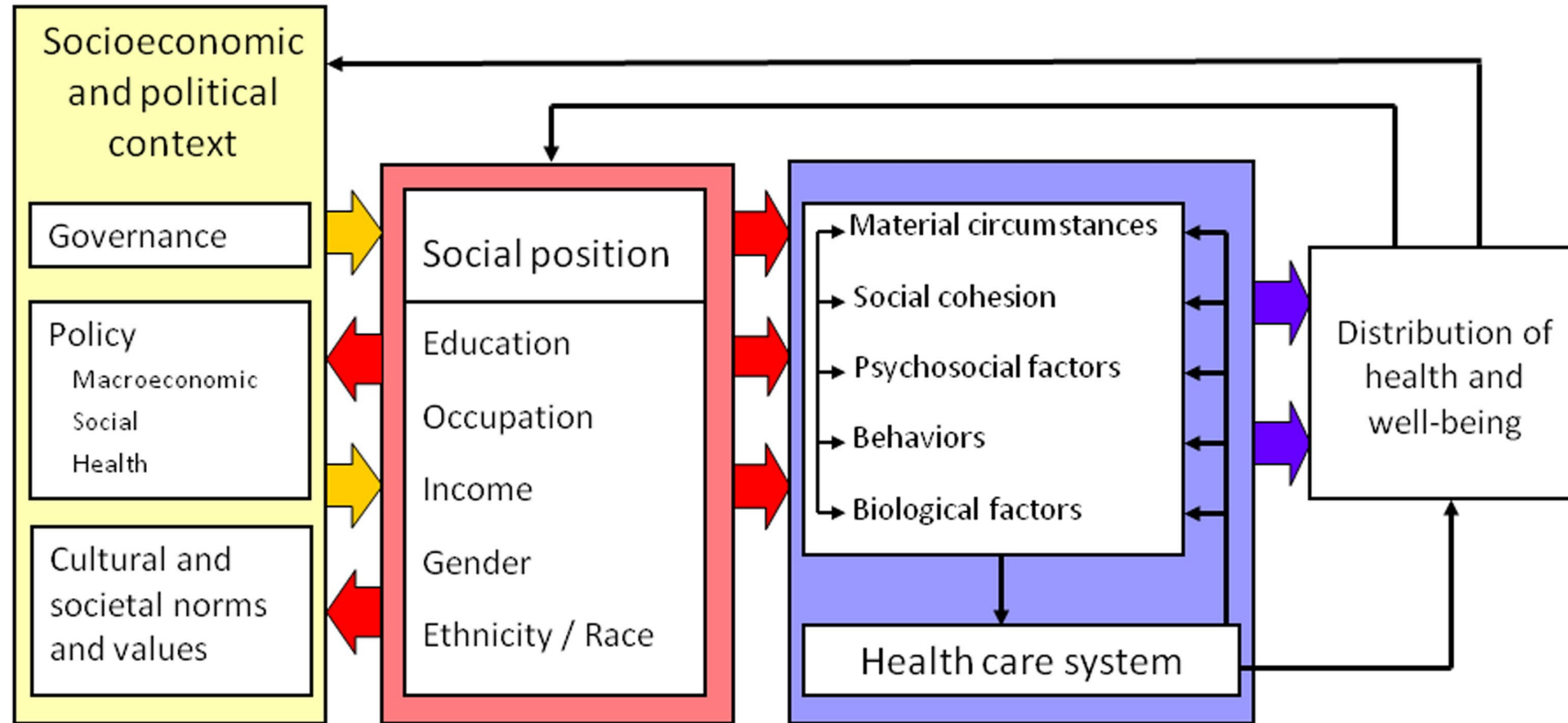


# Health-care related factors for health disparities

- 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



Social determinants of health and health inequities



World Health Organization Social Determinant of Health Conceptual Framework

World Health Organization: [http://www.who.int/social\\_determinants/en/](http://www.who.int/social_determinants/en/)

# Social Determinants of Health: Role in Health Care Utilization

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# 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

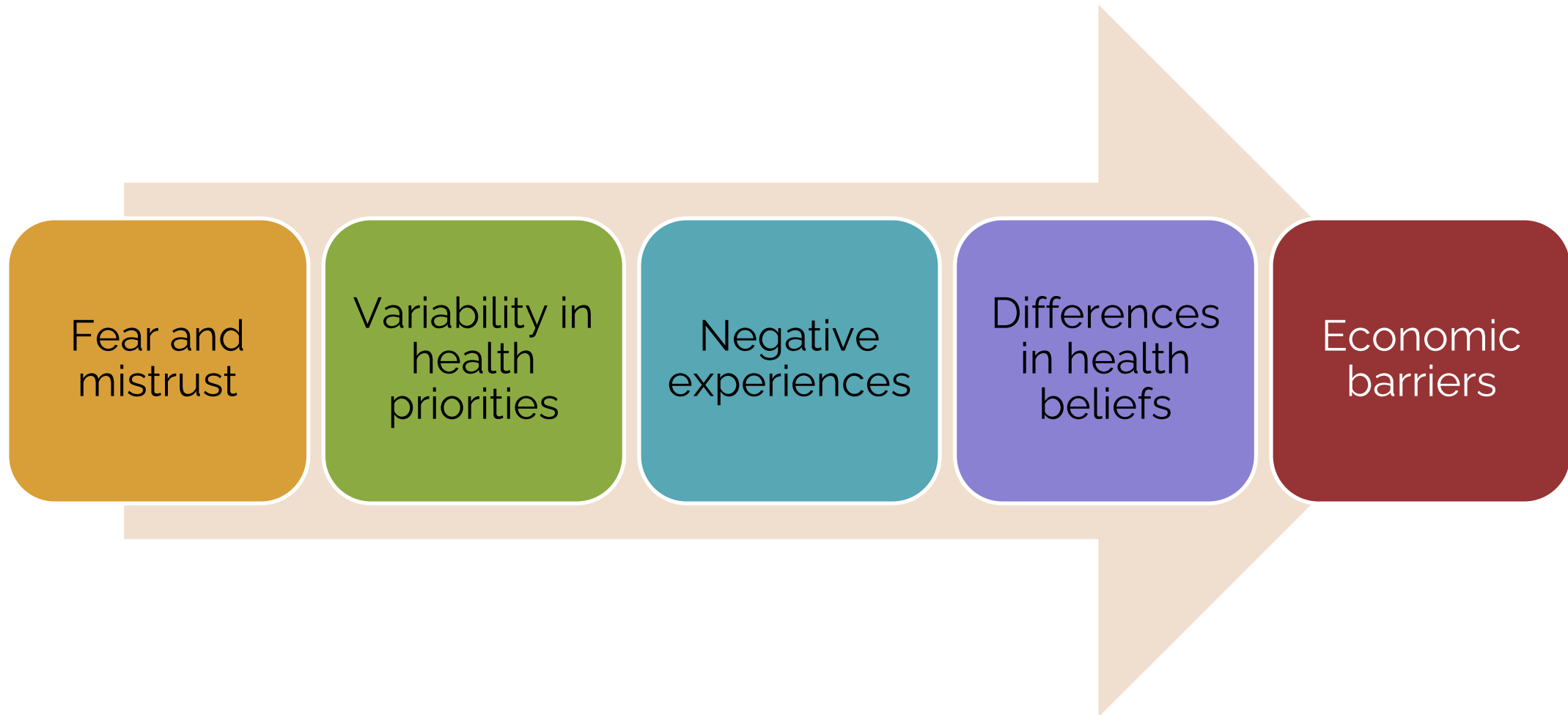


# Recruitment Barriers

- Barriers related to the targeted community
- Barriers related to health care providers
- Barriers related to study design



# Barriers related to the targeted community:



# Barriers related to health care providers:

Loss of authority

Legality

Uncertainty

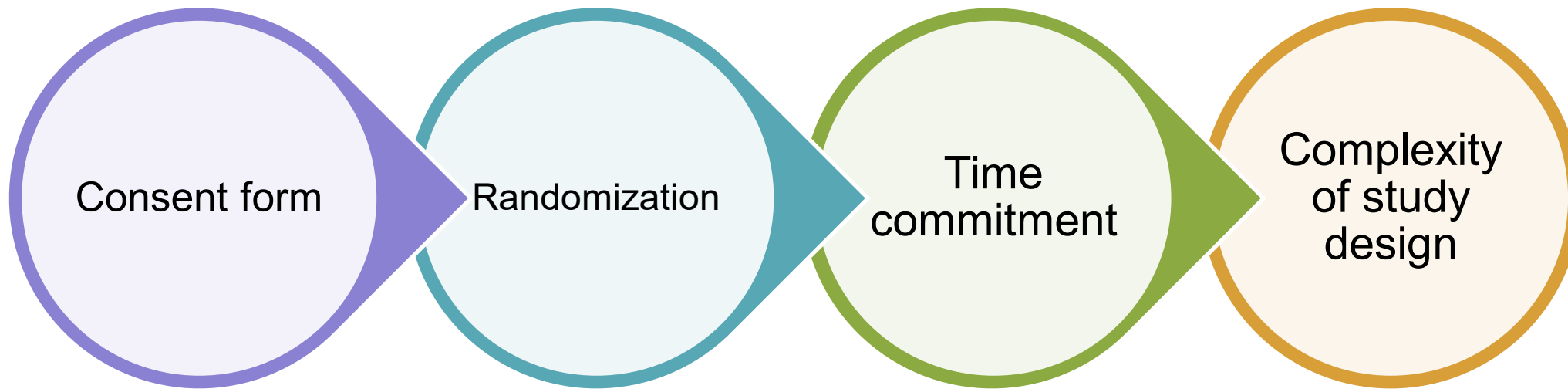
Clinician vs. Scientist

Lack of time





# Barriers related to 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

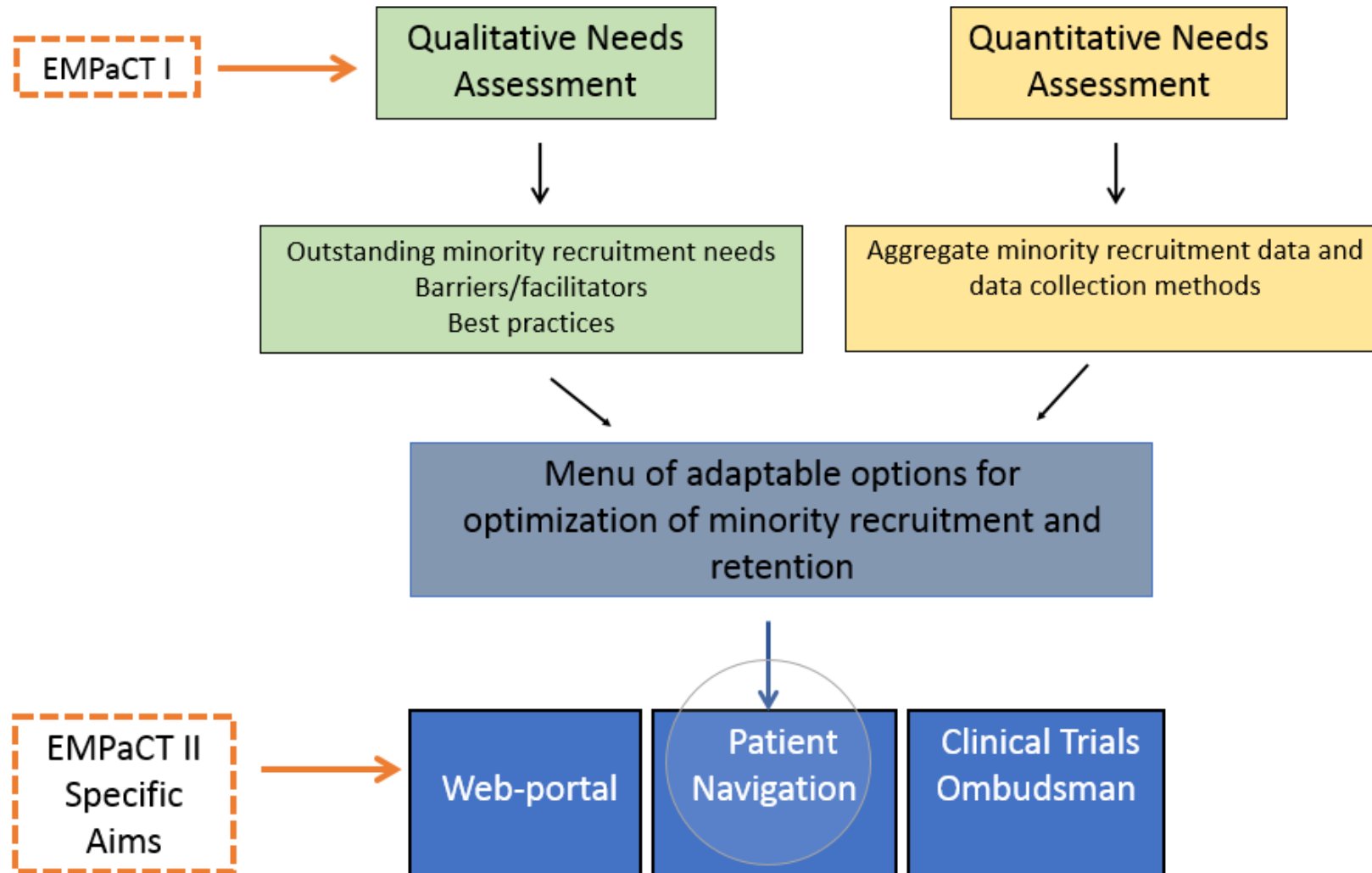
➤ Consortium of five regional leaders:

- East: Johns Hopkins University, Dr. Jean Ford
- Southeast: University of Alabama at Birmingham, Dr. Mona Fouad
- Midwest: University of Minnesota, Drs. Selwyn Vickers & Jasjit Ahluwalia
- Southwest: M.D. Anderson Cancer Center, Dr. Lovell Jones
- West: University of California Davis, Dr. Moon Chen



# EMPACT I → EMPACT II

## Strategies for Improving Minority Recruitment





# EMPaCT: Objective and Methods

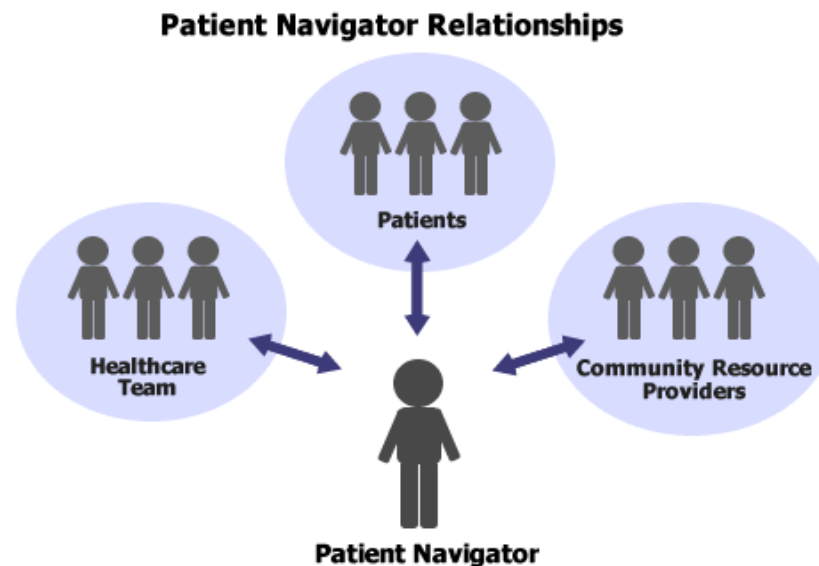


Objective for EMPaCT:

- 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



**EM**PACT

- Learn about new research protocols
- Learn about safety issues
- Provide feedback from patients (generally)
- Obtain new referrals

- [illegible]

# 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



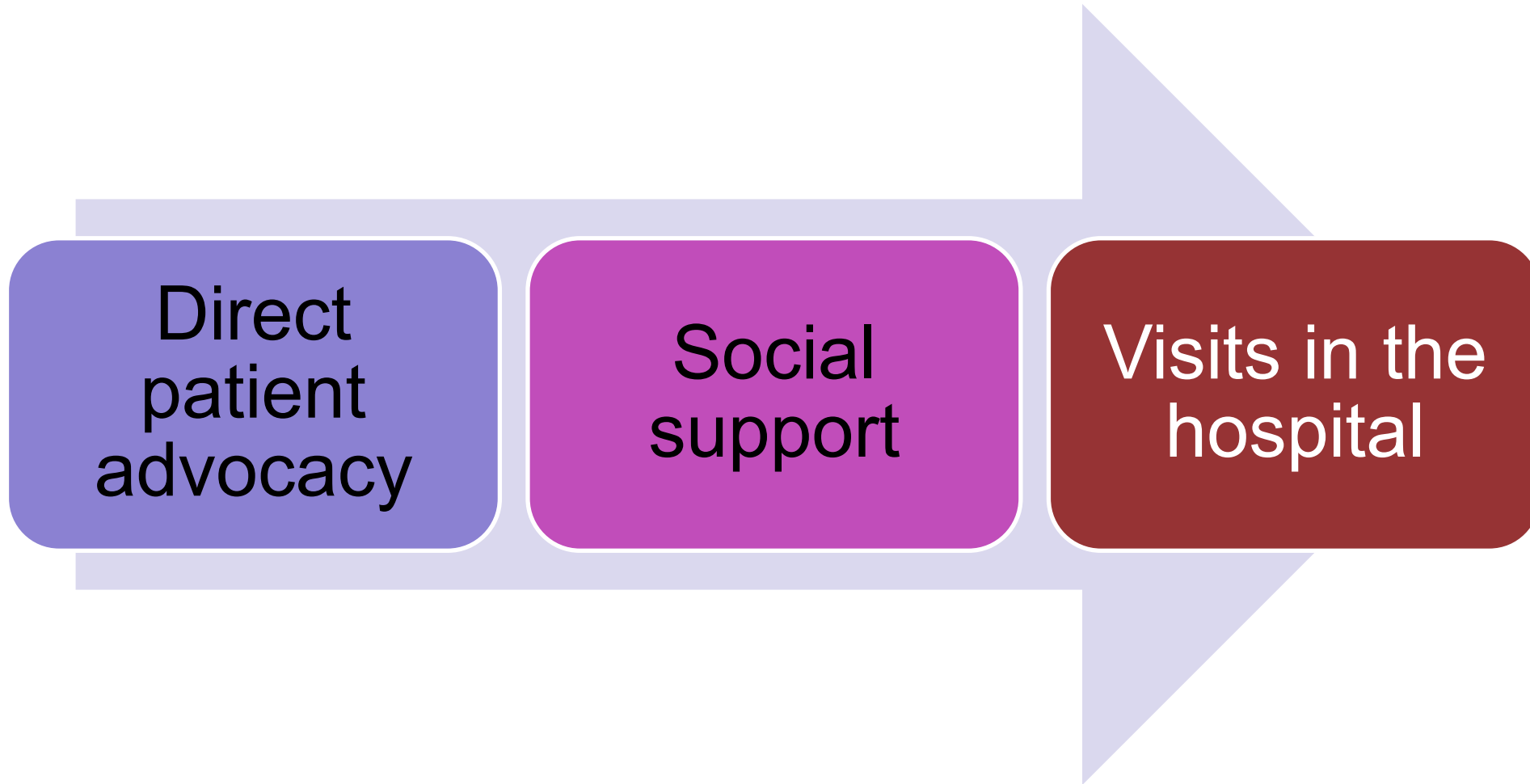
Bridging  
communication  
gaps

Orientation to  
appropriate  
clinical staff  
and resources

Problem  
solving to  
overcoming  
barriers

Referral to  
other support  
services

# EMPaCT: Program Implementation



# EMPaCT: Program Outcomes



Services Provided by Clinic/Site:

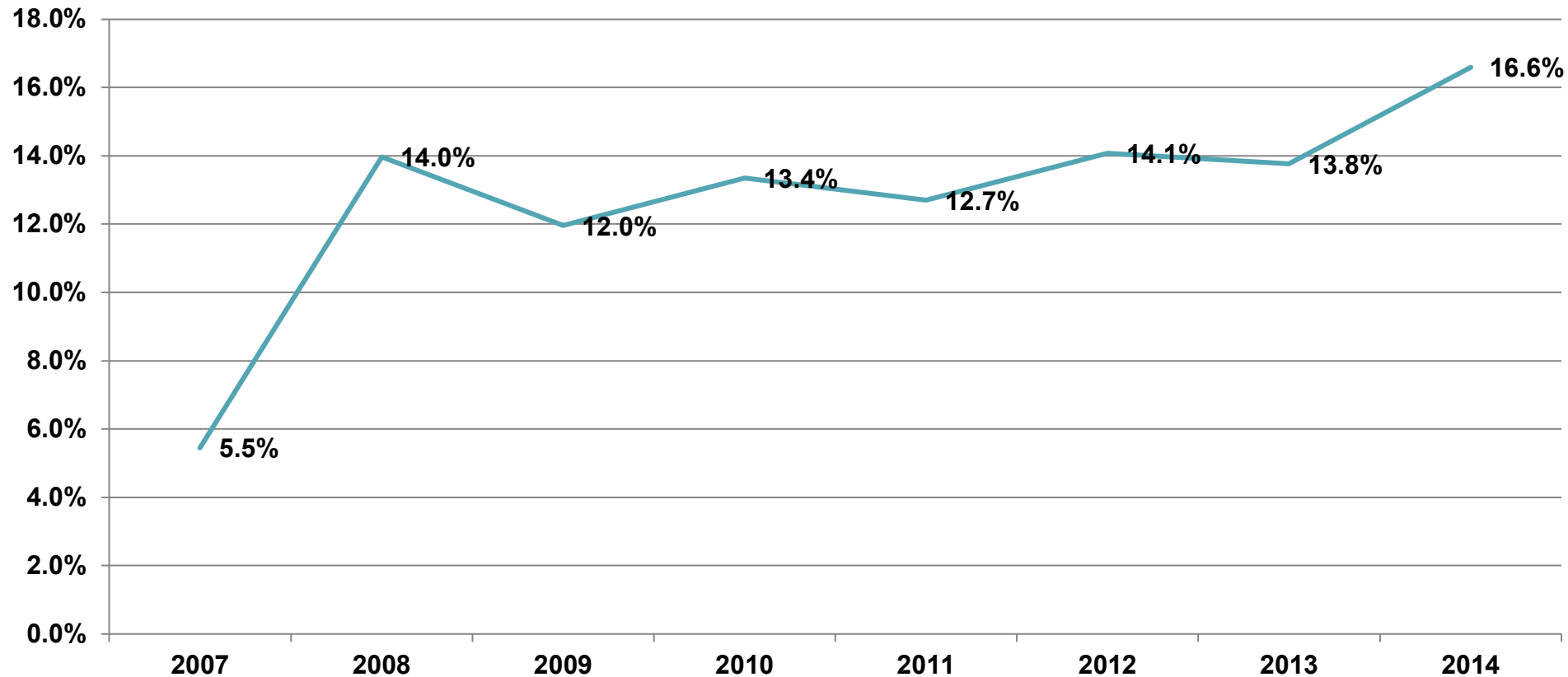
Clinic	Transportation	Lodging	Insurance	Social and Emotional Support
Bone Marrow Transplantation	4	1	0	43
Gastrointestinal/Genitourinary	62	3	0	348
Gynecologic Oncology	137	15	4	913
Head and Neck Hematology Oncology	27	7	0	223
Invasive Ductal Breast Carcinoma	168	13	2	958
Cooper Green Mercy Hospital	394	10	1	1,463
Lung	28	0	0	86
Neuro Oncology	25	12	0	415
Other	25	5	1	191
Radiation Oncology	0	0	0	21
Solid Tumors	45	2	0	344
Total	12	3	0	147
	927	71	8	5,152



# EMPaCT: Program Outcomes



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

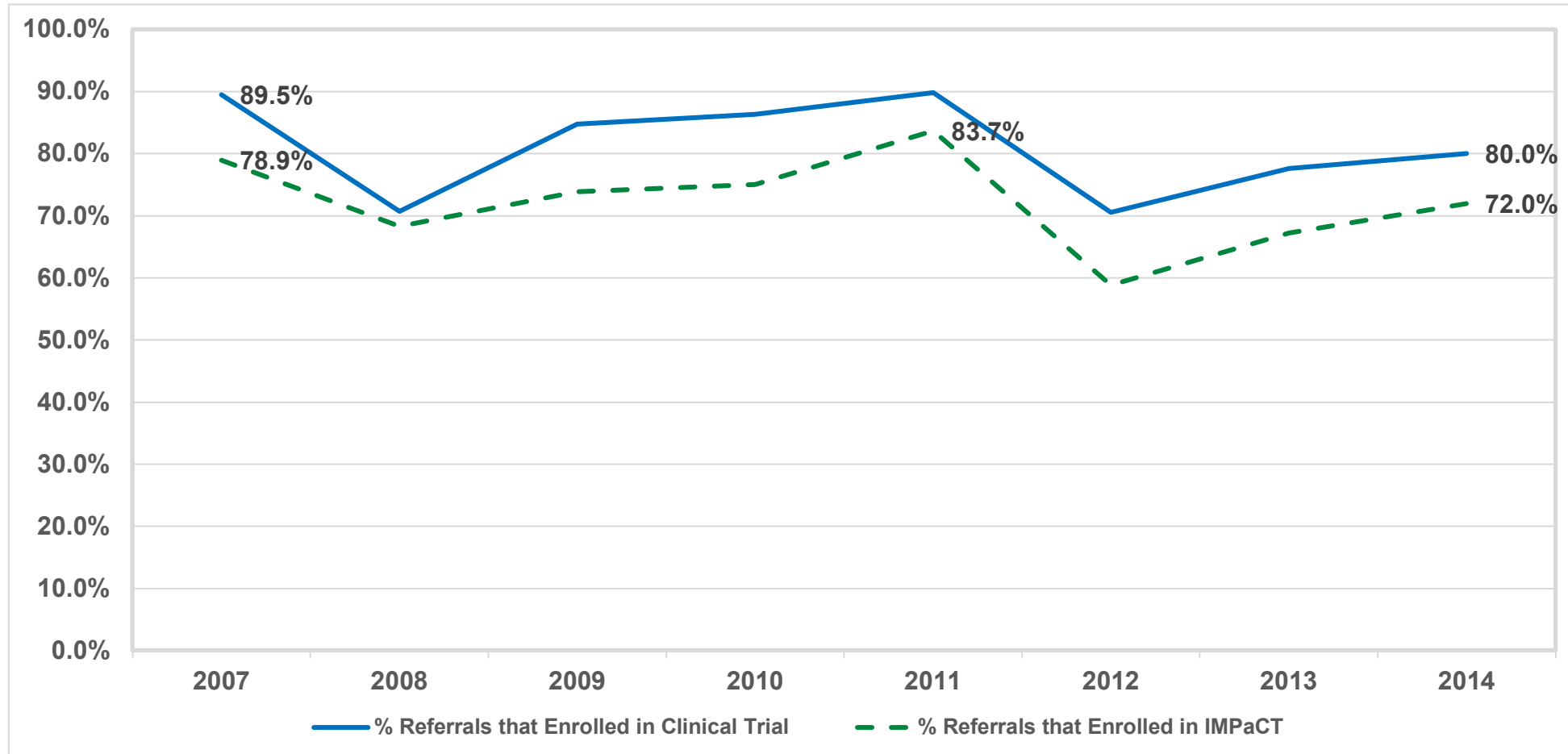




# EMPaCT: Program Outcomes

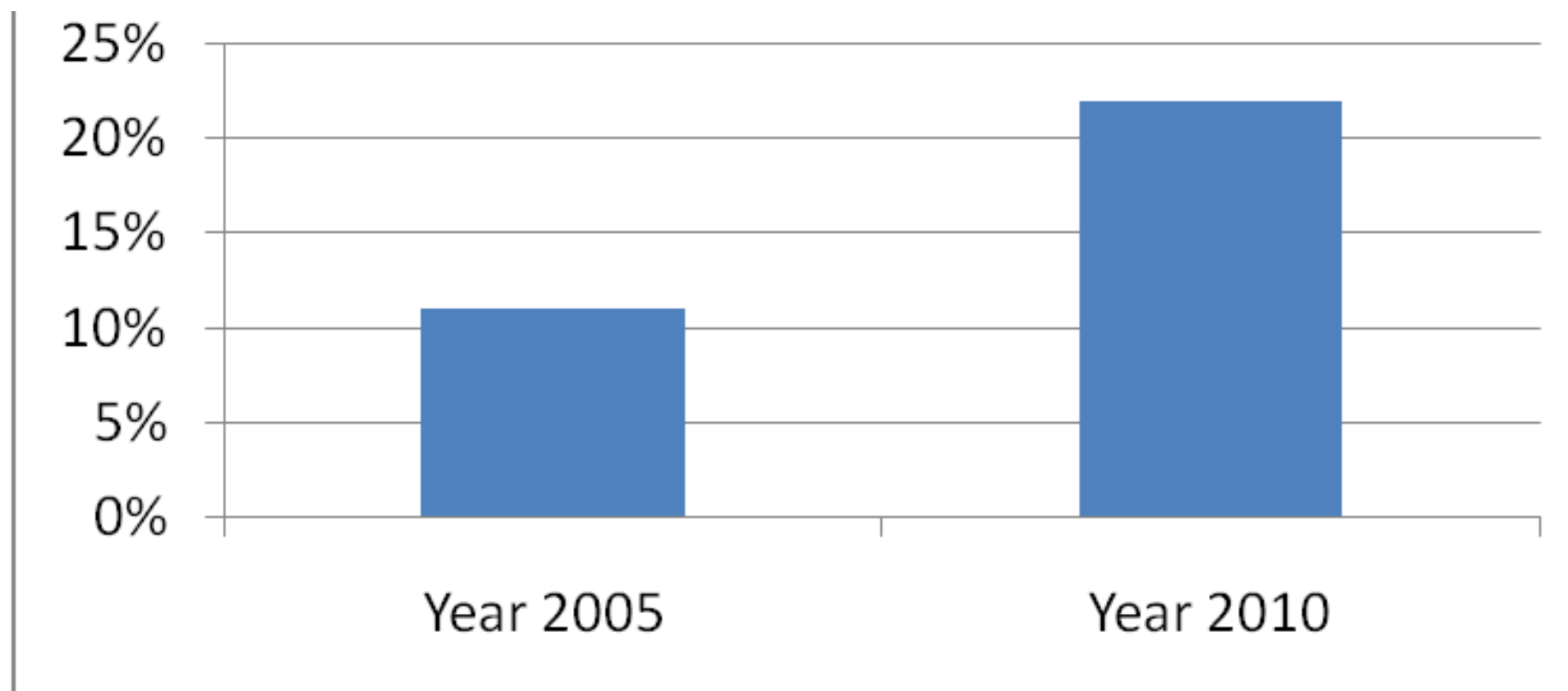


Percentage referrals for clinical trial and IMPaCT:



# EMPaCT: Program Outcomes

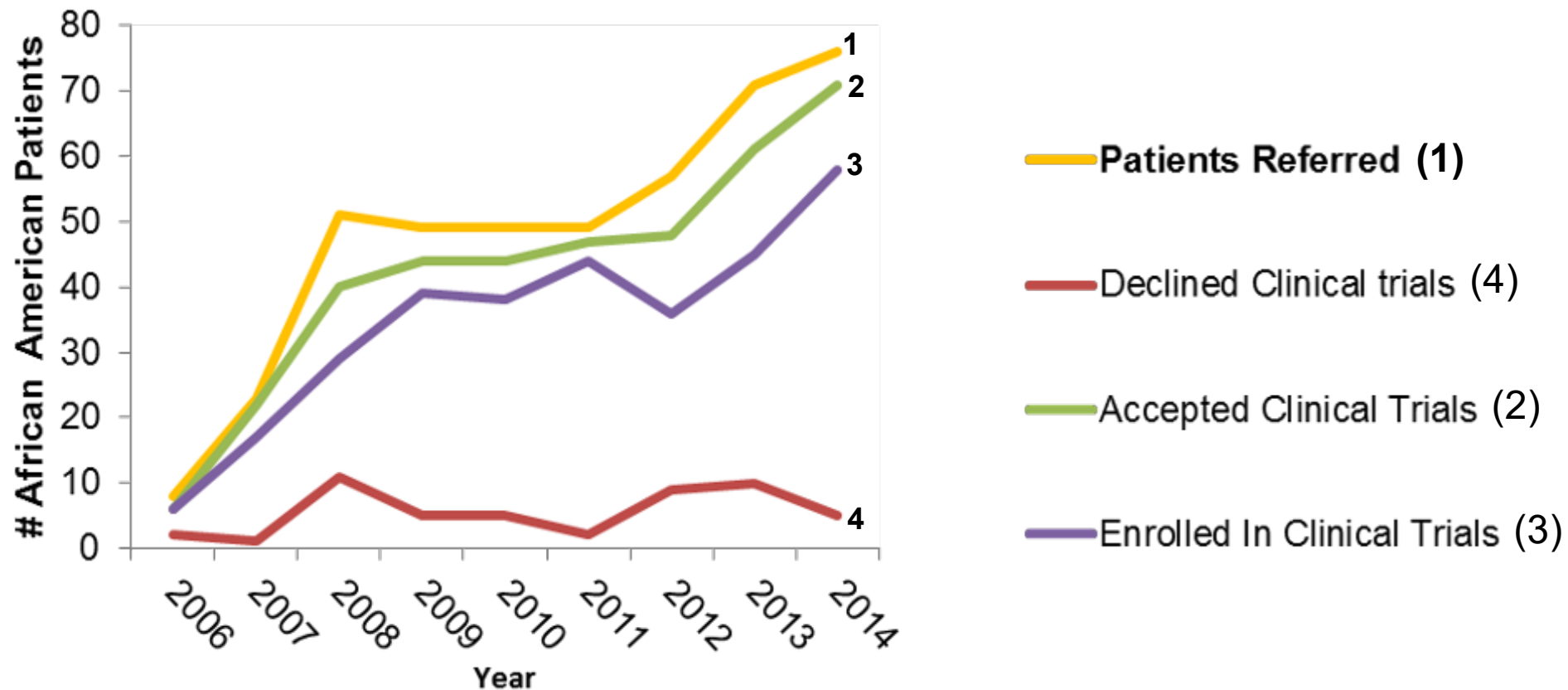
## African Americans Enrolled Pre/Post EMPaCT



# EMPaCT Outcomes

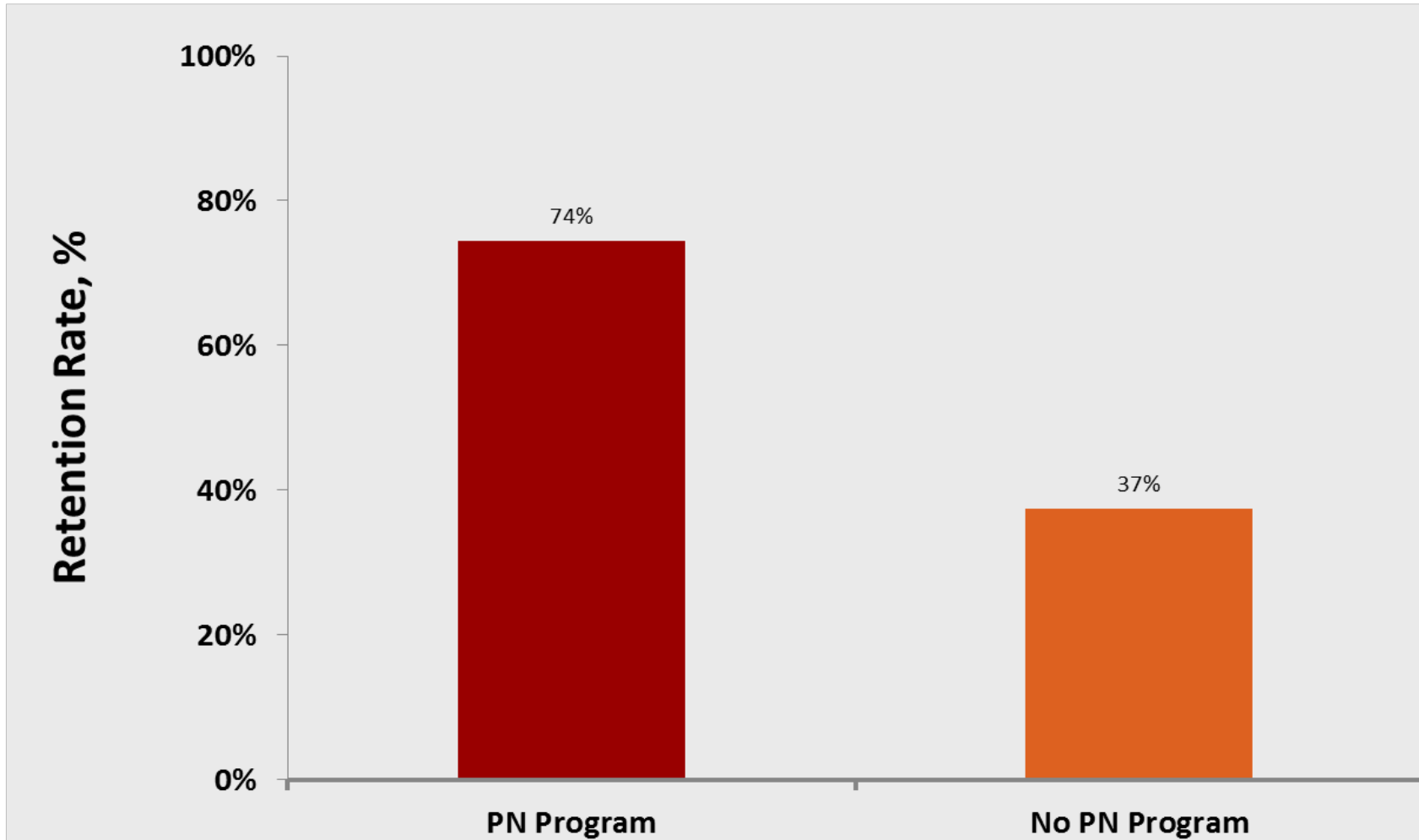


Enrollment Outcomes for African American Patients Referred to the Patient Navigation Program by Year, 2006-2014.



# EMPaCT Outcomes

Cancer Clinical Trial Completion Rate According to PN Program Enrollment



# EMPaCT in Publication

Original Contribution

CARE DELIVERY

EMPaCT

Volume 12 / Issue 6 / June 2016

ASCO<sup>®</sup>  
American Society of Clinical Oncology

Journal of  
**oncology  
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University of Alabama at Birmingham,  
Birmingham, AL

Anaplastic Thyroid Carcinoma:  
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Knowledge With Receipt of  
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Knowledge to Patients: An Overlooked  
Aspect of Personalized Medicine  
L.P. Wallner and S.T. Hawley

Lower Patient Ratings of Physician  
Communication Are Associated  
With Unmet Need for Symptom  
Management in Patients With  
Lung and Colorectal Cancer  
A.M. Walling et al

Harborside  
Press

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## Patient Navigation As a Model to Increase Participation of African Americans in Cancer Clinical Trials

Mona N. Fouad, MD, MPH, Aras Acemgil, MBA, Sejong Bae, PhD, Andres Forero, MD,  
Nedra Lisovicz, PhD, Michelle Y. Martin, PhD, Gabriela R. Oates, PhD,  
Edward E. Partridge, MD, and Selwyn M. Vickers, 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. The 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 tailored 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 37.5% of those not receiving patient navigation support. The difference in retention rates between the two groups was statistically significant ( $P < .001$ ). Participation of African Americans in therapeutic cancer clinical trials increased from 9% to 16%.

UAB

# 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?

