

Strengthening Translational Research in Diverse Enrollment (STRIDE) Webinar: Recruitment and Diversity

Jeroan Allison, MD, MS

Slide preparation by:

Isabelle Pierre-Louis

Joshua Melnick

Elizabeth Rahn

September 6, 2017

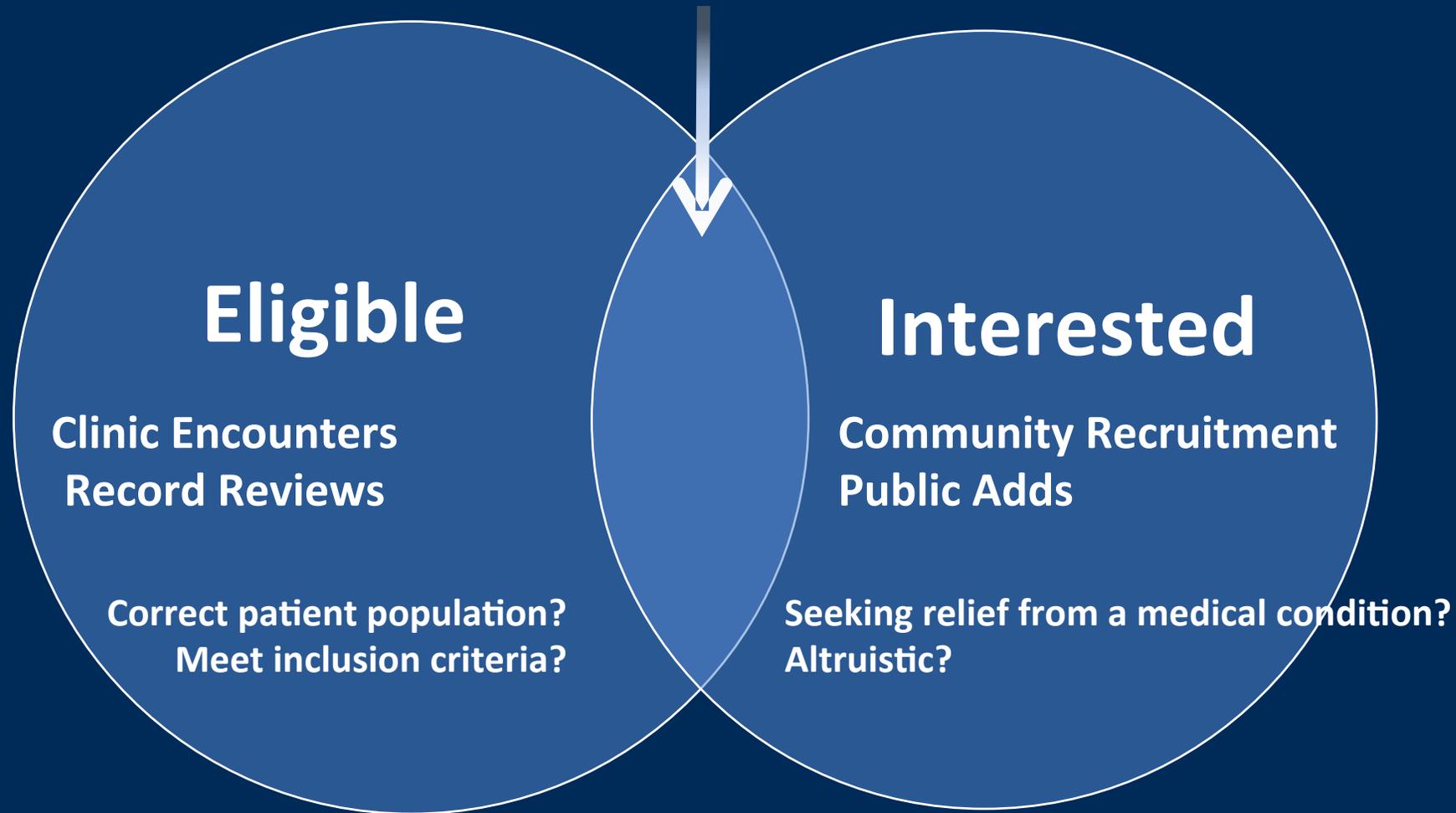
There are critical challenges in clinical trial recruitment.

- ~30% clinical trials have issues reaching enrollment goals¹
- ~20% clinical trials do not enroll a single patient¹
- >90% all clinical trials do not meet their proposed timelines because of difficulties with enrollment¹
- Time it takes to complete trials is biggest contributor to increased costs (i.e., longer trial = higher cost)²

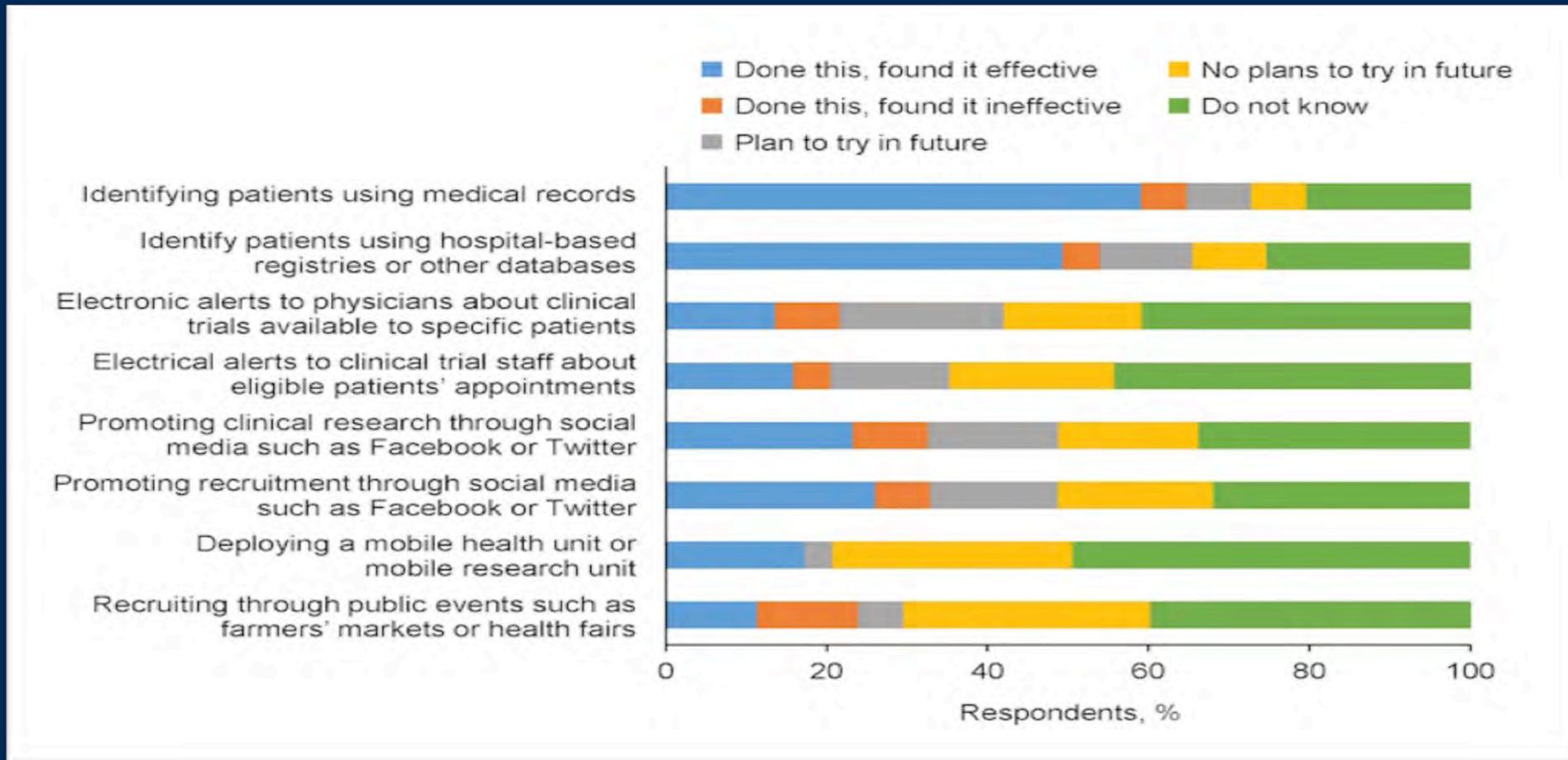
¹Tufts Center for the Study of Drug Development, 2014.

²Hargreaves. Clinical Trials and their Patients: The Rising Costs and how to Stem the Loss. 2016. www.pharmalife.com

The ideal study candidate is eligible and interested.



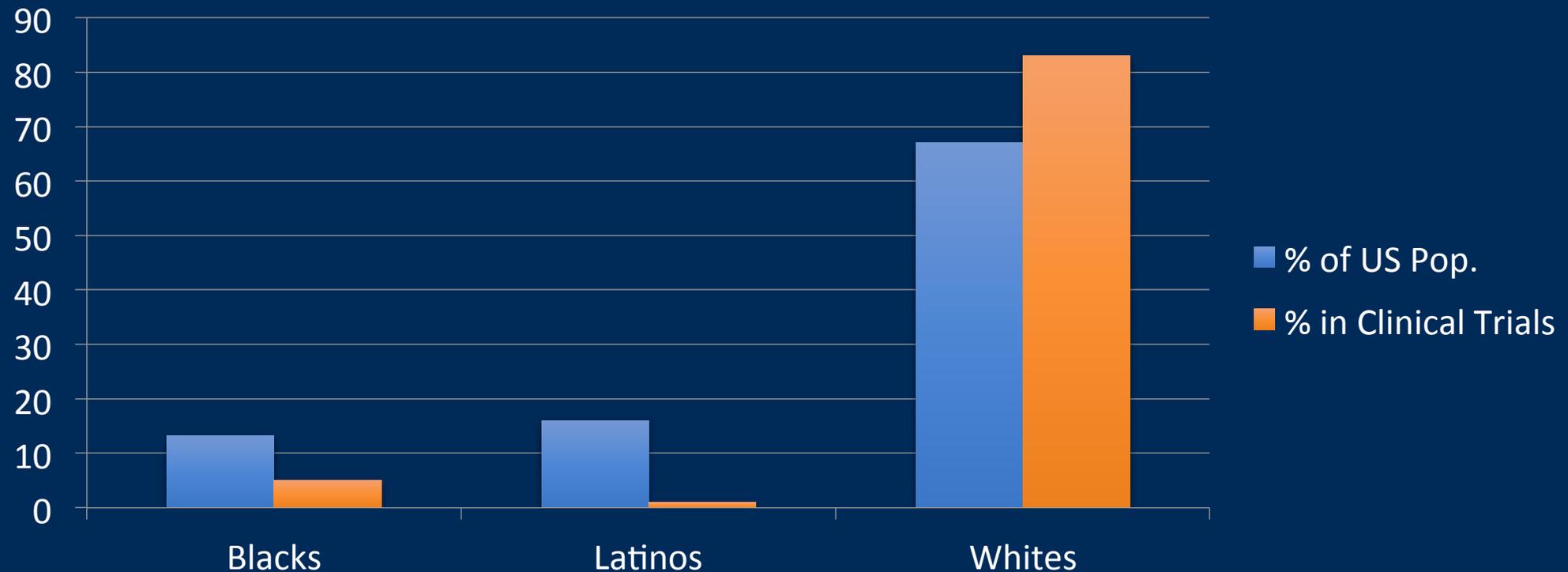
Stakeholder survey reveals successful recruitment strategies.



N=86-88 for each method rated

Mahon *et al.* Applied Clinical Trials 3 Sep 2015

Minorities are underrepresented in research.



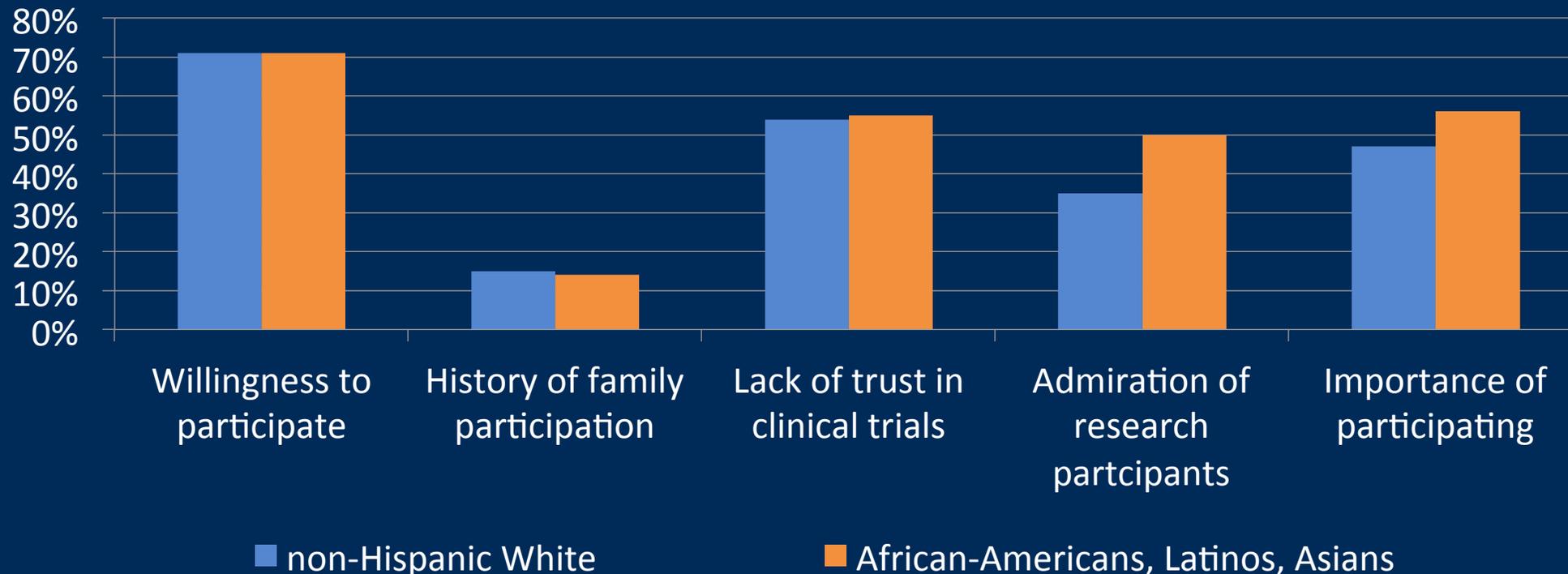
Tom Dorsett. Diversity in clinical trials is an issue that we can no longer ignore. MedCity News MedCitizens Program. January 2017. <http://medcitynews.com/2017/01/diversity-clinical-trials-issue-can-no-longer-ignore/?rf=1>

Contrary to popular belief, minorities consent to research studies at the same rate as Whites.

| Trial Type (examples) | Consent Rate (%) | | |
|-----------------------|------------------|------------------|----------|
| | White | African-American | Hispanic |
| In-person interview | 84 | 81 | 82 |
| 4-hour medical exam | 75 | 76 | 82 |
| Drug trial | 16 | 16 | 18 |
| Radiation | 46 | 53 | 50 |

Wendler, D. PLoS medicine 3.2 (2005): e19. Sample of 20 trials with 70,000 individuals.

Poll shows minority populations support clinical trials to improve health of others.



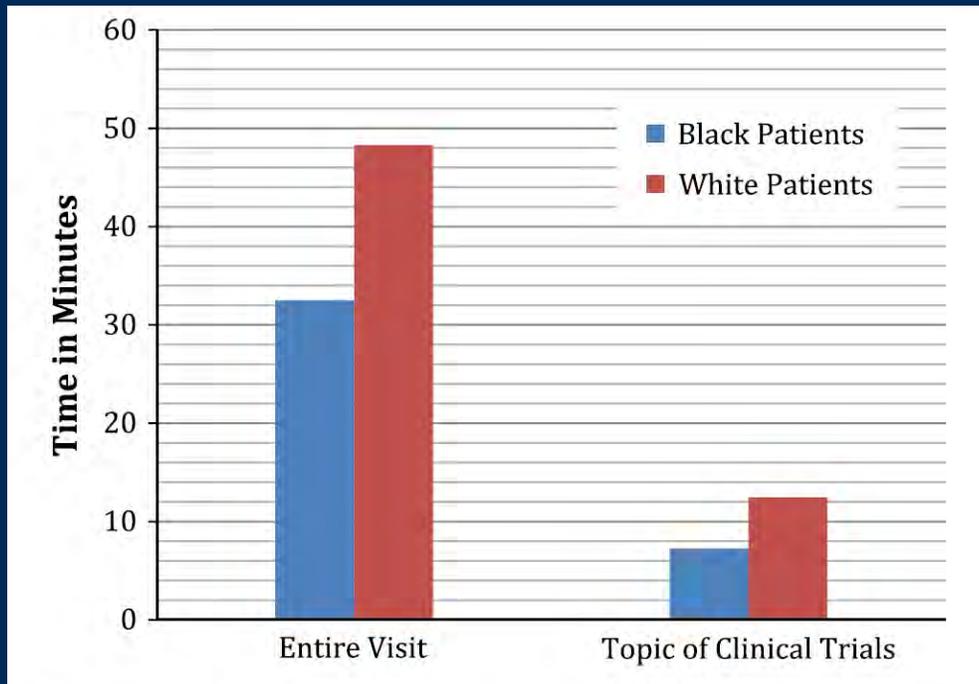
National Research! America (2013). National Probability Poll (n = 1793). <http://www.researchamerica.org/blog/new-poll-shows-minority-populations-support-clinical-trials-improve-health-others-participation>
George, S. American Journal of Public Health. 2014;104(2):e16-e31.

We should not assume that African-Americans don't build trusting relationships with health care professionals.

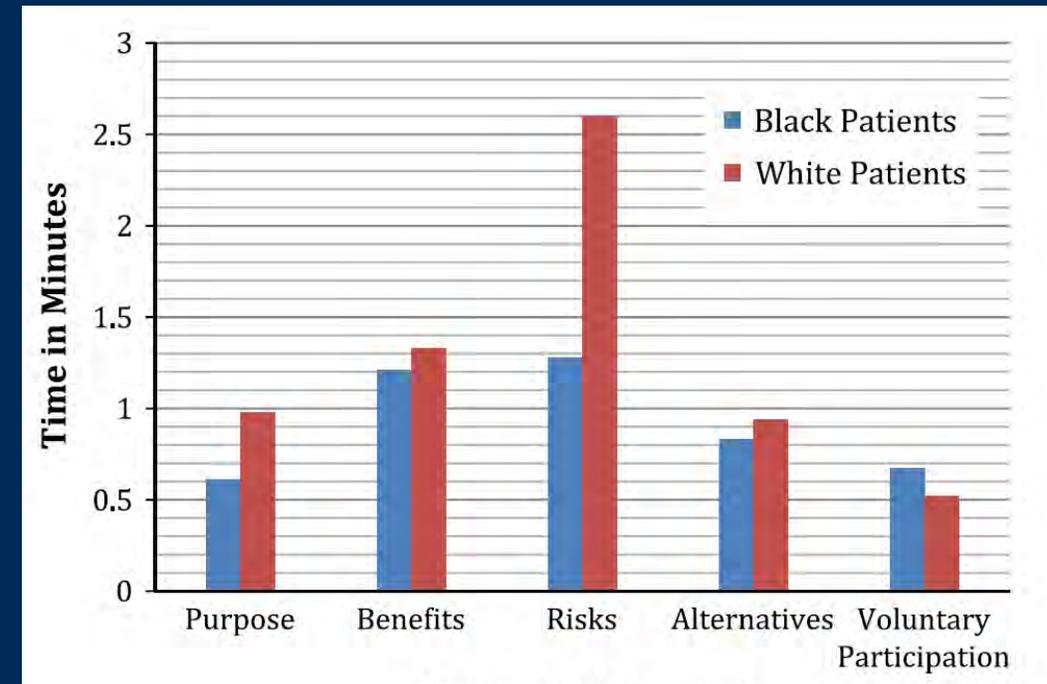
| | African-Americans (n=279) | Whites (n=473) |
|--|------------------------------|-------------------|
| Awareness of Tuskegee | 65% | 41% |
| Previous trial participation | 50% | 55% |
| Primary Care Assessment Physician Trust Scale (range 0 – 100) | 78 | 77 |

Durant R. J Cult Diversity; 2011; 18(1): 8 – 19.

Physicians talk to Black patients less than White patients.



Time spent talking with patients

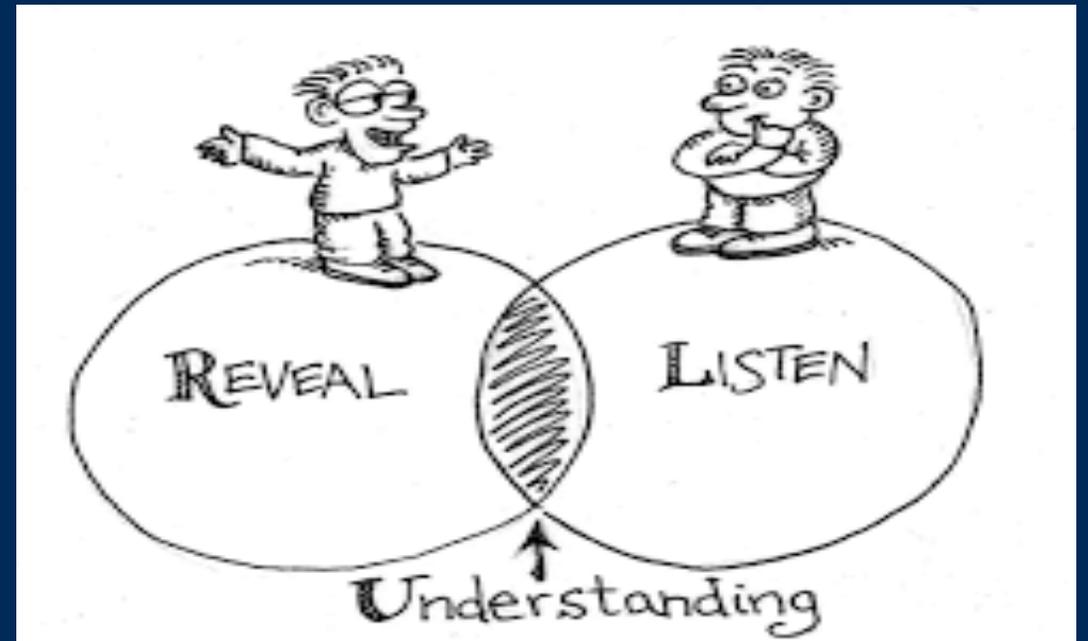


Time spent talking about research consent

Egley, S. *Health Expectations* 18.5 (2015): 1316-1326.

It's important to identify barriers to recruitment so we can build strategies to overcome them.

- Participant barriers
- Investigator barriers
- Protocol barriers



https://www.bioethics.nih.gov/courses/pdf/2015/session3_grady.pdf

The burden of increasing diversity in clinical trial participation falls on us.

- The studies reviewed have important limitations, but raise overall considerations and point in useful directions.
- Reservoirs of altruism and the ability to build authentic and trusting relationships among minority patients and health professionals offer intriguing possibilities for increasing recruitment success.
- Possibilities for effective interventions include changing how we interact with potential research participants and changing the current clinical trials “system.”



Our goal is to collaboratively develop innovative strategies that will both increase diversity in clinical trials and help meet overall recruitment targets, without generating undue system burden.

Why Clinical Trials?

Mona Fouad, M.D., MPH

Director, Minority Health and Health Disparities Research Center
Senior Associate Dean of Diversity and Inclusion, School Of Medicine



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



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



RECRUITMENT AND RETENTION SHARED FACILITY

(RRSF)

Expert Team of Recruiters

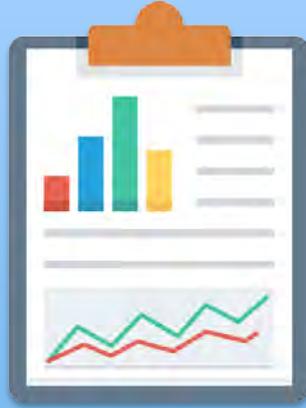
- RRSF provides an experienced team that has enrolled over 33,000 participants for more than 90 studies since 1997.
- Team includes project planners and coordinators, telephone interviewers, data managers and analysts, community outreach personnel, and patient navigators.
- Experience with population-based studies, therapeutic clinical trials, behavioral intervention trials, telephone surveys, focus groups, and in-person qualitative interviews.
- Expertise in recruiting African Americans and women.



One-Stop Shop for Recruitment for Any Study



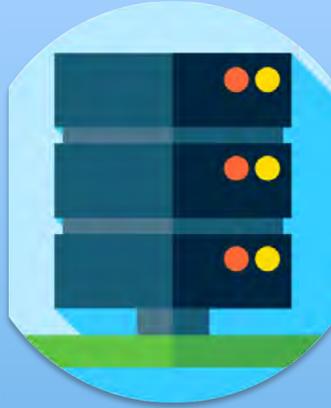
Identify potential participants and target them with culturally relevant recruitment messages.



Consent, enroll, and schedule participants in studies.



Generate standard reports for the IRB; progress and customized reports to suit investigator needs.



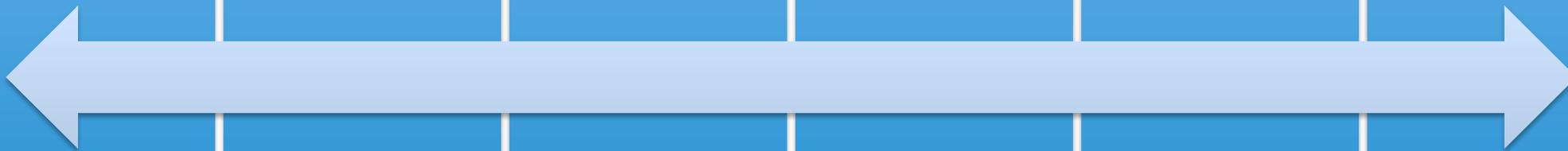
Provide databases in requested format.



Provide access to data analysts, behaviorists, statisticians, and epidemiologists with expertise in health disparities.



Provide retention services for follow-up data collection.



Examples of RRSF Studies

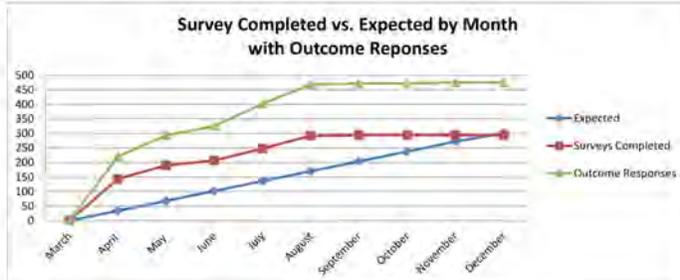
| STUDY | SPONSOR | RECRUITED |
|--|---------|---------------|
| Women's Health Initiative (WHI) | NIH | 4355 (40% AA) |
| Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial | NCI | 6188 (30% AA) |
| National Lung Screening Trial (NLST) | NCI | 5052 (6% AA) |
| Impact of Religiosity on Cancer Behaviors | NCI | 400 (100% AA) |
| Deep South Navigation Network | CMS | 1558 (16% AA) |
| IMPACT: Increasing Minority Participation Clinical Trials | NCI | 270 (100% AA) |
| Multiple Myeloma | NIH | 301 (44% AA) |

Recruitment Process

- Identify essential characteristics of audience:
 - ✓ Who (target population)
 - ✓ Where (geographical location)
 - ✓ How (mode of contact)
- Select strategies (mode of contact)
 - ✓ Media: Radio and Television (Paid ad, PSA, Talk show)
 - ✓ Mass mailing (population and study specific material)
 - ✓ Community outreach (churches, organizations, word of mouth)
 - ✓ Physician referrals
 - ✓ Social Media (Web sites, Facebook, email)
- Create recruitment materials
 - ✓ Tailor culturally-appropriate messages to fit target population
- Track and monitor recruitment progress
 - ✓ Short-term and long-term goals
 - ✓ Daily, weekly, and monthly reports

Samples of Recruitment Progress Reports

| | UAB | MMC | MH | FWBMC | GCMC | SAMC | NARMC | MCI | TOTALS |
|------------------------------------|-----|-----|-----|-------|------|------|-------|-----|--------|
| Total Surveys Mailed | 191 | 50 | 166 | 56 | 69 | 109 | 108 | 162 | 911 |
| Survey Completed | 81 | 16 | 50 | 14 | 18 | 32 | 33 | 50 | 294 |
| Patient Reports No CG | 14 | 1 | 18 | 5 | 8 | 11 | 14 | 15 | 86 |
| Patient Not Willing to Participate | 4 | 0 | 7 | 1 | 2 | 1 | 2 | 4 | 21 |
| CG Not Willing to Participate | 3 | 1 | 3 | 2 | 1 | 2 | 0 | 1 | 13 |
| Patient Deceased | 2 | 0 | 2 | 1 | 1 | 2 | 0 | 1 | 9 |
| Invalid Address | 4 | 1 | 5 | 1 | 5 | 3 | 5 | 6 | 30 |
| Other | 4 | 0 | 3 | 2 | 0 | 0 | 3 | 10 | 22 |
| Pending Surveys | 79 | 31 | 78 | 30 | 34 | 58 | 51 | 75 | 436 |



| Recruitment and Retention Shared Facility | | | | |
|---|-----------|------------|--------|--------|
| Going Forward | | | | |
| 6/30/2012 | | | | |
| Description | Fairfield | Forestdale | Totals | % |
| Houses Approached | 336 | 419 | 755 | 100% |
| Survey Completed | 97 | 105 | 202 | 26.75% |
| Ineligible | 12 | 15 | 27 | 3.58% |
| Age < 21 | 7 | 7 | 14 | |
| Lived at Address < 2 yrs | 5 | 8 | 13 | |
| Pregnant | 0 | 0 | 0 | |
| Refusal | 50 | 98 | 148 | 19.80% |
| Refused | 43 | 91 | 134 | |
| Opt Out Chosen | 7 | 7 | 14 | |
| Other | 177 | 201 | 378 | 50.07% |
| Not A Good Time | 19 | 14 | 33 | |
| No Answer | 151 | 183 | 334 | |
| Non-Resident | 7 | 4 | 11 | |
| Mailings | | | | |
| Results | Fairfield | Forestdale | Totals | |
| Total Pieces Dropped | 796 | 824 | 1620 | |
| Returned | 189 | 104 | 293 | |
| Vacant | 53 | 22 | 75 | |

T-TRIAL PHONE PRESCREENING REPORT

10/28/2015

| | CY | Tawny | Vicki | Julie | ALL | % |
|--------------------|------------|-------|-------|-------|------|-------------|
| Number of Calls | 1603 | 120 | 35 | 358 | 2116 | |
| Eligible | ELIGIBLE | 974 | 77 | 15 | 244 | 1310 61.91% |
| Ineligible | INELIGIBLE | 515 | 40 | 17 | 98 | 670 31.66% |
| Bad Phone Number | | | | | | |
| FAX/Business Phone | | | | | 0 | 0.00% |
| Disconnected Phone | 8 | | | | 8 | 0.38% |
| Wrong Number | 3 | | | | 3 | 0.14% |
| No Incoming Calls | 1 | | | | 1 | 0.05% |
| Other | | | | | | |
| Refused | 69 | 2 | 3 | 10 | 84 | 3.97% |
| No Answer | 9 | | | 3 | 12 | 0.57% |
| Left Message | 18 | | | 2 | 20 | 0.95% |
| Not a Good Time | | | | 1 | 1 | 0.05% |
| Hang Up | | | | | 0 | 0.00% |
| Call Back | 3 | 1 | | | 4 | 0.19% |
| Line Busy | 1 | | | | 1 | 0.05% |
| Deceased | 2 | | | | 2 | 0.09% |

Comprehensive RRSF Services

Help with developing recruitment and retention plans for research proposals or funded projects;

Identifying potential participants and reaching them with targeted mass mailings and population-specific recruitment materials;

Conducting community outreach activities, on-site clinic recruitment with patient navigators, phone surveys, focus groups, and qualitative in-person interviews.

Examples of Recruitment Strategies

- Community Intervention Retention Strategy (CRIS) Funded by: National Cancer Institute (NCI)
- Enhancing Minority Participation in Clinical Trials (EMPaCT) Funded by: NIMHD



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



COMMUNITY-BASED RETENTION INTERVENTION STUDY

(CRIS)

Funding Agency: NCI

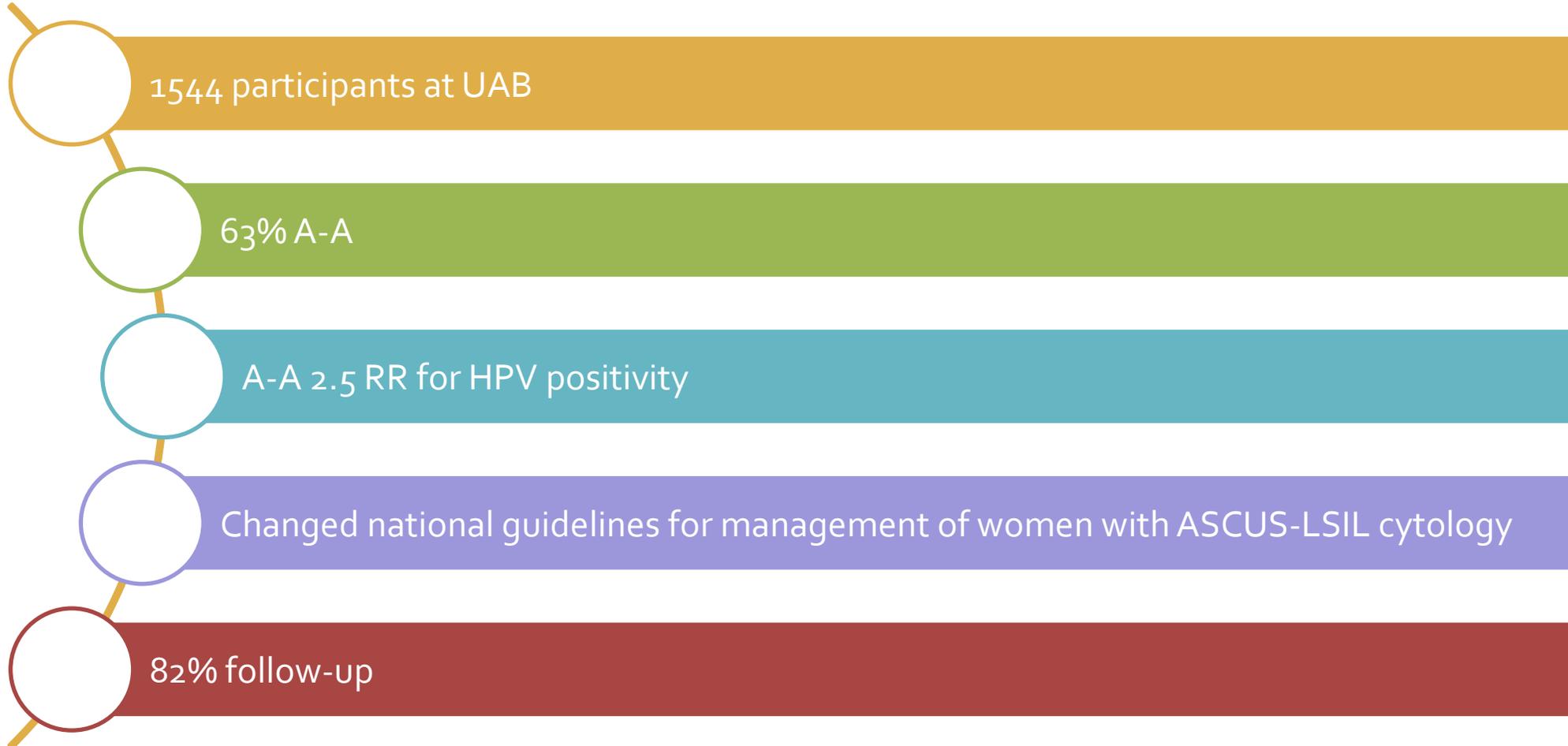
CRIS Objective

This study evaluated the effectiveness of a community-based intervention strategy based on Community Health Advisors (CHAs) to increase compliance and adherence in randomized clinical trial funded by NCI for management of abnormal Pap Smear (ALTS Trial). The study included the training and use of volunteers CHAs as research partners.



CRIS – ALTS Trial

ASCUS – Low Grade Triage Study (NCI)



CRIS Design and Methods

Two matched communities randomly assigned to Community Health Advisors (CHAs) supported intervention vs. control.



Training Community Health Advisors



Jefferson County Graduation Ceremony



Results

Adherence rates for scheduled clinic visits were significantly higher in the intervention group (80%) compared to the control group (65%) ($P < 0.0001$). These results indicated that volunteer CHAs can be effective in improving the retention and adherence of minority and low-income women in clinical trials.

| Attendance | No. of Participants (%) | |
|---------------------------|-------------------------|------------------|
| | Controls | CHA Intervention |
| Visit shows | 449 (65) | 642 (80) |
| Visit no-shows | 238 (35) | 163 (20) |
| Total no. of appointments | 687 | 805 |

Abbreviations: CRIS, Community-Based Retention Intervention Study, CHA, Community Health Advisor.

a $P < .0001$.



Published Results

Cancer



Original Article

Adherence and Retention in Clinical Trials: A Community-Based Approach

Mona N. Fouad, MD, MPH¹; Rhoda E. Johnson, PhD²; M. Christine Nagy, PhD³; Sharina D. Person, PhD⁴; and Edward E. Partridge, MD⁵

BACKGROUND: The Community Health Advisor (CHA) model has been widely used to recruit rural and low-income, mostly African American women into clinical and behavioral research studies. However, little is known about its effectiveness in promoting retention and adherence of such women in clinical trials. **METHODS:** The Community-Based Retention Intervention Study evaluated the effectiveness of a community-based intervention strategy using the CHA model and the empowerment theory to improve the retention and adherence of minority and low-income women in clinical trials. The research strategy included the training and use of the volunteer CHAs as research partners. The target population included women participating in the University of Alabama at Birmingham clinical site of the Atypical Squamous Cells of Undetermined Significance–Low-Grade Squamous Intraepithelial Lesion (ASCUS–LSIL) Triage Study (ALTS), a multicenter, randomized clinical trial. Two communities in Jefferson County, Alabama, that were matched according to population demographics were identified and randomly assigned to either an intervention group or a control group. Thirty community volunteers were recruited to be CHAs and to implement the intervention with the ALTS trial participants. In total, 632 ALTS participants agreed to participate in the project, including 359 in the intervention group, which received CHA care, and 273 in the control group, which received standard care. **RESULTS:** Adherence rates for scheduled clinic visits were significantly higher in the intervention group (80%) compared with the control group (65%; $P < .0001$). **CONCLUSIONS:** The results indicate that volunteer CHAs can be trained to serve as research partners and can be effective in improving the retention and adherence of minority and low-income women in clinical trials. *Cancer* 2014;120(7 suppl):1106–12. © 2014 American Cancer Society.

KEYWORDS: clinical trials, adherence, retention, minority women, underserved women, African American women.



ENHANCING MINORITY PARTICIPATION IN CLINICAL TRIALS

(EMPaCT) Phase II

Funding Agency: NIMHD



EMPaCT: Filling a Need

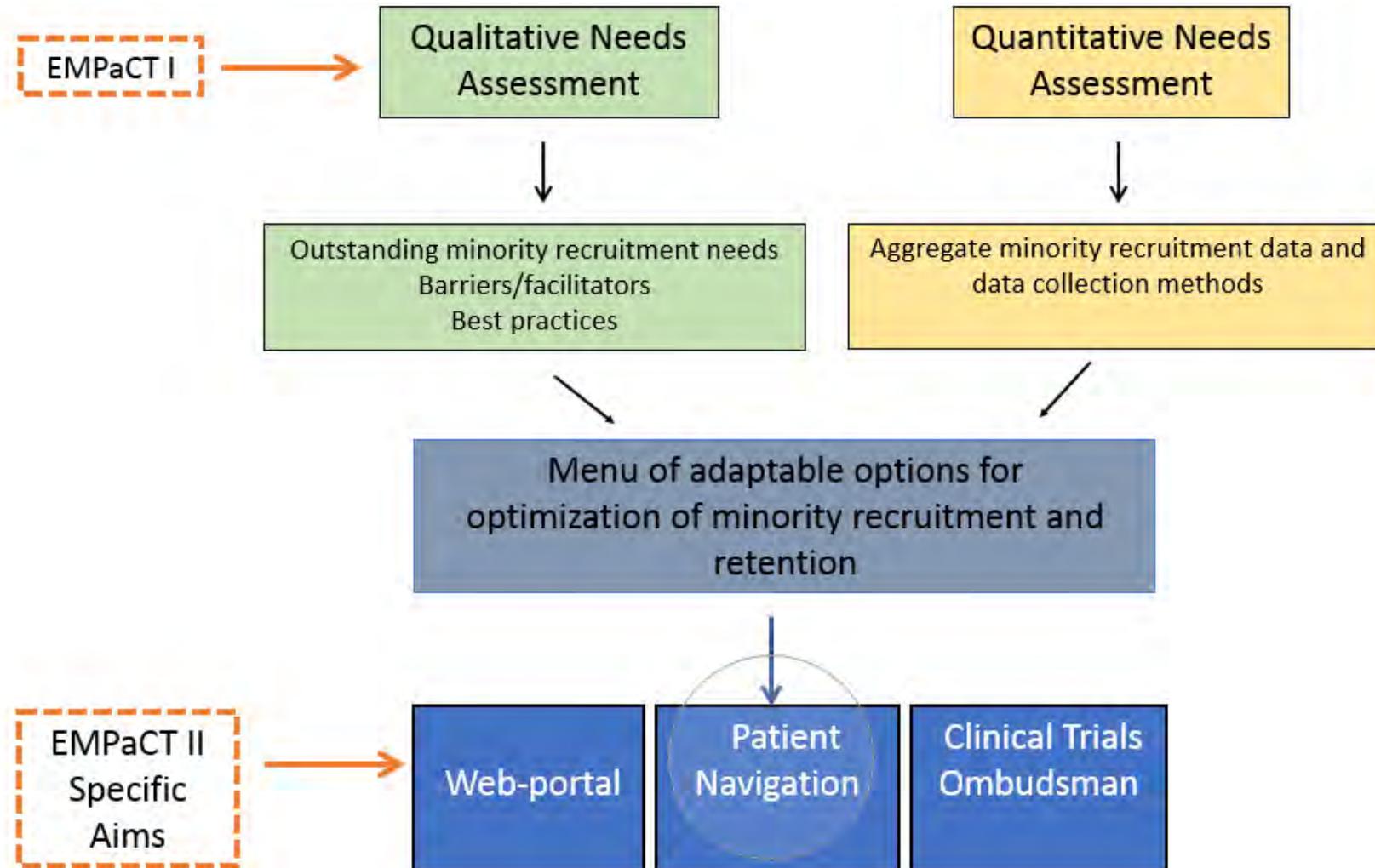


- Developed in response to data from UAB indicating a gap in the number of African Americans (AAs) and other underserved groups diagnosed with cancer and the number who enroll in trials
- AAs in UAB catchment area = 23.2%
- AA participants in UAB clinical trials = 11.4%



EMPaCT I → EMPaCT II

Strategies for Improving Minority Recruitment



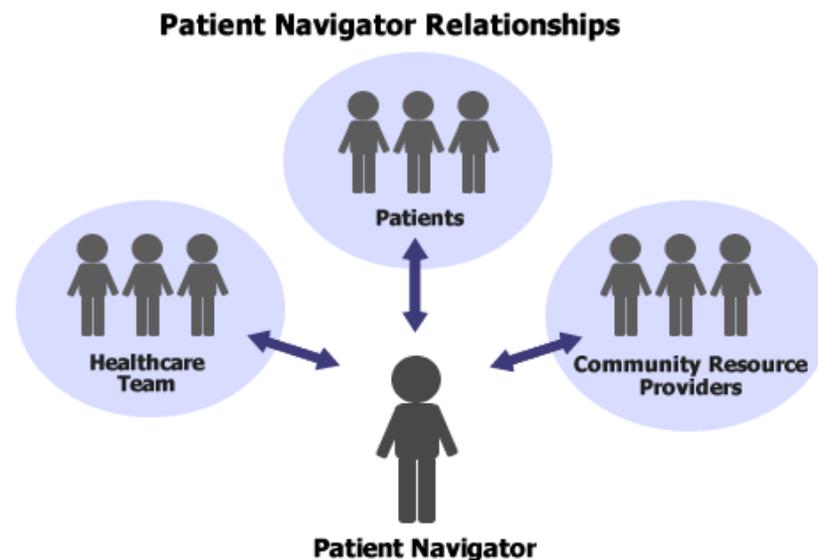
EMPaCT: Objective and Methods

Objective for EMPaCT:

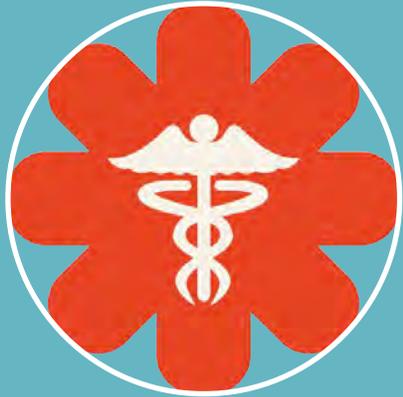
- Develop an innovative approach to enhance minority participation in cancer trials conducted mainly at UAB CCC

Methods to accomplish the objective:

- Identify and train Community Health Advisors (CHAs) as patient navigators



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



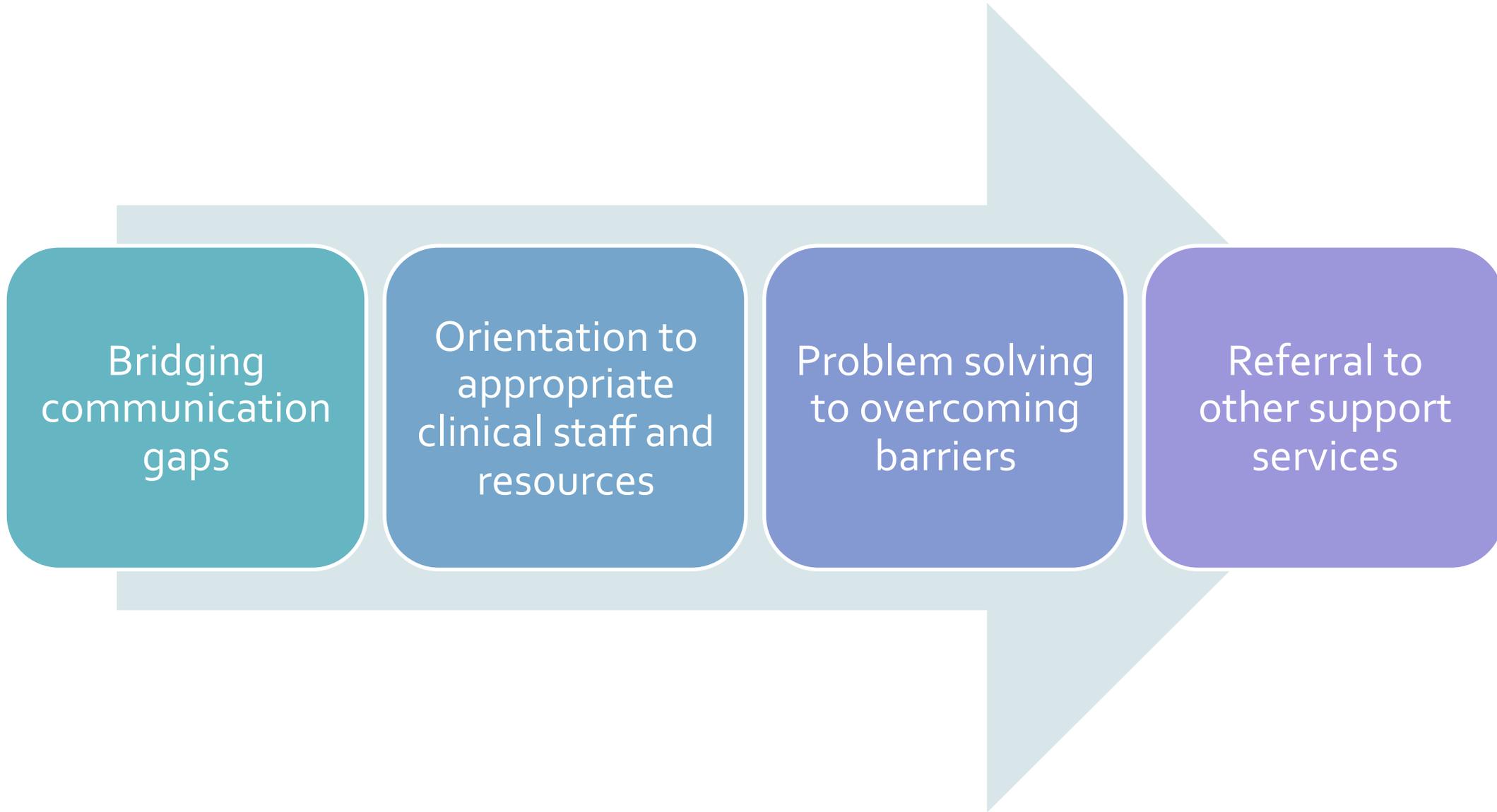
Community partnerships
(gas cards,
meal vouchers
etc.)

Identifying
lodging
options and
making special
arrangements

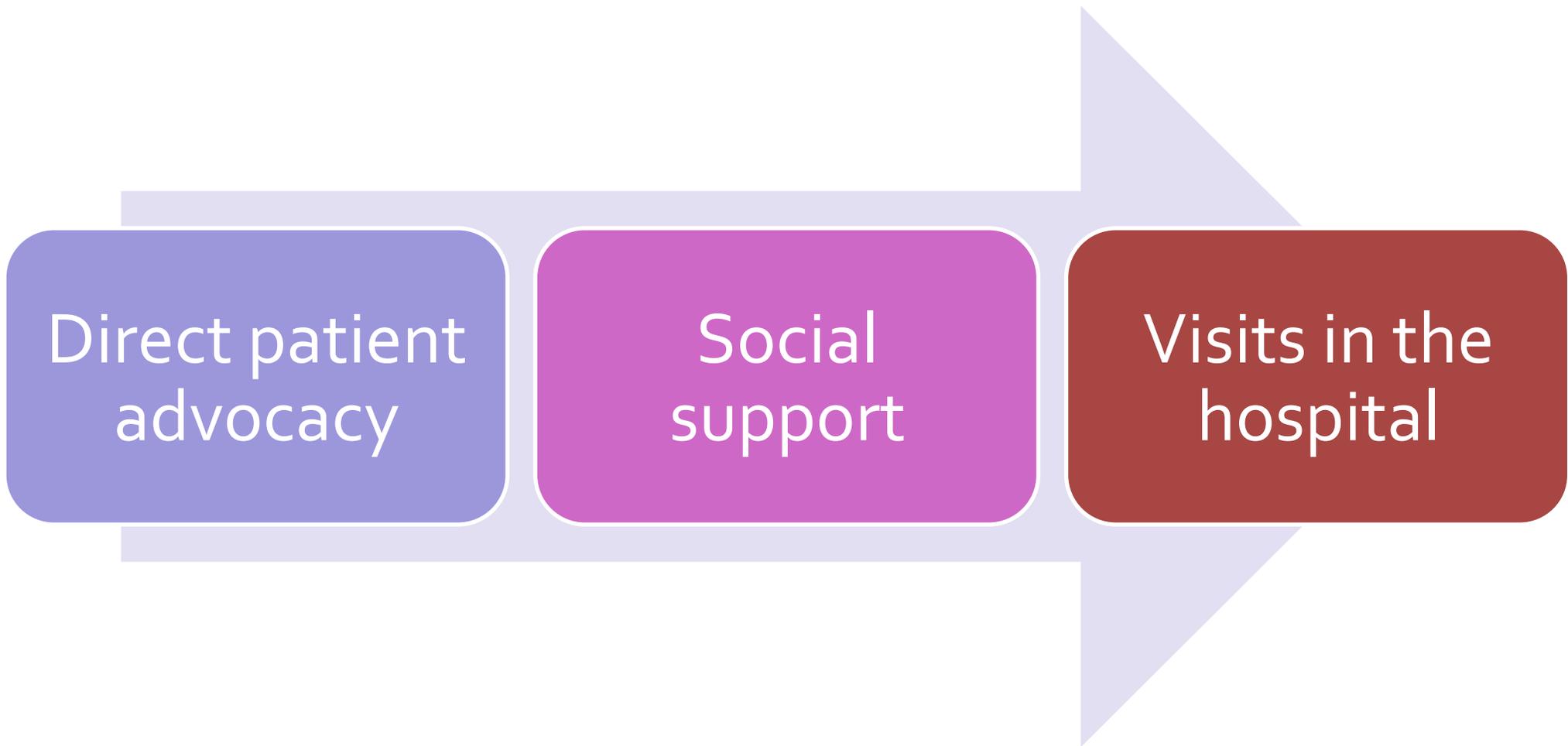
Referral to
appropriate
service
provider

Counseling
patients to be
proactive

EMPaCT: Program Implementation



EMPaCT: Program Implementation



EMPaCT: Program Outcomes



Services Provided by Clinic/Site:

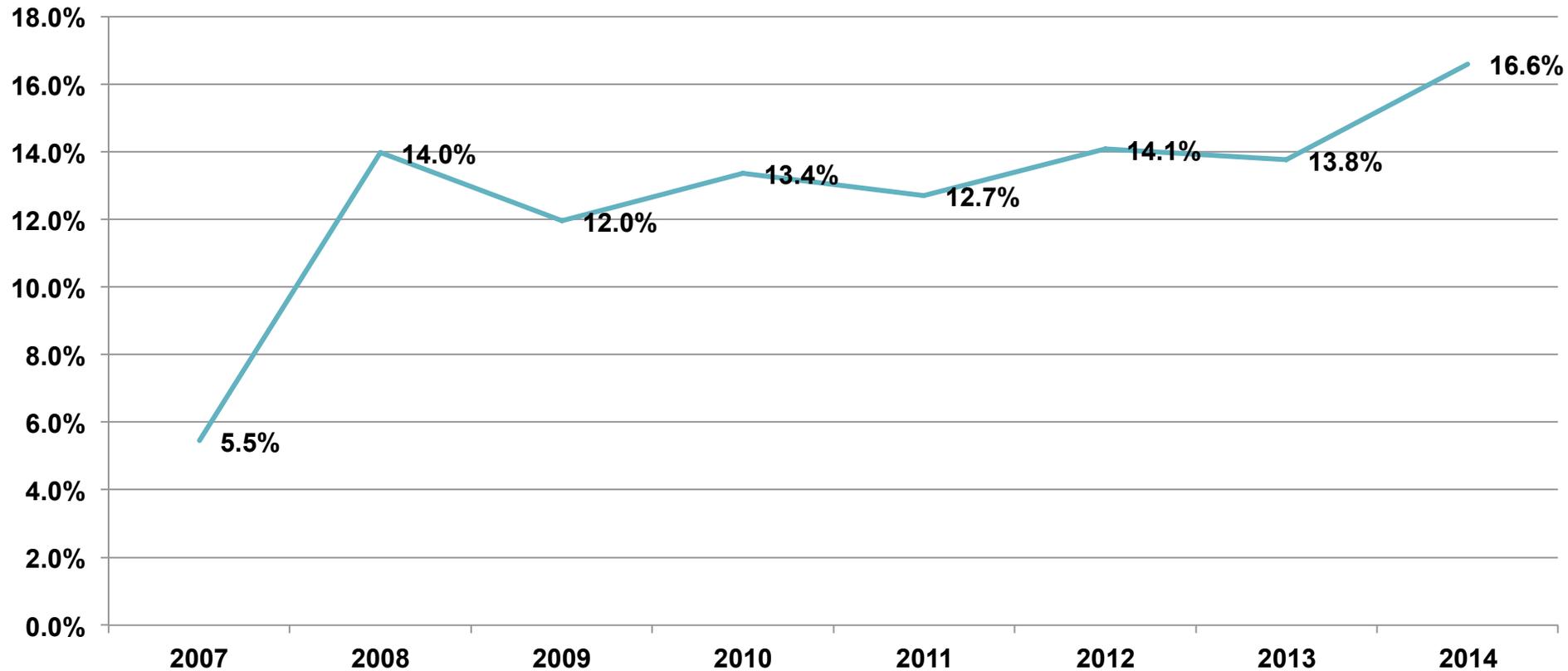
| Clinic | Transportation | Lodging | Insurance | Social and Emotional Support |
|-----------------------------------|----------------|-----------|-----------|------------------------------|
| Bone Marrow Transplantation | 4 | 1 | 0 | 43 |
| Gastrointestinal/Genitourinary | 62 | 3 | 0 | 348 |
| Gynecologic 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 |
| Lung | 25 | 12 | 0 | 415 |
| Neuro Oncology | 25 | 5 | 1 | 191 |
| Other | 0 | 0 | 0 | 21 |
| Radiation Oncology | 45 | 2 | 0 | 344 |
| Solid Tumors | 12 | 3 | 0 | 147 |
| Total | 927 | 71 | 8 | 5,152 |



EMPaCT: Program Outcomes



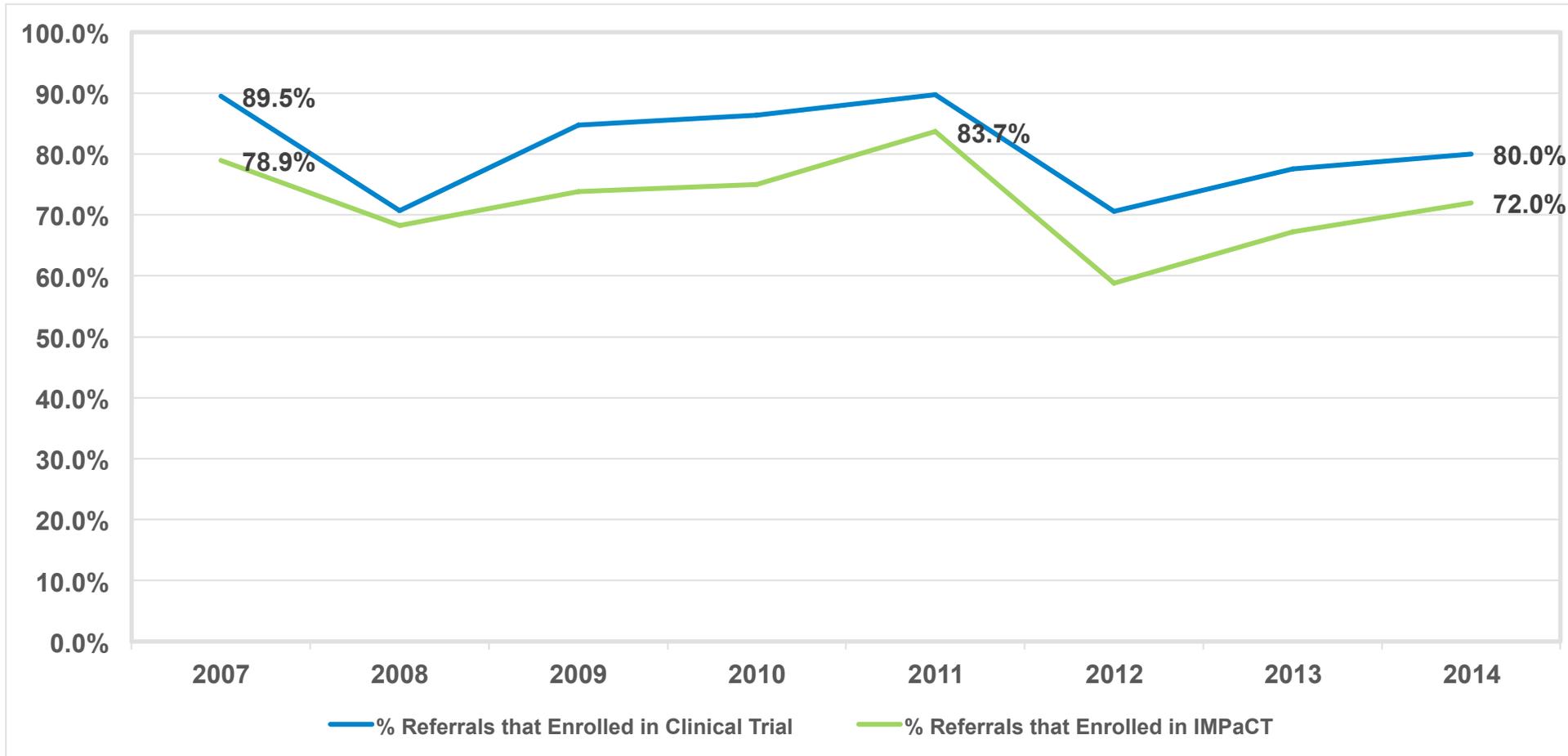
Percentage of new patients referred to IMPaCT from Oncology Clinics by year:



EMPaCT: Program Outcomes

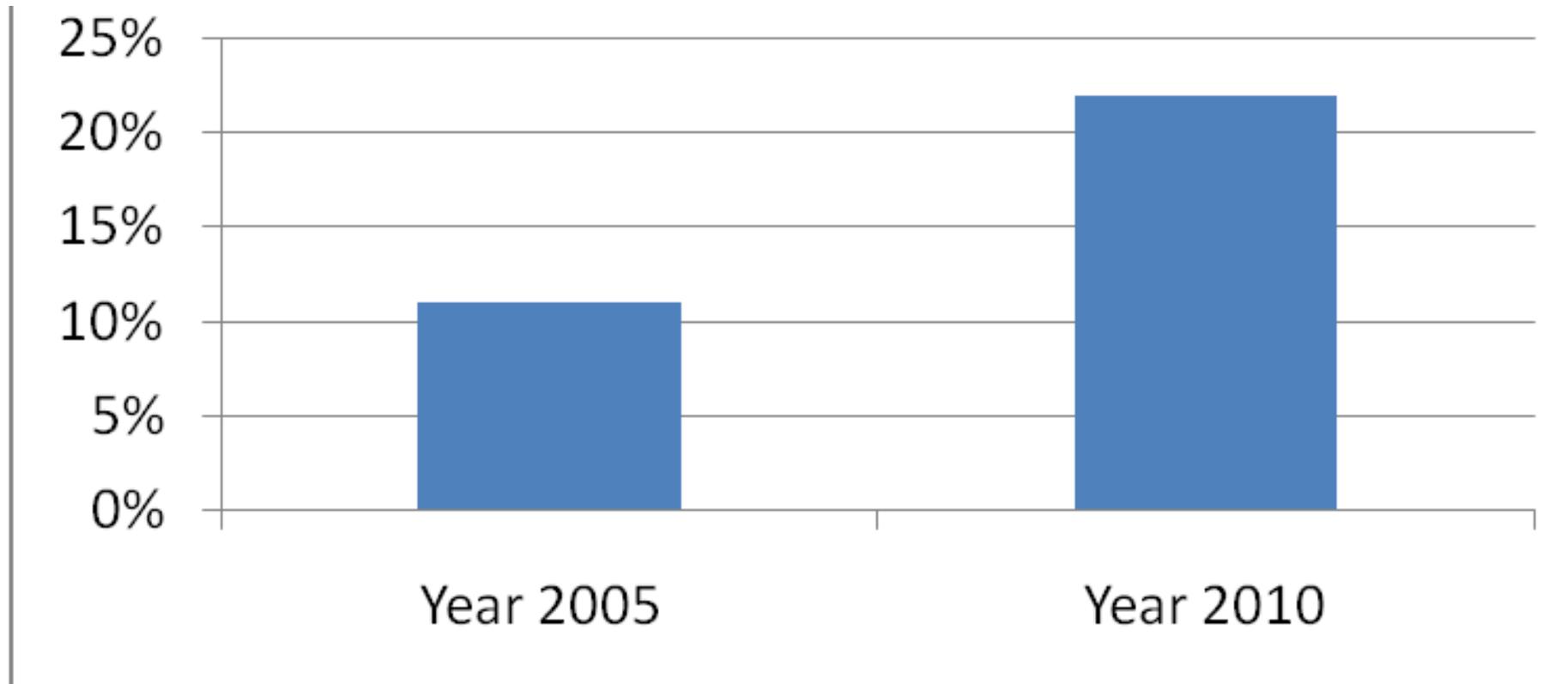


Percentage referrals for clinical trial and IMPaCT:



EMPaCT: Program Outcomes

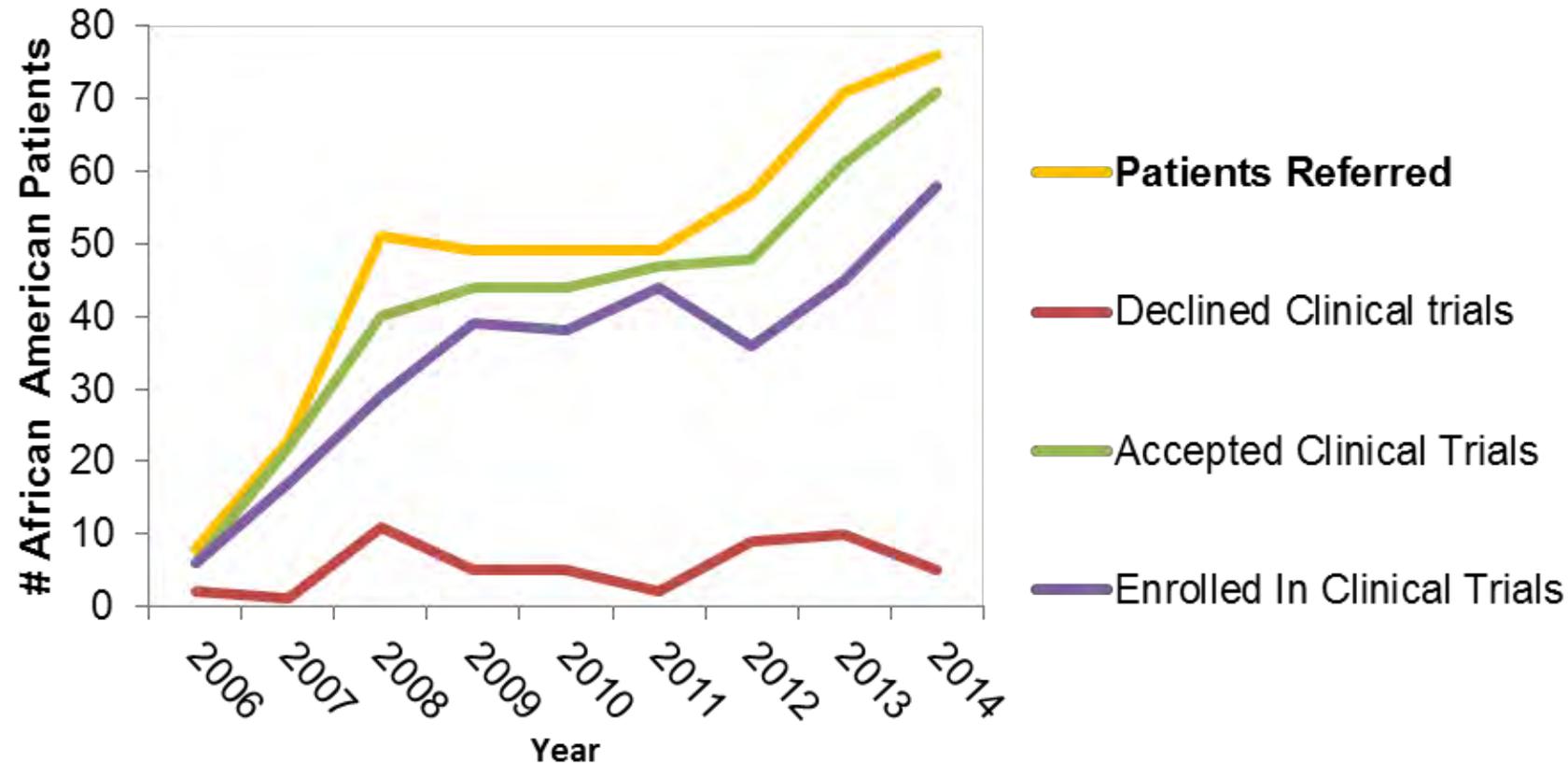
African Americans Enrolled Pre/Post EMPaCT



EMPaCT Outcomes



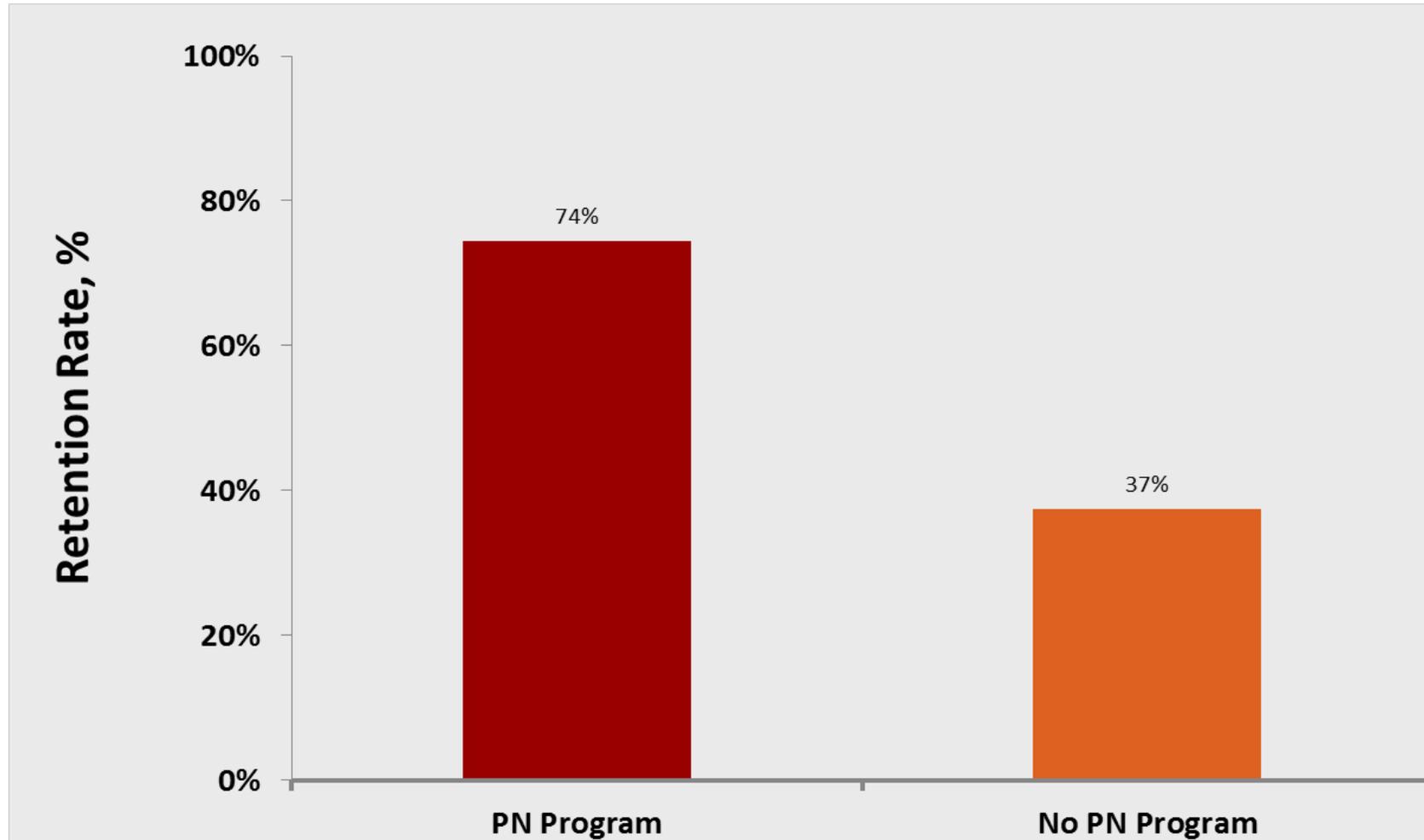
Enrollment Outcomes for African American Patients Referred to the Patient Navigation Program by Year, 2006-2014.



EMPaCT Outcomes



Cancer Clinical Trial Completion Rate According to PN Program Enrollment



EMPaCT Patient Navigators Intervention



A Patient Navigator model to enhance participation of African American cancer patients in therapeutic clinical trials at the UAB Comprehensive Cancer Center.

- 424 AA cancer patients were referred to EMPaCT. Of those eligible for a clinical trial (N=378), 304 (80.4%) enrolled in a trial and 272 (72%) consented to receive PN support. 74.5% completed the trial, compared to 37.5% of those not receiving PN support.
- The difference in retention rates between the two groups was statistically significant ($p < 0.001$).
- Participation of AAs in therapeutic cancer clinical trials increased from 9% to 16%.

EMPaCT in Publication

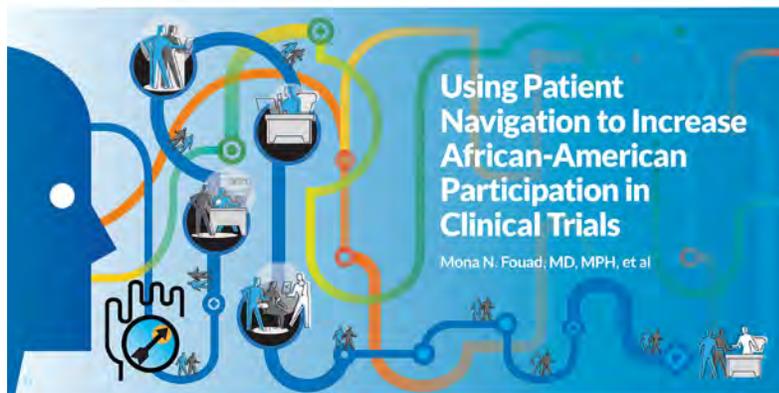
Original Contribution | CARE DELIVERY

EMPaCT

Volume 12 / Issue 6 / June 2016

ASCO
American Society of Clinical Oncology

Journal of
**oncology
practice** *The Authoritative Resource
for Practicing Oncology*



University of Alabama at Birmingham,
Birmingham, AL

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%.

Anaplastic Thyroid Carcinoma: Treatment in the Age of Molecular Targeted Therapy
M.E. Cabanillas et al

Microangiopathic Hemolytic Anemia and Thrombocytopenia in Patients With Cancer
J.M. Morton and J.N. George

Management of Brain Metastases in Patients With Melanoma
U. Chakraborty et al

Association of Breast Cancer Knowledge With Receipt of Guideline-Recommended Breast Cancer Treatment
R.A. Freedman et al

Communicating Disease-Specific 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

jop.ascopubs.org

UAB



STRIDE

Strengthening Translational Research In Diverse Enrollment

Stephenie Lemon, PhD and Jeroan Allison, MD, MSc,
University of Massachusetts Medical School

Paul Harris, PhD, Vanderbilt University Medical Center

Kenneth Saag, MD, MSc, University of Alabama at Birmingham

STRIDE is a research study supported by the National Institutes of Health/National Center for Advancing Translational Sciences under award number U01TR001812. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

The Goal of STRIDE

To improve racial and ethnic minority recruitment in clinical trials by creating culturally relevant tools and interventions

STRIDE Specific Aims

Aim 1: Expand 3 previously developed intervention components: *Storytelling* for promotion of research literacy; *Simulation-based training* for improving culturally appropriate recruitment and informed consent; *eConsent*

Aim 2: Test effectiveness of STRIDE multi-modal intervention to improve participation of African Americans and Latinos in ongoing clinical trials at each of 3 partnering CTSA hubs

Aim 3: Promote widespread translation/dissemination to CTSA hubs, other research institutions and community organizations

STRIDE Intervention Approach

- Comprehensive, multi-component approach
- Aims to provide clinical trial research teams with the training and tools for culturally adapted informed consent



STRIDE is a Three CTSA Collaboration



- **Simulation:** training research assistants to be culturally aware when consenting participants
- **Storytelling:** participant stories to **increase understanding of** clinical trials



- **eConsent**
- **Community Studios** to provide feedback on intervention components.



- Intervention **pilot testing**
- **Integrating components** (storytelling, simulation, eConsent) **into existing clinical trials**

STRIDE Intervention - Community Input

Community Investigators



Fred
Jenoure,
UMMS

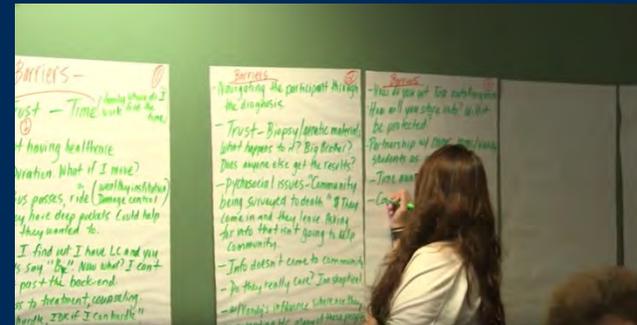


Jackie
Simms,
VUMC



Clarice
Davis,
UAB

Community Engagement Studios



Collaboration with Community Campus Partnerships for Health (CCPH)

STRIDE Intervention Steps



Develop with
community input



Evaluate in
collaboration
with ongoing
clinical trials

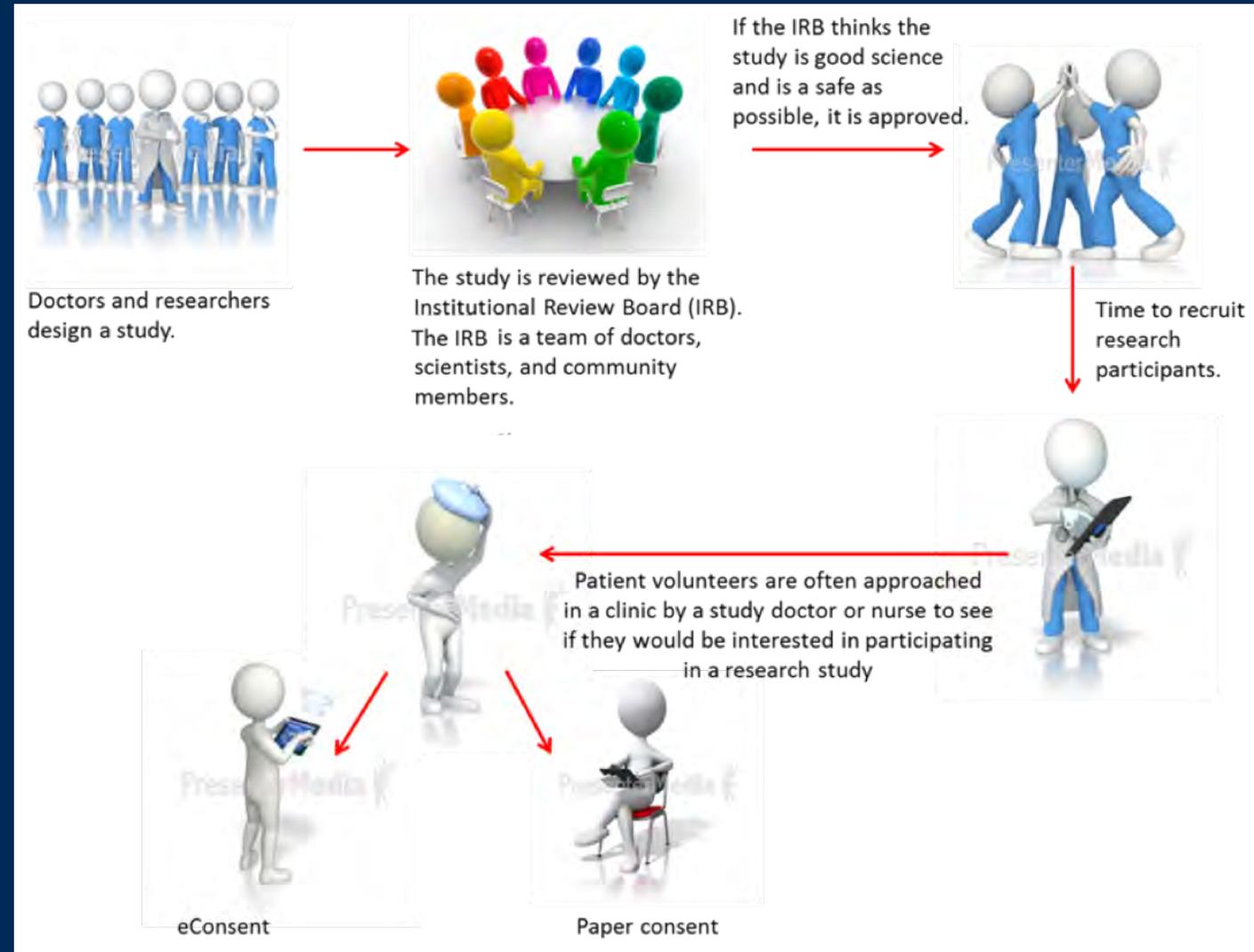


Disseminate
throughout the
CTSA program
and Trial
Innovation
Network



STRIDE Intervention eConsent

- Delivered using REDCap
- Covers all traditional elements of consent
- Adds new elements:
 - Video Library
 - Avatars
 - Hover-over definitions
- Plan to ensure Part 11 compliance



STRIDE Intervention eConsent

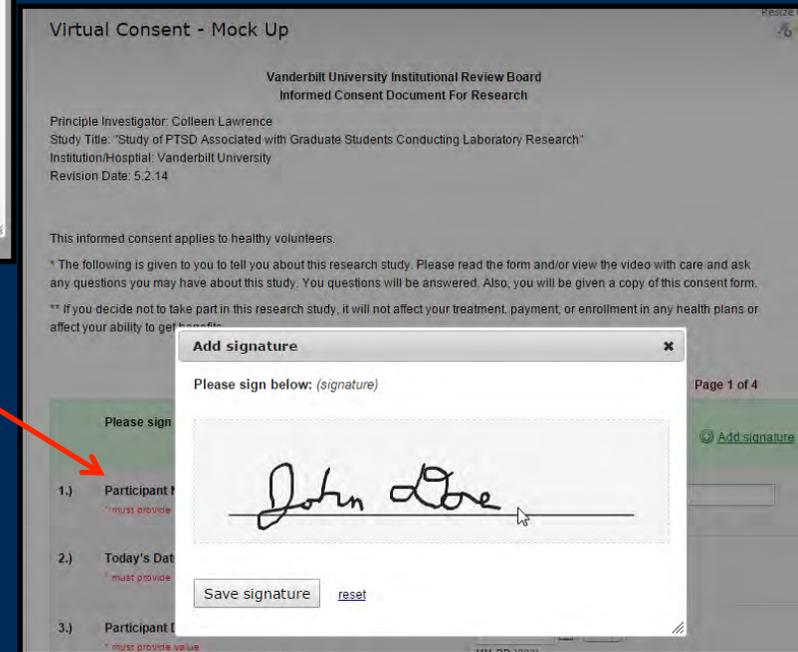
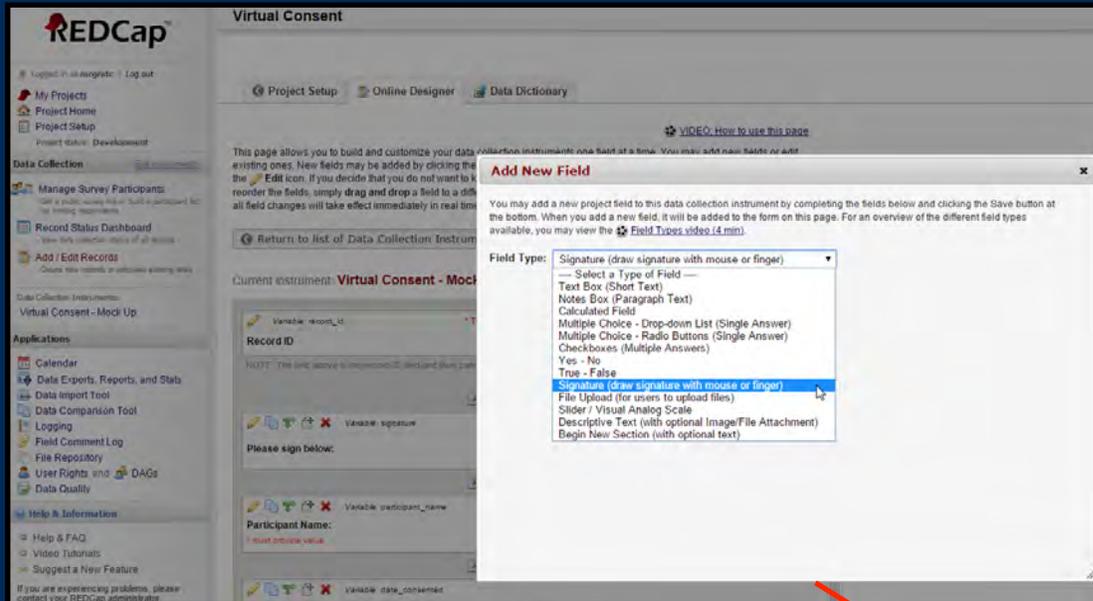
- Virtual repository to serve as an institution-wide “lock box” for consents
- Specific meta-data elements can be used to link consents in the repository to their respective studies
- Working with Vanderbilt, UMass, UAB IRBs to ensure this repository will fulfill standards of Part 11 compliance



STRIDE Intervention eConsent – “Signature” Process

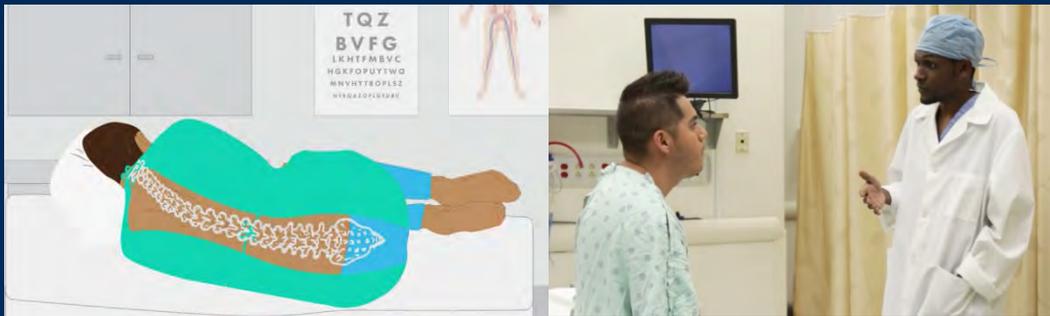
Patients can “sign” an eConsent document by:

- Typing in their name
- Signing their name via stylus/finger
- Entering a personalized PIN number



STRIDE Intervention eConsent - Video Library

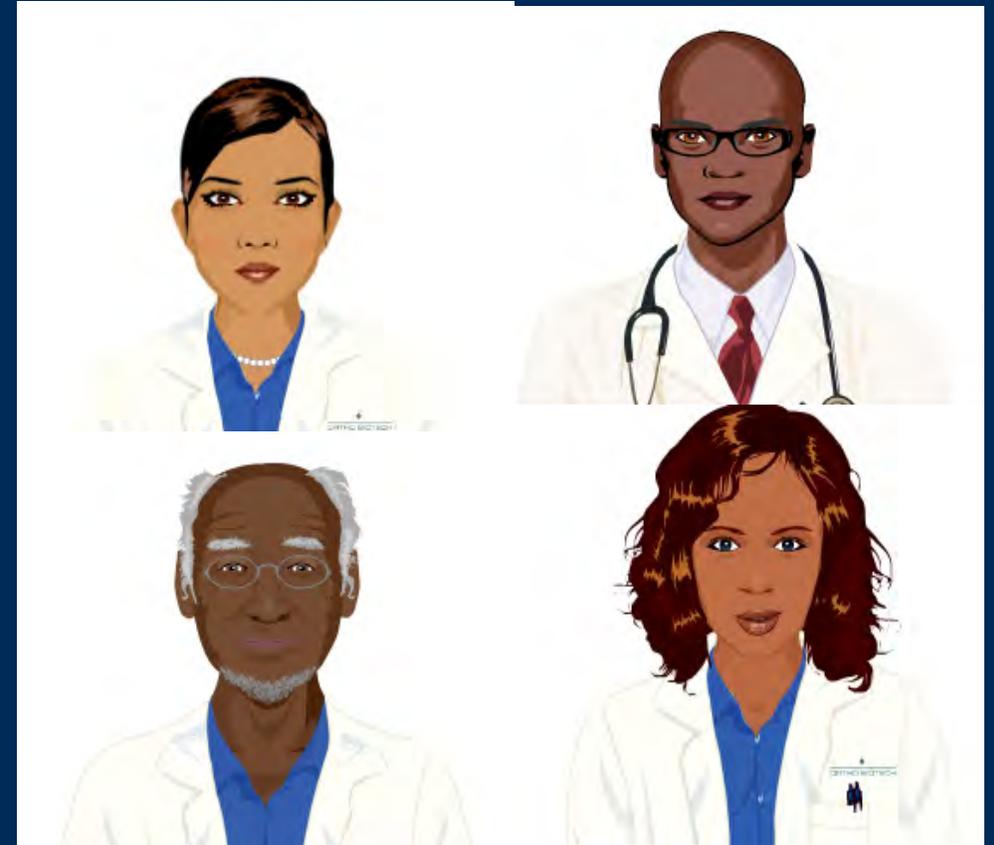
- Collection of videos for 10-15 most commonly consented research procedures, available through REDCap
- IRB will review videos post production
- Videos informed by community feedback and scripts reviewed by Vanderbilt Effective Health Communication Core



Videos embedded in eConsent in-line or as a link

STRIDE Intervention eConsent - Avatars

- eConsent platform will use Avatars to guide participants through the consent process
- Scripted voice-over
- Avatar can respond to questions, repeat information and provide additional information





Hi. This iPad is a new type of learning device for patients like you who may be interested in participating in clinical research studies.

Doctor comes in, speech bubble appears immediately. As iPad comes down into doctor's hand, the speech bubble goes away. The "new" burst comes in after the iPad and then goes away.

STRIDE Intervention eConsent - Hover-Over Features

- Participants may hover-over keywords to see pronunciation, definitions or more information about a word
 - Gives participants ownership
- Researcher will determine keywords and information that appears



You will come in to the lab annually on National Running Day.

Each year on the first Wednesday in June, people across the United States participate in National Running Day. This day was designated as a day for runners to reaffirm their passion for running.

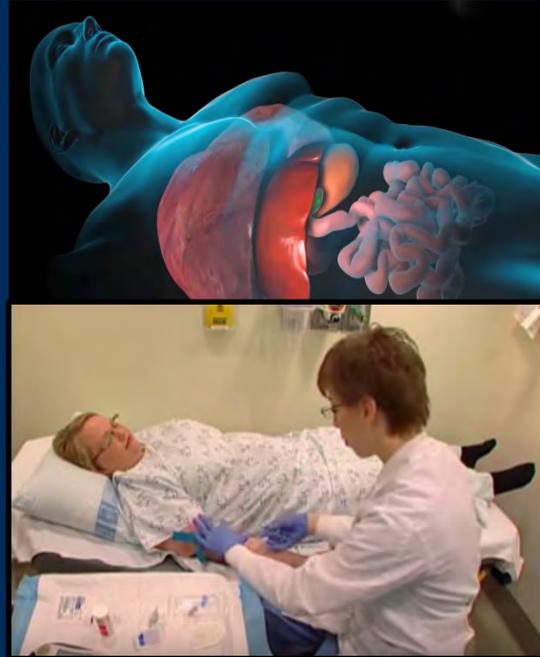


STRIDE Intervention eConsent - Community Feedback

Community Engagement Studios: consultative session for researchers interested in getting input on work from stakeholders.

Feedback on Videos:

- Preference for animated sequences for invasive procedures
- Quality of filming makes video appear more trustworthy



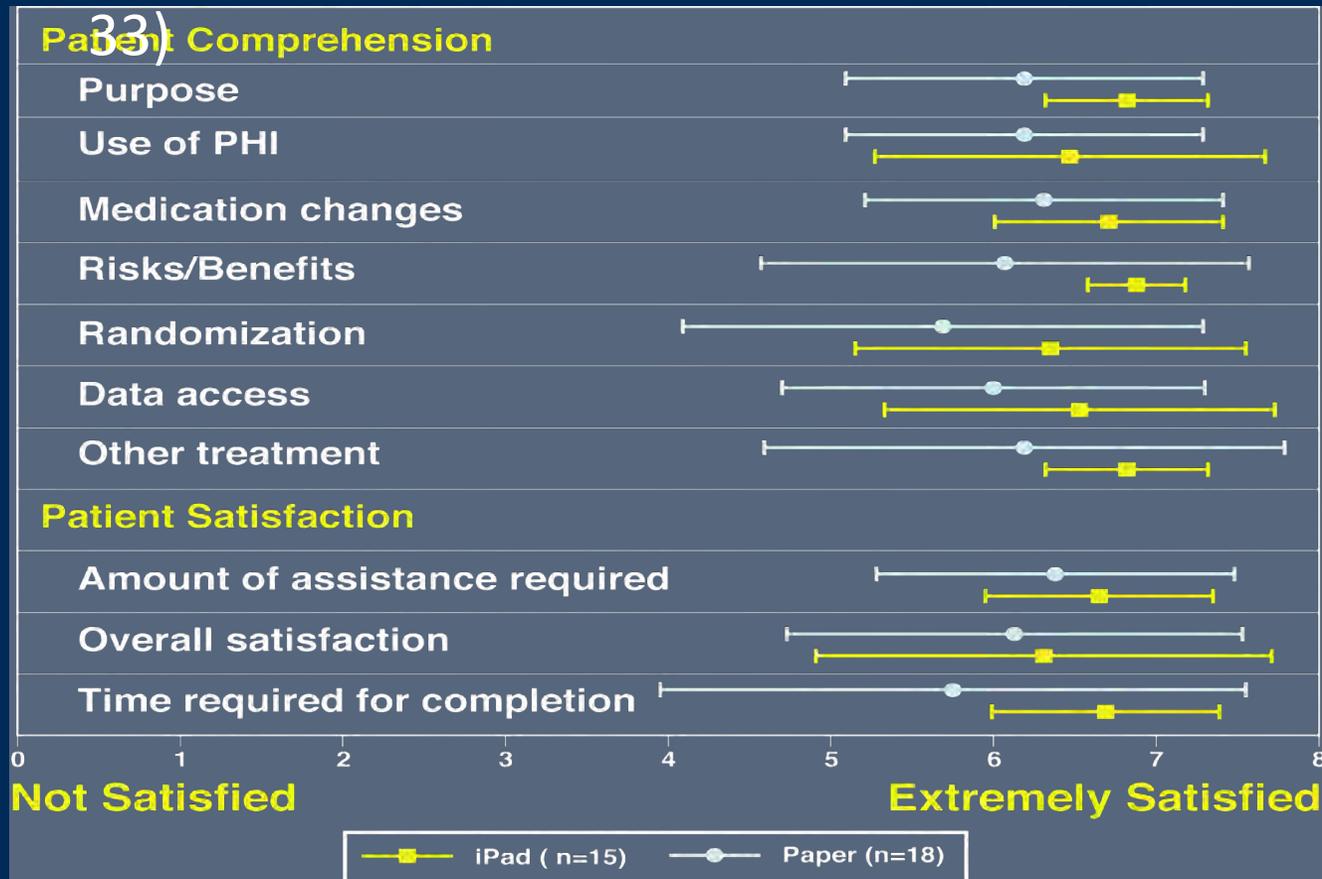
Feedback on Avatar:

- Participants emphasized that Avatar should not replace human interactions
- Preference for 2D (rather than 3D)
- Avatar should be dressed as medical professional



eConsent Acceptability - Results from UAB eConsent EDGE Pilot

iPad vs. Paper – Patient Perceptions (n =



Warriner A. *Contemp Clin Trials Comm*, 2015



STRIDE Intervention Research Assistant (RA) Training

- Simulation-based training
- Modeled after medical school experiential learning using standardized patients
- Training based on previously established core competencies
- 2-day intensive training
- Delivered at UMass Medical School



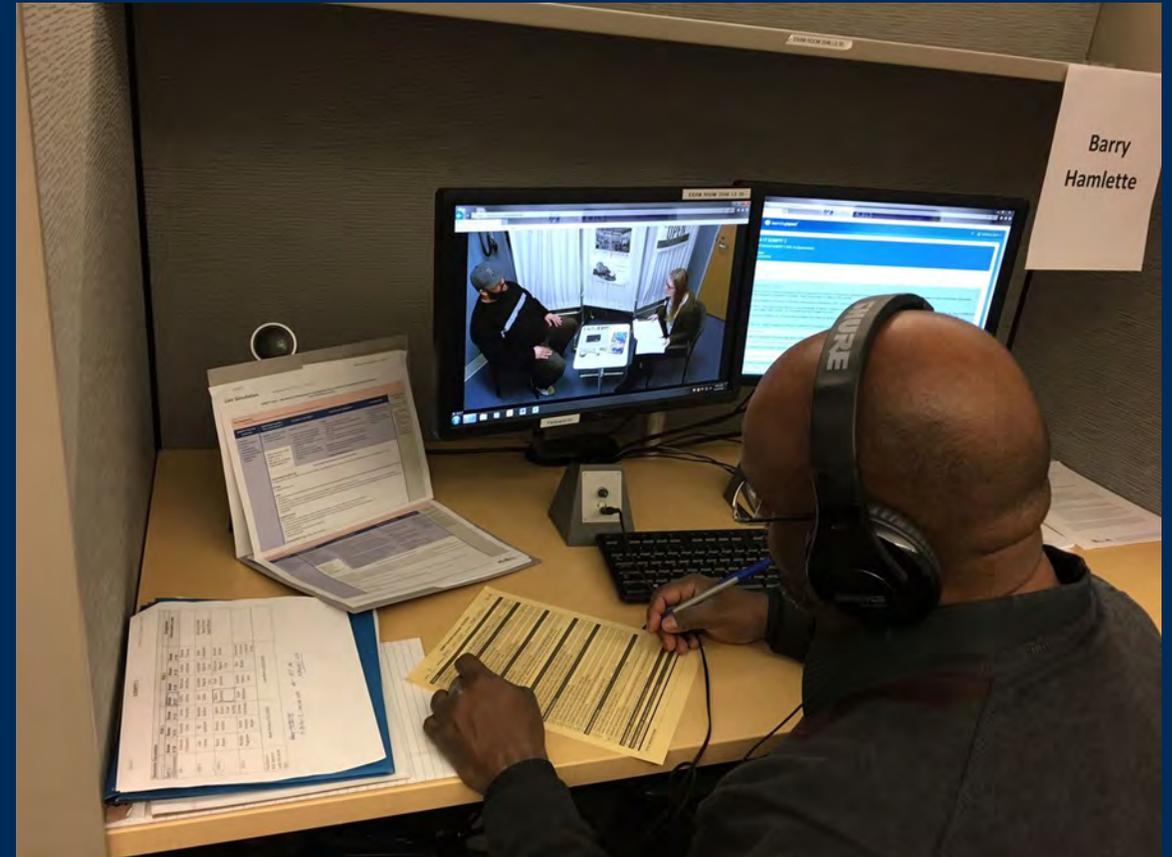
STRIDE Intervention RA Training - Core Competencies

- Focused on relational skills in domains of
 - establishing rapport
 - supporting understanding
 - responding to emotion



STRIDE Intervention RA Training – Research Assistant Evaluation

- Standardized checklist based on core competencies in each domain
- Minimum passing score
- Opportunities to retrain and reassess as needed



STRIDE Intervention RA Training – Training Method

- Remote pre-work (home site)
- Pretest, training and post-test (UMMS)
- Debriefing (UMMS)
- Deliberate practice (home site)
- *In situ* validation



STRIDE Intervention RA Training - “Acting Research Participants”

- Trained community members
- From diverse backgrounds and geographic regions
- Similar to standardized patients





STRIDE Intervention Storytelling - Stories about Participation in Clinical Research

- Short video stories
- Real participants in clinical trials
- Describe personal experiences with research
- Used as an ancillary to eConsent
 - Introduce potential participants to what research is
 - Clarify what research is during the informed consent process



STRIDE Intervention Storytelling - Why Stories?

- Provide information for people unsure about participating
- Provide role models from similar demographic backgrounds
- Promotes understanding through use of lay language
- Typically address common barriers and facilitators to participation

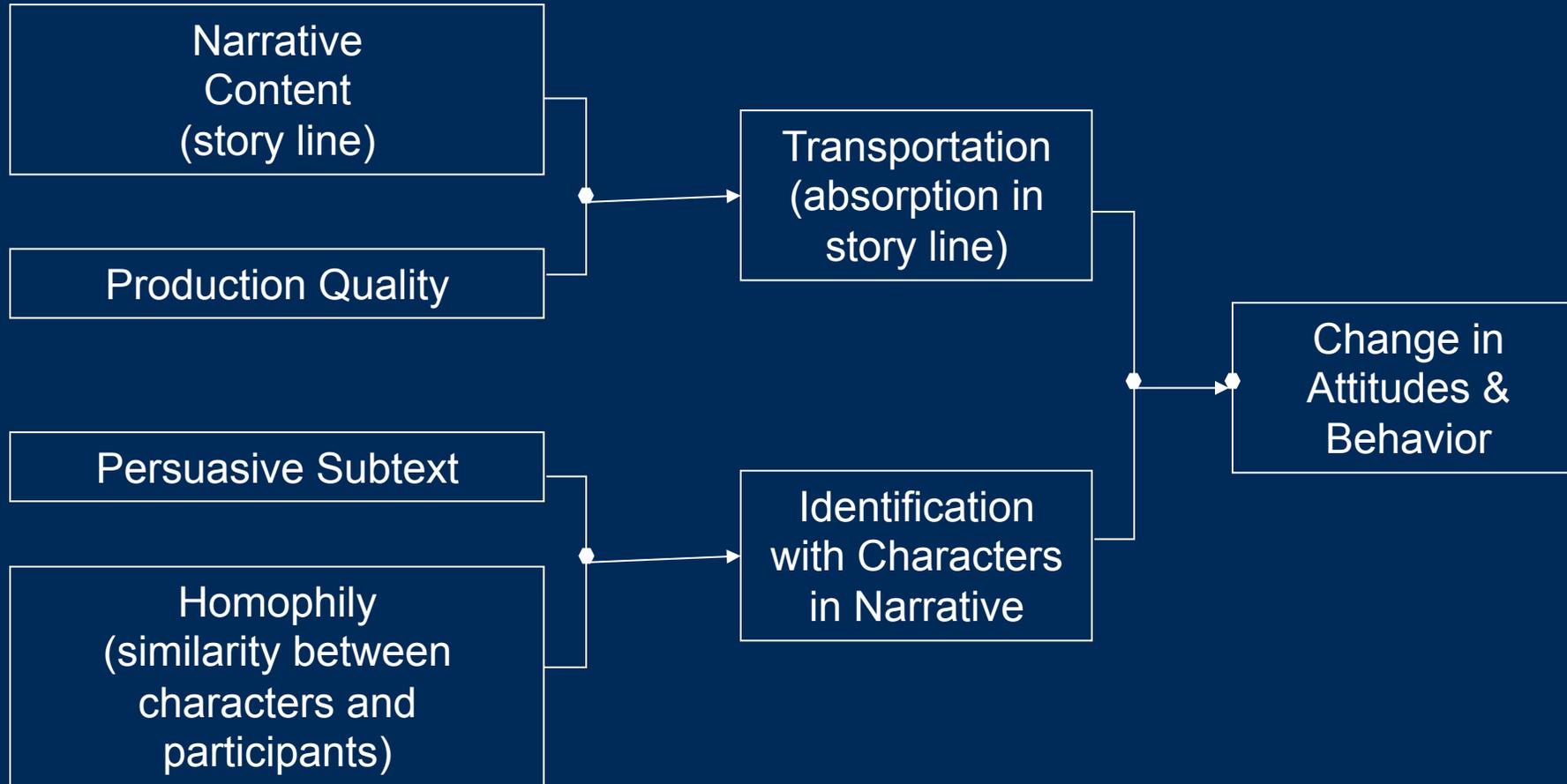


STRIDE Intervention Storytelling- Why Stories?

“The power of narratives to change belief has never been doubted and has always been feared.”

Green MC. *Journal of Personality and Social Psychology*. 2000; 79 (5): 701-21

STRIDE Intervention Storytelling – Narrative Communication



Slater M. *Communication Theory*. 2002; 12 (1): 173-191.

Storytelling and Blood Pressure Medication Adherence

Culturally Sensitive Intervention (CSI)
Cooper Green Jefferson County Hospital

| | <u>Baseline</u> <u>systolic BP</u> | <u>3-Month Follow-up</u> <u>systolic BP*</u> |
|--------------|---------------------------------------|---|
| Intervention | 132.5 mmHg | 127.5 mmHg |
| Control | 131.1 mmHg | 132.2 mmHg |

Beneficial effect greatest among those with uncontrolled BP at baseline

(-17 mmHg intervention, -7 mmHg control, $p = 0.03$) Houston T. Ann Int Med 2011;154:77

* $p = 0.04$, intervention vs. control

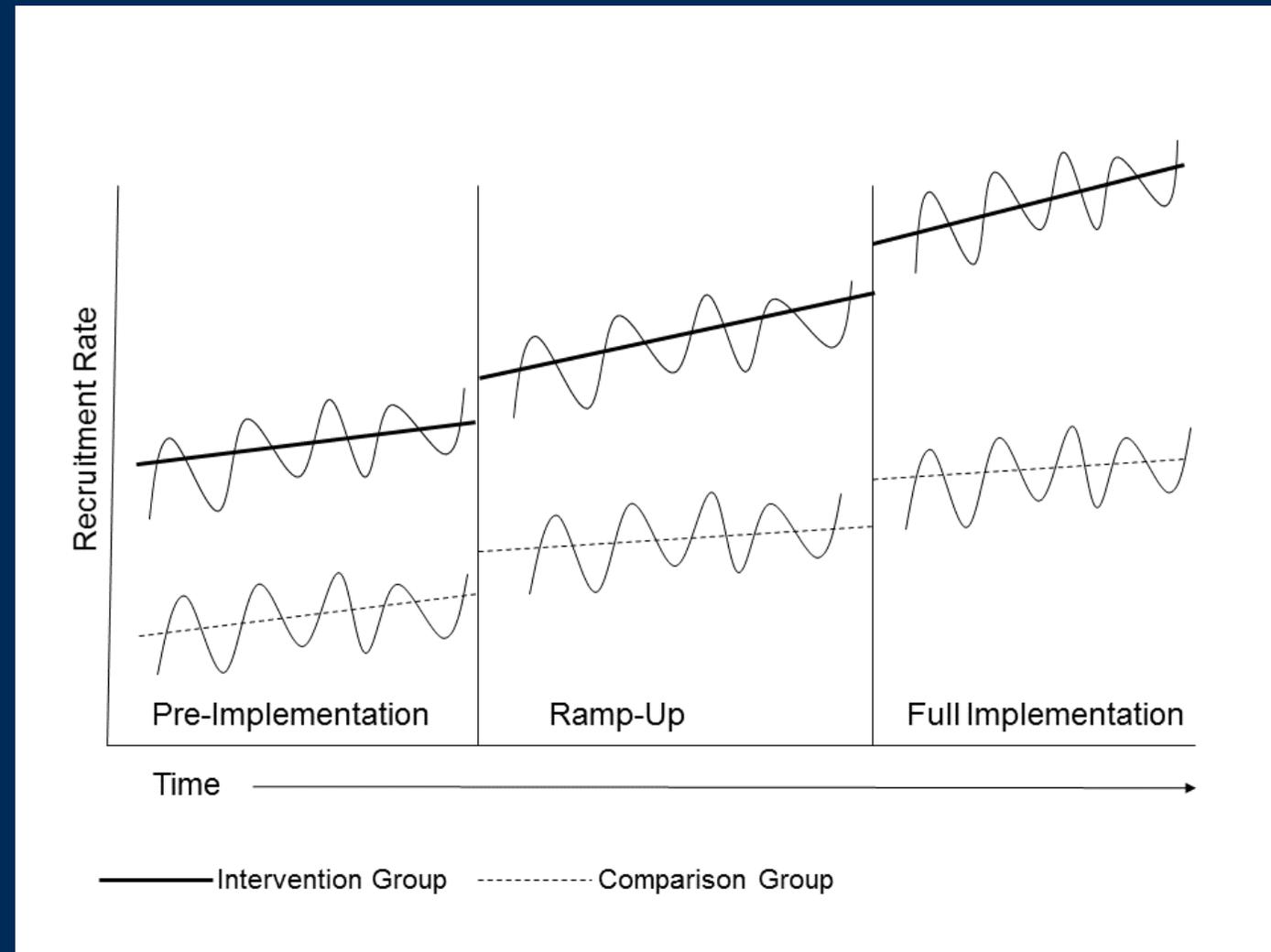
STRIDE Intervention Storytelling - What Storytellers Talk About

- Interview Guide Constructs
 - Purpose of study involved in
 - Informed consent process
 - Involvement in study
 - What was learned
 - Advice for others
 - Questions for those who decided not to participate



STRIDE Intervention Evaluation

- Quasi-experimental design:
 - Intervention: Integration into ongoing clinical trials at UAB, UMass and Vanderbilt (n=3 trials)
 - Comparison: Usual protocol (n=3 trials)
- Interrupted time-series design
- Assess number/rates of recruitment of under-represented minorities before and after the STRIDE intervention is introduced



What does collaborating with STRIDE involve?

Intervention Arm Only

- STRIDE team will collaborate with investigators to integrate the eConsent platform with ancillary components into an ongoing clinical trial
- Research assistants will participate in a weekend training session at UMass Medical School, all travel expenses covered and honoraria provided

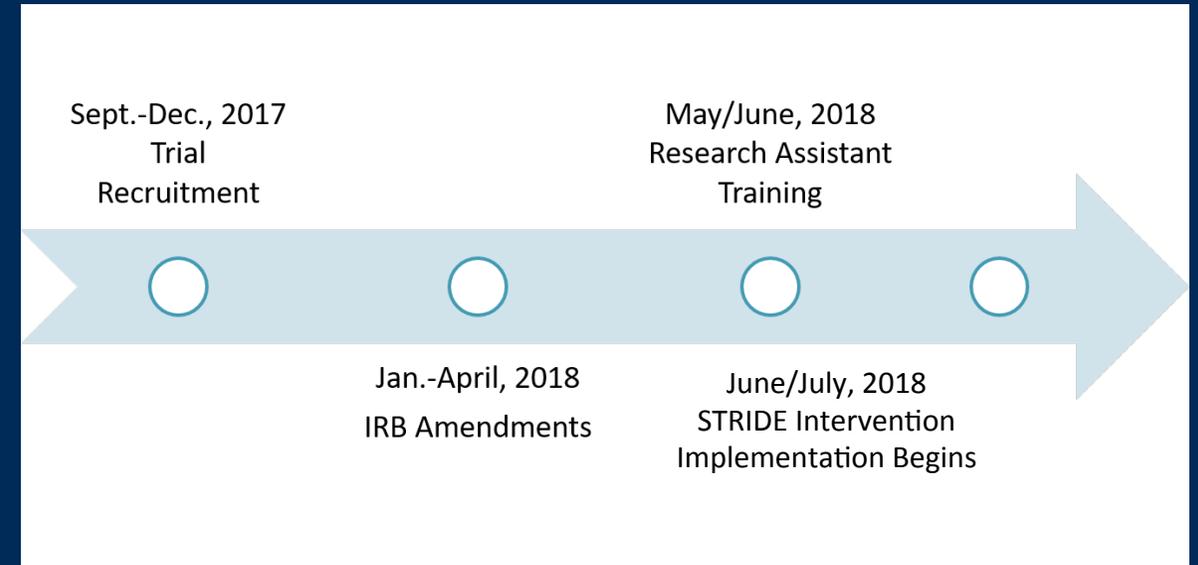
Intervention and Comparison Arms

- Investigators will provide the STRIDE team with aggregate recruitment data (e.g. race/ethnicity, gender, age) before and after the STRIDE intervention is deployed

Does my study qualify for STRIDE?

Preliminary trial criteria

- Adults 18+
- Chronic condition (e.g. diabetes, cancer, HIV)
- Evaluating a drug or therapeutic (e.g. not device)
- Consent goal (not randomization): n=30, at least half not recruited yet
- Recruitment timeline: at least 30 weeks



How does the STRIDE team support clinical trial collaborators?

- Supports data management tools for data sharing (iPads provided)
- Covers simulation-based training expenses
- Collaborates with the trial team to facilitate IRB amendment approvals
 - All IRB amendment fees provided
- Collaborates with the trial team to tailor the eConsent platform and ancillary tools
- Collaborators are also invited to participate in manuscripts and other dissemination products developed from the study

We need input from potential study investigators to understand impact of STRIDE on their study and better understand their needs and interests related to successful participation

For More Information About STRIDE

Ken Saag

ksaag@uabmc.edu

Maio Danila

mdanila@uabmc.edu

Liz Rahn

elizabethrahn@uabmc.edu

STRIDE Intervention Dissemination

- Scientific publications
- REDCap consortium
- CTSA conferences and other channels
- STRIDE Toolkit