

Overcoming Barriers for Latinos On Cancer Clinical Trials

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Overcoming Barriers for Latinos on Cancer Clinical Trials

- Increasing complexity of accrual on clinical trials for all populations
- Barriers that may disproportionately impact Latino patient enrollment
- Strategies to facilitate clinical trial participation
- Next Steps

Cancer Clinical Trials

Many Different Populations

Prevention
Screening

Treatment
Symptom Control
Care Delivery
Research

Survivorship
Outcomes
Post Therapy

Cancer Clinical Trials

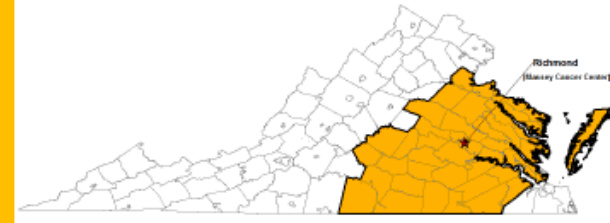
Complexity in 2018 – Partial List

- Narrowed eligibility criteria (i.e. mutation needed for enrollment)
- Randomization and the internet
- More non experimental treatment options
- Expense
 - Direct “standard of care expenses”
 - Hassle of participation
 - Third party payer exclusion

Cancer Clinical Trials

Complexity in 2018 – Partial List

- Concerns of being a Guinea Pig for research
- Concerns of greater toxicity
- Bombardment of medical information in the lay press



Engaging Underrepresented Minorities in Clinical Trials: Challenges and Opportunities

Vanessa B. Sheppard, PhD, Associate Director, Disparities Research
2017 AACI/CCAF Meeting

Perceptions of African American Trial “Refusers”

Key Points

- Semi-structured audio interview with 22 African American patients who declined clinical trial participation
- Top Refusal Reasons
 - Fear of additional burdens
 - Fear of adverse effects
- Others – Mistrust, Family members against participation
- Most would participate if given access to a decision aid AND the ability to discuss with a provider



HHS Public Access

Author manuscript

J Oncol Pract. Author manuscript; available in PMC 2016 May 03.

Published in final edited form as:

J Oncol Pract. 2013 November ; 9(6): 287–293. doi:10.1200/JOP.2013.001039.

Perceptions of Participation in a Phase I, II, or III Clinical Trial Among African American Patients With Cancer: What Do Refusers Say?

Richard F. Brown, PhD, Debbie L. Cadet, PhD, Robert H. Houlihan, DHA, Maria D. Thomson, PhD, Emily C. Pratt, Amy Sullivan, EdD, and Laura A. Siminoff, PhD

Virginia Commonwealth University School of Medicine; Massey Cancer Center, Virginia Commonwealth University, Richmond, VA; and Beth Israel Deaconess Medical Center-Harvard Medical School, Boston, MA

Challenges with Clinical Trial Accrual

Patient-related barriers (N=25 patients)

- **Additional Patient Burden.** In addition to the burden of the disease itself, patients reported their reluctance to undergo more testing and more office visits. Lost time at work and trouble finding transportation were cited most often.
- **The “Guinea Pig” Analogy.** Patients did not want to participate in an “experiment.”
- **Benefits of Clinical Trials** Many patients didn’t understand that they would continue to treat their cancer and receive high-quality care through the clinical trial.
- **Possible Side Effects.** Most patients were frightened about possible side effects from clinical trials, though, in some cases, the effects were the same as those associated with the standard of care.

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Research Article

Open Access

Promoting Factors and Barriers to Participation in Early Phase Clinical Trials: Patients Perspectives

Patricia Chalela¹, Lucina Suarez¹, Edgar Muñoz¹, Kipling J Gallion¹, Brad H Pollock², Steven D Weitman³, Anand Karnad³ and Amelie G Ramirez^{1*}

¹Institute for Health Promotion Research, The University of Texas Health Science Center at San Antonio, USA

²Department of Epidemiology and Biostatistics, The University of Texas Health Science Center at San Antonio, USA

³Cancer Therapy & Research Center, The University of Texas Health Science Center at San Antonio, USA

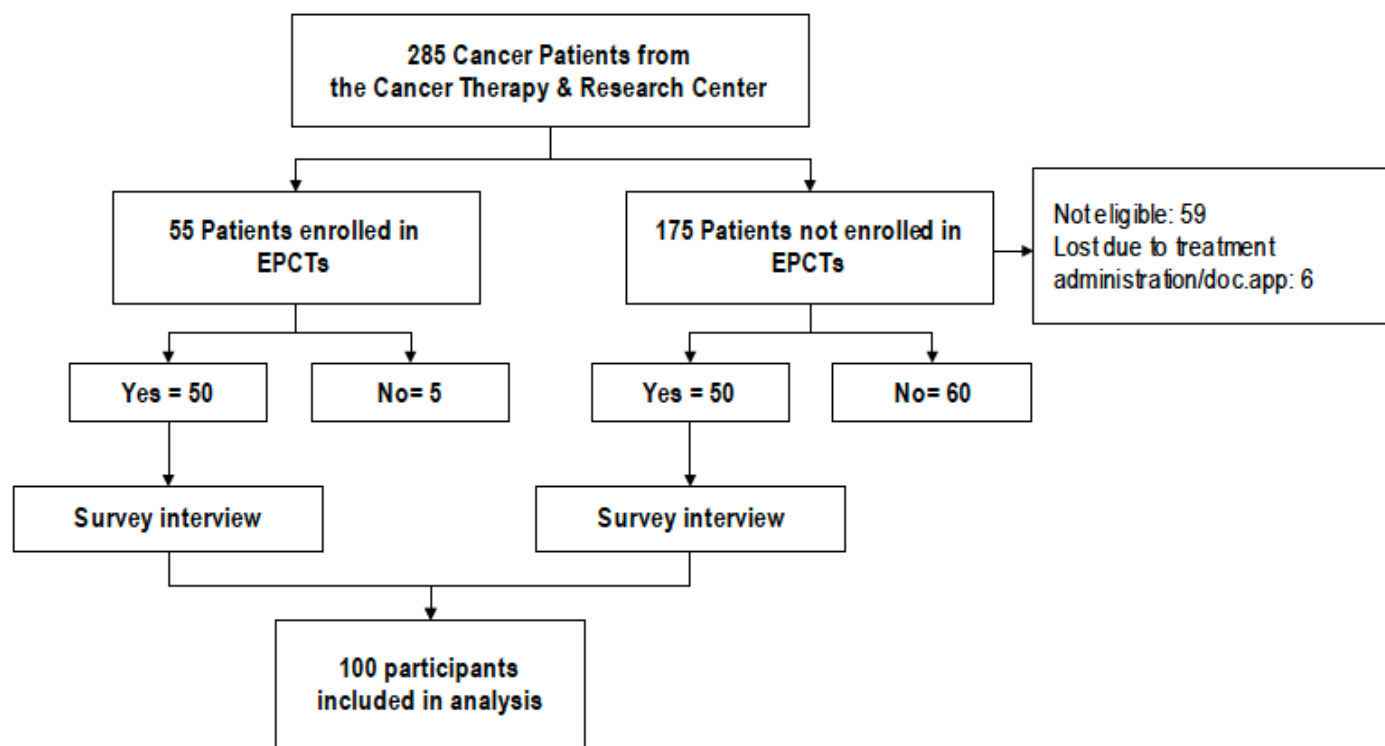


Figure 1: Participant recruitment flow chart.



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Factors/(min-max values)	Enrollment Status by Ethnicity							
	Enrolled (n=47)				Non-Enrolled (n=39)			
	Whites (n=39)		Latinos (n=8)		White (n=8)		Latinos (n=31)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Symptoms improvement (5-25)	18.54	5.47	21.13	3.31	22.00	2.14	22.97	2.93
Distrust (3-12)	6.90	2.91	6.88	2.48	9.38	3.16	8.90	2.83
Fear/Uncertainty (4-16)	11.49	3.63	9.88	3.80	10.25	3.73	12.61	2.90
Fatalism/Spiritual beliefs (4-16)	11.39	3.21	11.13	2.59	7.50	2.62	9.26	3.53

Table 5: Means Comparison of Summary Scores of Promoters and Barriers by Enrollment Status and Race/Ethnicity (N=86).

Observations:

- More Latinos declines EPCTs
- Latinos more concerned with symptom improvement, hospitalizations, potential for better outcomes
- Fear/uncertainty over experimental treatment efficacy a barrier in all groups, greater in Latino group suggesting communication and understanding the opportunity

Clinical trials attitudes and practices of Latino physicians [☆]

Amelie G. Ramirez ^{a,*}, Kimberly Wildes ^a, Greg Talavera ^b, Anna Nápoles-Springer ^c,
Kipling Gallion ^a, Eliseo J. Pérez-Stable ^c

^a Institute for Health Promotion Research, Department of Epidemiology and Biostatistics, School of Medicine,
University of Texas Health Science Center at San Antonio; San Antonio, TX, USA

^b Division of Health Promotion, School of Public Health, San Diego State University; San Diego, CA, USA

^c Division of General Internal Medicine, Department of Medicine, Medical Effectiveness Research Center for Diverse Populations,
University of California San Francisco; San Francisco, CA, USA

Received 25 May 2007; accepted 13 November 2007

Takeaways

- Latino Physicians
 - Less connection with Clinical Trials
 - See less value in clinical trials
 - Opportunities for education and engagement

Table 2
Association of physician race/ethnicity and clinical trials participation

Item	Percent distribution			<i>p</i> -value ^a
	Overall	Latino (<i>N</i> =297)	White (<i>N</i> =398)	
Clinical trials involvement				
Patients inquired about clinical trials (CT)	29.4%	21.5%	35.2%	0.000
I referred patients, CT administered by other	48.8	42.1	53.8	0.002
I recruited patients, CT administered by self	20.0	16.2	22.9	0.029
I referred patient, patient not accepted	17.0	8.4	23.4	0.000
Patient enrolled without my knowledge	39.1	30.6	45.5	0.000
I participated in design and implementation	9.2	9.4	9.0	0.863
I administered a CT	14.1	12.5	15.3	0.282
I participated in evaluation	9.6	8.4	10.6	0.345
I participated in other ways	19.0	16.8	20.6	0.210
I have never been involved	36.5	43.4	31.4	0.001

Types of clinical trials				
Screening/diagnostic trial	68.9	72.1	66.6	0.123
Prevention action study	48.6	48.8	48.5	0.932
Prevention agent study	31.7	29.0	33.7	0.186
Treatment	61.9	56.6	65.8	0.013
Clinical trials value				
Strongly disagree	3.5	4.1	3.0	0.006
Disagree	9.6	13.9	6.3	
Undecided	17.9	19.4	16.7	
Agree	59.1	53.7	63.0	
Strongly agree	10.0	8.8	10.9	
Factors influencing recommendations				
Will improve medical condition	85.0	84.2	85.7	0.583
My familiarity with protocol, physician, or institution	58.3	52.2	62.8	0.005
Patient's lack of means to pay	49.5	45.8	52.3	0.091
Patient's desire to take active role	50.4	47.8	52.3	0.246
Patient's desire to get medical attention	39.7	37.7	41.2	0.351
Patient's desire to advance medical knowledge	50.8	43.8	56.0	0.001
Patient's desire for latest treatment options	67.3	65.3	68.8	0.327
Other	2.2	2.0	2.3	0.829

^a Two-sided *p*-value from Chi-square tests for comparison of proportions.

Racial/Ethnic Differences in Clinical Trial Enrollment, Refusal Rates, Ineligibility, and Reasons for Decline Among Patients at Sites in the National Cancer Institute's Community Cancer Centers Program

Aisha T. Langford, PhD, MPH¹; Ken Resnicow, PhD¹; Eileen P. Dimond, RN, MS²; Andrea M. Denicoff, MS, RN³; Diane St. Germain, RN, MS²; Wortia McCaskill-Stevens, MD, MS²; Rebecca A. Enos, RN, MPH⁴; Angela Carrigan, MPH⁵; Kathy Wilkinson, RN, BSN, OCN⁶; and Ronald S. Go, MD⁷

Cancer March 15, 2014

Takeaways

- Ineligibility due to comorbidities higher in NH Blacks, not hispanics
- Consent readability factor across the board
- No decreased enrollment of hispanics in community cancer centers

TABLE 3. Multivariate Logistic Regression Model 1: Physical/Medical Conditions as the “Reason for Ineligibility” by Demographic Characteristics (N = 4184)

	Odds Ratio	95% CI	P
Age ≥ 65 (ref, <65) ^a	1.51	1.28-1.79	<.001
Males (ref, females) ^a	2.28	1.92-2.71	<.001
Race and ethnicity ^a			.005
Non-Hispanic white (ref)	1.0		
Non-Hispanic black ^a	1.53	1.20-1.96	
Hispanic	0.66	0.4-1.11	
Asian	0.85	0.51-1.53	
Other	1.1	0.45-2.71	

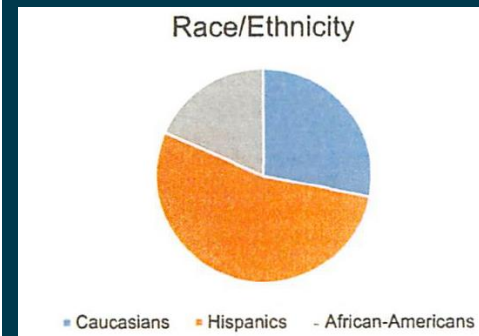
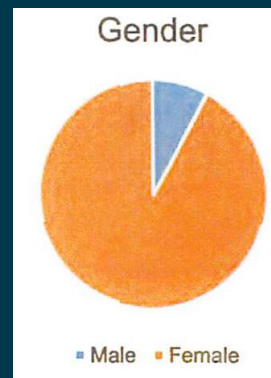
TABLE 5. Multivariate Logistic Regression Model 3: “Patient Eligible but Declined a Clinical Trial” by Demographic, Region, and Consent Form Correlates (N = 4184)

	Odds Ratio	95% CI	P
Age ≥ 65 (ref, < 65)	0.86	0.73-1.01	.07
Males (ref, females) ^a	0.78	0.65-0.94	.001
Race and ethnicity			.78
Non-Hispanic white (ref)			
Non-Hispanic black	1.05	0.82-1.35	
Hispanic	0.97	0.63-1.49	
Asian	0.85	0.51-1.44	
Other	1.44	0.68-3.04	
Consent form page length			.28
≥20 pages (ref, < 20 pages)	0.91	0.77-1.08	
Consent readability ^a			.005
SMOG score	0.9	0.83-0.97	
Region of country			.45
West (ref)			
Midwest	0.83	0.36-1.91	
South	0.7	0.27-1.81	
Northeast	1.42	0.59-3.42	

Underrepresentation of Hispanics and Other Minorities in Clinical Trials: Recruiters' Perspectives

Aurora Occa¹ • Susan E. Morgan¹ • JoNell E. Potter²

April 2017



Key Points from Focus Groups

- Adaptation to potential participants language competency and literacy levels
- Engaging in culturally appropriate verbal and non-verbal communication
- Establishing a sense of “connection” between recruiters and patients
- Accommodating socioeconomic concerns
- Adapting to contextual factors
- Responding to potential participants mistrust of medical research

Barriers to clinical trial participation: a comparison of rural and urban communities in South Carolina.

Kim SH¹, Tanner A, Friedman DB, Foster C, Bergeron CD.

Phone Survey of residents of South Carolina

Key Takeaways:

- No significant differences in willingness to participate based on rural vs. urban
- Distrust and fear of clinical trials a barrier in both groups
- Rural > urban for
 - Perceived limited access to clinical trials
 - Greater lack of knowledge regarding clinical trials (process and availability)

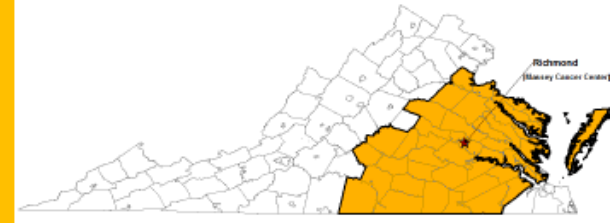
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Improving accrual (General)

Iruku & Kaklamani (Colorado, UT Health SA Cancer Center) *in preparation*

- Predictive Model of Trial Accrual (297 Trials)
- Observational, interventional, industry-sponsored trials and trials authored by the local PI more likely to meet accrual goals



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Strategies to Improve Accrual to trials

- **Dedicated Resource Specialists**

- Clinical Social Workers are available to clinic patients to help identify resources, including alternative transportation grants, childcare or legal assistance.
- Clinical research nurses are now better able to focus on patient care and treatment.

- **Insurance Coordination**

- Dedicated **insurance authorization coordinator** → explains insurance policies to determine coverage and financial obligations.

- **Communications Training**

- “Support Services for Clinical Trials” brochure for patients, physicians and health care staff

- **Education and Marketing**

- Massey actively promotes its trials in clinics, at community events and within the larger health system.
- African-Americans are targeted with key messages about clinical trials through faith-based health fairs, community gatherings, and urban radio campaigns.
- Massey’s Web site - clinical trials section featuring testimonials from African-American participants who share their experiences in research trials.

“I’m so glad I had the treatment and participated in this trial. I am more than convinced I am cancer-free.”

- Rev. Linwood James, colon cancer survivor and clinical trial participant



Automated Data Screening Tool for Trials



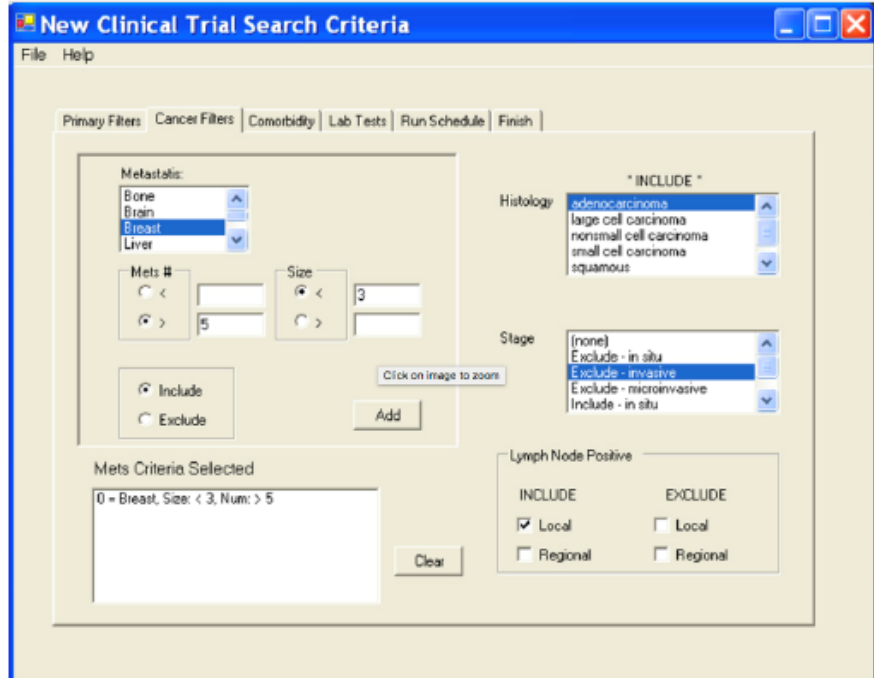
Contemporary Clinical Trials
Volume 31, Issue 3, May 2010, Pages 207-217

ELSEVIER

Automated matching software for clinical trials eligibility: Measuring efficiency and flexibility

Lynne Penberthy ^{a,*,} Richard Brown ^{b,} Federico Puma ^{c,} Bassam Dahman ^d

^a Massey Cancer Center/ Dept of Internal Medicine, School of Medicine, Virginia Commonwealth University
^b Department of Social and Behavioral Health, School of Medicine, Virginia Commonwealth University, United States
^c Department of Microbiology and Immunology, School of Medicine, Virginia Commonwealth University, United States
^d Department of Public Health Management and Policy, School of Medicine, Virginia Commonwealth University, United States



New Clinical Trial Search Criteria

File Help

Primary Filters | Cancer Filters | Comorbidity | Lab Tests | Run Schedule | Finish

Metastasis:
Bone
Brain
Breast
Liver

Mets #
◀ ▶
◀ ▶

Size
◀ 3 ▶
◀ ▶

Include
 Exclude

Click on image to zoom

Add

Mets Criteria Selected
0 = Breast, Size: < 3, Num: > 5

Clear

* INCLUDE *

Histology
adenocarcinoma
large cell carcinoma
nonsmall cell carcinoma
small cell carcinoma
squamous

Stage
(none)
Exclude - in situ
Exclude - invasive
Exclude - microinvasive
Include - in situ

Lymph Node Positive

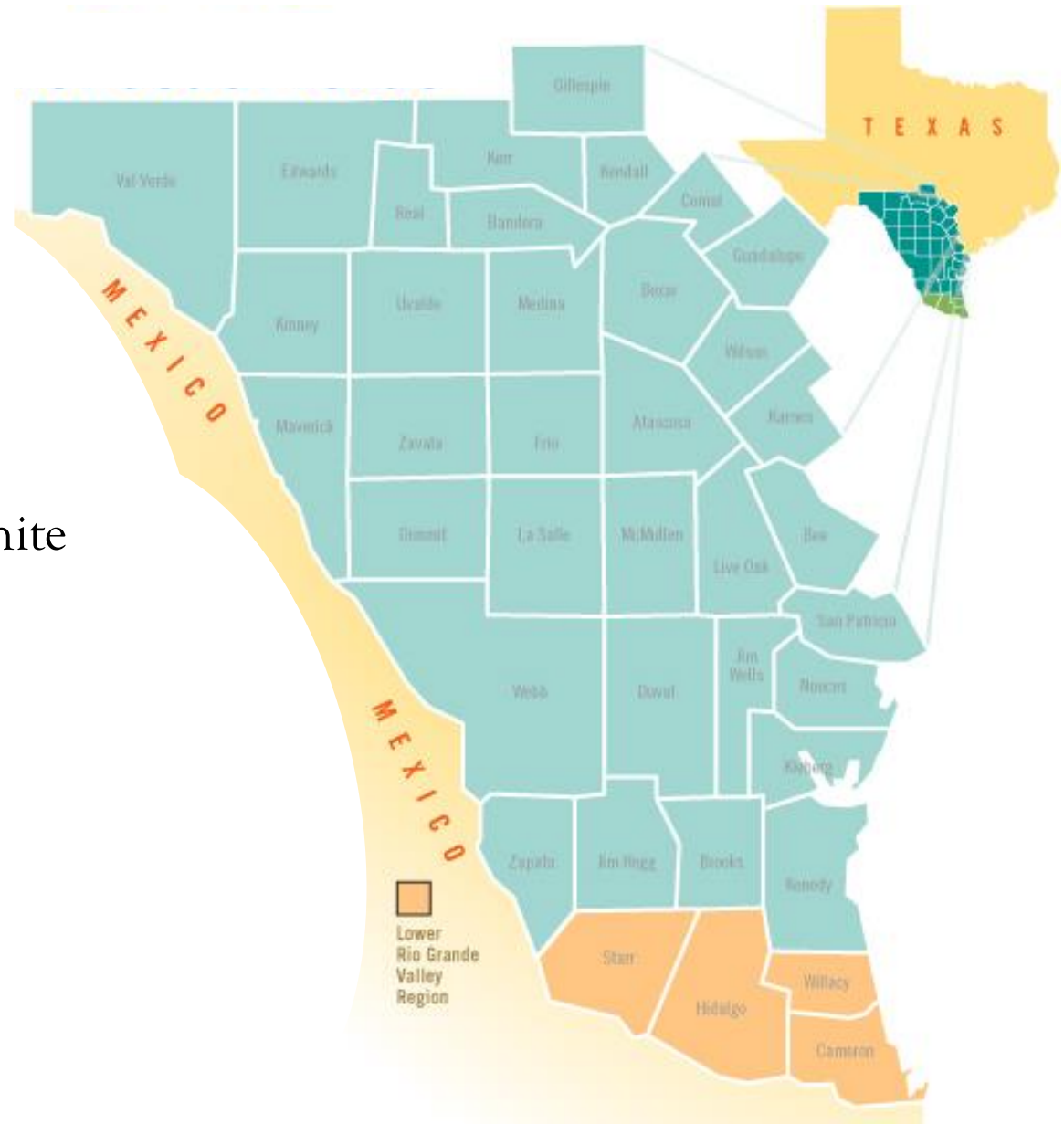
INCLUDE EXCLUDE
 Local Local
 Regional Regional

- Evaluating automated clinical trials eligibility tool
- **Total Staffing Time Saved: 165 to 1,329 hours**

Mays Cancer Center Catchment Area

Race/Ethnicity

- 69% Hispanic
- 24% Non-Hispanic White
- 4% African American
- 3% Other





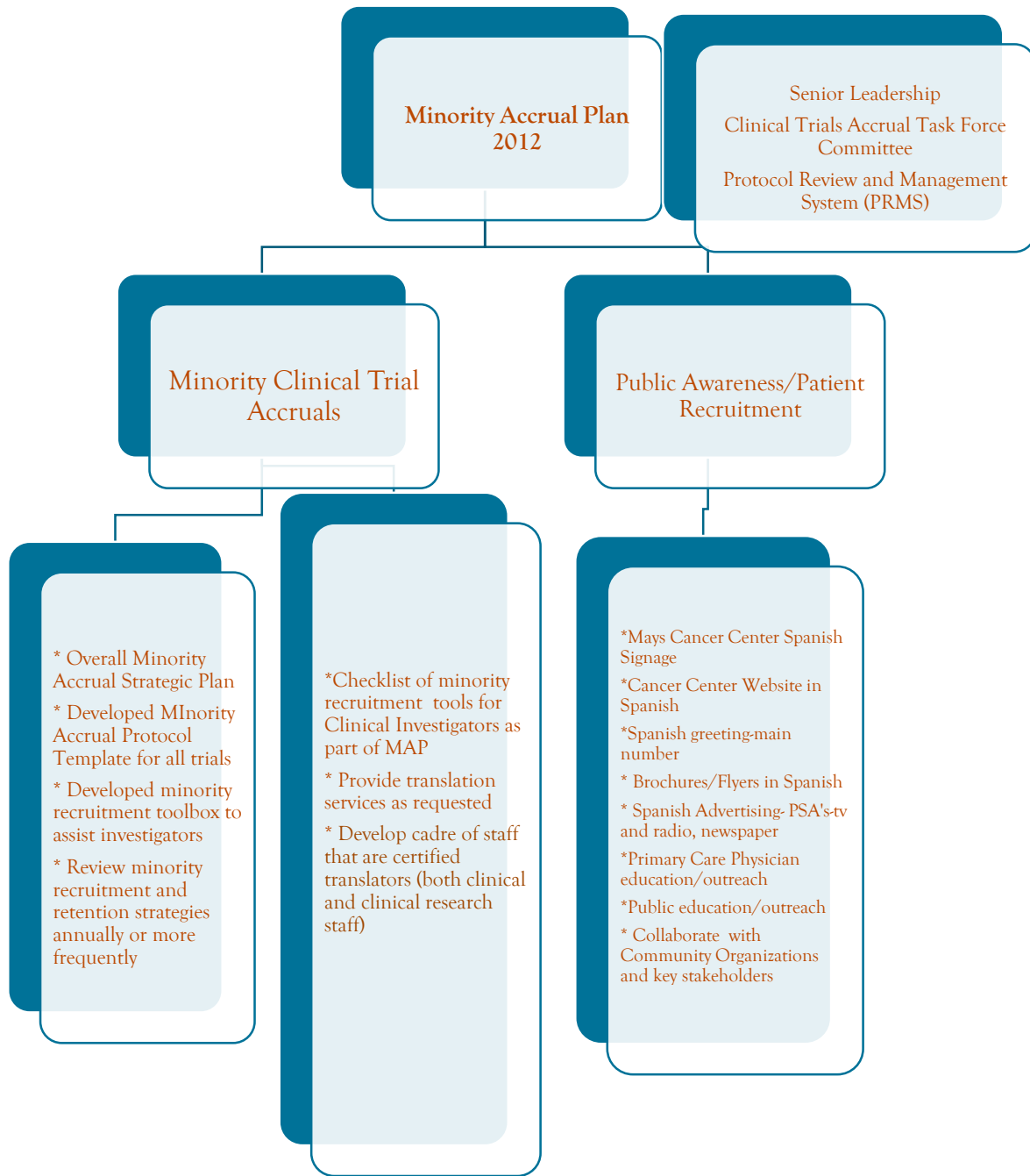
Research Article

Open Access

The Development of a Minority Recruitment Plan for Cancer Clinical Trials

Monica Trevino¹, Susan Padalecki^{1,2}, Anand Karnad^{1,3}, Alberto Parra³, Steve Weitman^{1,4}, Melissa Nashawati¹, Brad H. Pollock^{1,5}, Amelie Ramirez^{1,5,6} and Ian M. Thompson^{1,2*}

Tool included in study	List of Tools and Actions for Increasing Minority Accruals to Clinical Trials
Yes No	1. Include Clinical Trial information on CTRC website in both English and Spanish
Yes No	2. Use of Bilingual Research Team Member or Translation services
Yes No	3. Identification of bilingual Patient Navigator representative of the Target Population. Please Specify:
Yes No	4. Informed Consent available in Spanish
Yes No	5. Information Brochures in English and Spanish (IRB approval required)
Yes No	6. Flyers in English and Spanish (two-sided, printed in English on one side and Spanish on the other) (IRB approval required)
Yes No	7. Public Service Announcements (PSAs) or Advertisements- Spanish Radio (IRB approval required)
Yes No	8. PSA's or Advertisements -Spanish newspapers (IRB approval required)
Yes No	9. PSA's or Advertisements -Spanish Television (IRB approval required)
Yes No	10. Patient Friendly Fast Facts in English and Spanish (IRB approval may be required)
Yes No	11. Outreach to advocacy or community organizations (including presentations or awareness campaigns). Please specify:



- RESOURCES**
- *Wellness Center
 - *San Antonio Cancer Council Council
 - *Alamo Breast Cancer Foundation
 - *American Cancer Society (San Antonio Chapter)
 - *The Lymphoma and Leukemia Society (San Antonio Chapter)
 - *Redes en Accion
 - *CHOICES-Patient Navigator Intervention
 - *Susan B. Komen Grant-Increasing Latina access in breast cancer clinical trials

Recruiting Minority Patients to Clinical Trials

Clinical Trials Minority Accrual Committee (10 Members)

Reduce barriers to minority patient accrual

Implement strategies to enhance minority recruitment

Coordinator of Minority Programs

Leticia De Los Santos

Minority Accrual Plan (MPA) required for all clinical trials

Toolbox developed to help investigators create MRP

(Journal of Community Medicine & Health Education, 2013)

Monitoring/evaluation process in place

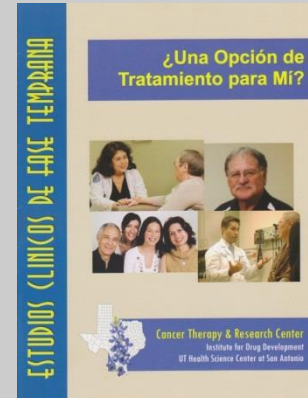
Reducing Barriers to Minority Enrollment

Identified
barriers

- Research
- Focus groups
- Interviews
- Physician outreach

Developed
strategies and
materials

- Virtual tumor boards
- Spanish translations
 - Signs, brochures, consent forms
 - Many translators



Expanded media
outreach

- *Univision*
- *La Prensa*

Minority Accrual Plan Toolbox

Informed consent in Spanish (translation offered)

Bilingual Research Team Member or Translation services

Culturally tailored communications

Flyers/Advertisements in English and Spanish

PSAs/Advertisements

- Spanish Radio

- Spanish Newspapers

- Spanish Television

PSAs/Advertisements—Spanish newspapers

Translation of consents

MAP Assessments

Implemented in August 2013

Requests for assistance: ~50/year mostly translation

Between 2013-2017:

Trials with MAP: 226

Each estimates minority accrual

Minority accrual metric: 33% of target or better

Assessed at 6mos and then annually

At 6mos: 12% meet metric

To date: 54% meet metric

Currently assessing if we have data to compare trials prior to MAP implementation

Minority accrual to interventional studies

prior to MAP: 46%

currently 57%

Minority Inclusion 2013-2017

Interventional Treatment Accruals		2013	2014	2015	2016	2017
	Total	326	378	244	274	232
Ethnicity	Hispanic/Latino	46%	45%	45%	47%	56%
Race	White	91.7%	90.8%	93%	93.8%	94.4%
	Black or African American	6.4%	6.9%	4.1%	2.9%	3.4%
	Asian	0.9%	1.8%	0.4%	2.9%	2.2%
	Native Hawaiian /Other Pacific Islander	0.3%	0%	0%	0%	0%
	American Indian /Alaskan Native	0.3%	0%	1.2%	0.4%	0%
	Unknown/Patient not reported/ Other	0.3%	0.5%	1.2%	0%	0%

Minority Inclusion 2013-2017

Interventional Non-Treatment Accruals		2013	2014	2015	2016	2017
	Total	499	418	126	62	109
Ethnicity	Hispanic/Latino	71%	62%	49%	29%	59%
Race	White	87.2%	82.1%	87.9%	91.9%	89.0%
	Black or African American	4.8%	3.8%	7.9%	4.8%	4.6%
	Asian	1.0%	1.5%	0.8%	0%	2.8%
	Native Hawaiian /Other Pacific Islander	0%	0%	0%	0%	0%
	American Indian /Alaskan Native	0.2%	0.4%	0%	0%	0%
	Unknown/Patient not reported/ Other	6.8%	12.2%	4.0%	3.2%	3.7%

Minority Inclusion 2013-2017

Non-Interventional (Observational & Ancillary/Correlative) Accruals		2013	2014	2015	2016	2017
	Total	1,517	1,167	1,337	1,022	648
Ethnicity	Hispanic/Latino	47%	48%	48%	42%	37%
Race	White	84.5%	88.5%	89%	83.1%	75.2%
	Black or African American	7.0%	6.2%	7.2%	7.4%	11.6%
	Asian	1.3%	6.2%	1.6%	2.0%	0.6%
	Native Hawaiian /Other Pacific Islander	0.1%	0%	0%	0%	0%
	American Indian /Alaskan Native	0.3%	0.2%	0%	0%	0%
	Unknown/Patient not reported/ Other	6.9%	3.4%	2.2%	8.1%	12.3%

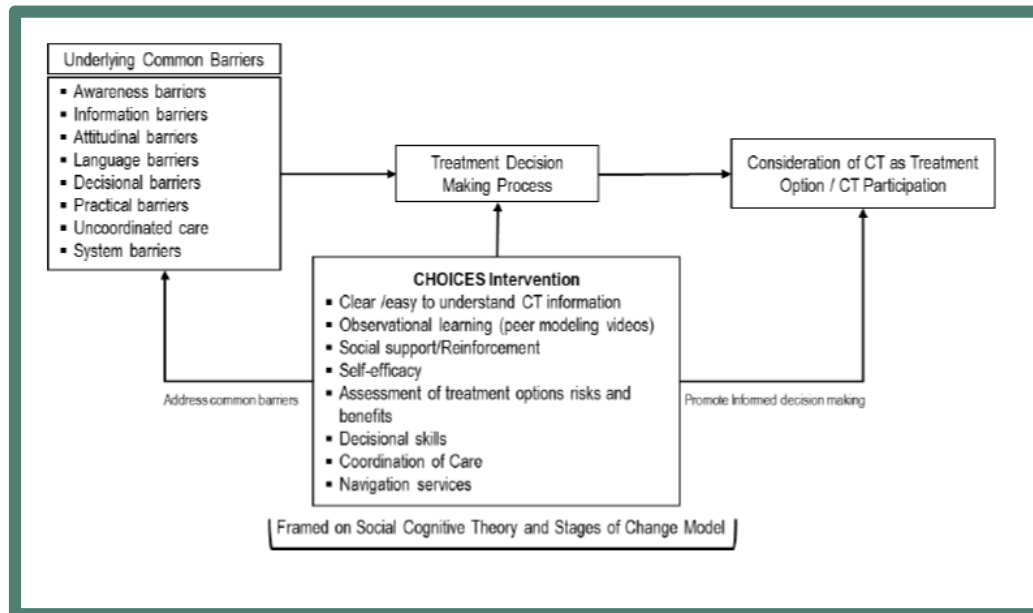
Empowering Latina Breast Cancer Patients to Make Informed Decisions about Clinical Trials: a pilot study

Patricia Chalela, DrPH,¹ Edgar Muñoz,¹ MS, Kipling J. Gallion, MA,¹ Virginia Kaklamani, MD² & Amelie G. Ramirez, DrPH¹

¹Institute for Health Promotion Research at UT Health San Antonio

²Cancer Therapy & Research Center at UT Health San Antonio

Translational Behavioral Medicine, In press 2018.



CHOICES > Control

- Understanding of Clinical Trials
- Consideration of Clinical Trials Appropriate

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Key Opportunities- Latinos and Clinical Trials

- Education of registering physicians
- Awareness building amongst latino populations of role of clinical trials in improving cancer care
- Care navigation enhancements to better support the role of cancer clinical trials in care treatment planning
- Language and cultural appropriate materials/ education/ clinical trial coordination
- Sharing of lessons learned between centers/investigators engaged with latino cancer patients

Mays Cancer Center
1-210-450-1000

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Thank You

We will always care for
San Antonio. We will always
educate healers. We will
always search for answers.

We will now take questions for Dr. Mesa.
Please use the question box on the lower right
to submit a question.
Questions will be answered as time permits.



Thank you for joining this Association of American Cancer Institutes
Physician Clinical Leadership Webinar. We would appreciate your
feedback and will send out an evaluation later today.