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Recruitment and retention

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Recruitment and Retention

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Disclosure Statement

● Source of Research Support

- 1. NIDA
- 2. NIAAA
- 3. NINR
- 4. WAF

● Consulting Relationships

- 1. None

Thank You for Recognizing the
Importance of Recruitment of
Vulnerable Populations

Members of EPRG

Goals for Presentation

- Review Literature about Barriers
- Present Successful Strategies from EPRG experience
- Explore Local Problems to Recruitment

Table A–1: Representation of Minorities in Randomized Controlled Trials for Treatment of Bipolar Disorder.

Study	Sample	Information on ethnicity of sample	Analyses by ethnicity
Dubovsky, Franks, Allen, & Murphy, (1986)	N = 7	No	No
Giannini, Taraszewski, & Loiselle, (1987)	N = 20	All white, male patients	N/A
Cohn, Collins, Ashbrook, et al., (1989)	N = 89	No	No
Gelenberg, Kane, Keller, et al., (1989)	N = 94	No mention	No
Clarkin, Glick, Haas, et al., (1990)	N = 50	35 white 15 nonwhite	No
Gallagher-Thompson, Hanley-Peterson, & Thompson, (1990)	N = 91	No	No
O’Leary & Beach, (1990)	N = 36 couples	No	No
Himmelhoch, Thase, Mallinger, et al., (1991)	N = 56	52 white 4 nonwhite	No
Jacobson, Dobson, Fruzzetti, et al., (1991)	N = 60 couples	No	No
Pope, McElroy, Keck, et al., (1991)	N = 36	No	No
Small, Klapper, Milstein, et al., (1991)	N = 52	No	No
Garza-Treviño, Overall, & Hollister, (1992)	N = 20	No	No
Lenox, Newhouse, & Creelman, (1992)	N = 20	No	No
Bowden, Brugger, Swann, et al., (1994)	N = 179	127 white 32 black 20 other	No
Sachs, Lafer, Stoll, et al., (1994)	N = 15	No	No

Table excludes studies published before 1986.
Table excludes studies with samples outside United States.

Who Does (or Doesn't) Participate?

- Fewer than 5% of adults over 20 years old participate in clinical trials (Taylor, 1994)
- The percentage drops to 1.5% among those over age 50 – although adults in this age range have the highest cancer incidence rates (Taylor, 1994)
- Over 90% of adults and 40% of children with cancer are not enrolled in RCTs (Peppercorn et al, 2004)
- Among women, those most likely to enroll in RCTs were younger, interested in taking an active role in healthcare decision making, and those who reported the impact of positive information related to RCTs outweighed the negative information (Ellis et al, 2001)

Why?

Common concerns regarding participation in RCTs . . .

- Time and inconvenience
- Negative personal and family beliefs and attitudes regarding RCTs
- Lack of perceived benefits of participation

Major Reasons for Recruitment Problems

- Inadequate planning
- Overestimation of the yield from a particular source
- Inability to alter existing plans rapidly

[Lovato LC, Hill K, Hertert S, Hunninghake DB, Prostfield JL, Recruitment for Controlled Clinical trials: literature summary and annotated bibliography. *Controlled Clinical Trials* 1997;18:328-57]

Most Common Barriers to Participation

- Lack of trust in medical research
- Absence of previous knowledge of the clinical trial process
- Unwillingness to be randomized
- Time commitment
- Difficulty with informed consent

Lovato LC, Hill K, Hertert S, Hunninghake DB, Prostfield JL, Recruitment for Controlled Clinical trials: literature summary and annotated bibliography. *Controlled Clinical Trials* 1997;18:328-57]

Vulnerable Populations

“Those who are relatively (or absolutely) incapable of protecting their own interests... have insufficient power, prowess, intelligence, resources, strength, or other needed attributes to protect their own interests through negotiations for informed consent”

Levine, R. (1986). *Ethics and Regulation of Clinical Research*. New Haven, CT: Yale University Press.

Who is Vulnerable?

Vulnerable populations may be comprised of individuals who encounter discrimination and negative attitudes due to . . .

- Race
- Sex
- Class
- Age
- Sexual preference
- Physical or mental ability
- Culture
- Behavior

Cumulative Vulnerabilities

- Being young or old
- Having low income
- No insurance or limited insurance
- No regular source of health care
- A drug addiction, especially with visual signs (i.e., track marks)
- No stable home address
- Being a member of an ethnic/racial minority

Striley, C. (2004). Racial and Ethnic Health Disparities: *Why we must include vulnerable populations in research?* EPRG Ethics Seminar, Washington University School of Medicine.

Motivation to participate

- Perception of receiving superior clinical care
- Contribution to medical knowledge or care of future patients
- Affinity with supervising physician or study staff

Lovato LC, Hill K, Hertert S, Hunninghake DB, Prostfield JL, Recruitment for Controlled Clinical trials: literature summary and annotated bibliography. *Controlled Clinical Trials* 1997;18:328-57]

“Lessons Learned” –from Literature

- Adequate funds are needed
 - supplemental funds can be obtained from NIH
- Some feel African Americans are harder to recruit; we found the opposite
- Face to Face recruitment is key
- Ads in media have low yield
- Transportation is important
- Important to gain the trust of the community to overcome African Americans’ historical distrust of research.
- Awarding certificates of completion is a way to formally recognize participants’ contributions

[Lovato LC Hill K, Hertert S, Hunninghake DB, Probstfield JL. Recruitment for Controlled Clinical trials: literature summary and annotated bibliography. *Controlled Clinical Trials* 1997;18:328-57.

[Loftin WA, Barnett SK, Bunn PS, Sullivan P. Recruitment and Retention of Rural African Americans in Diabetes Research: Lessons Learned. *Diabetes Educ.* 2005; 31(2):251-9

Distrust, Race and Research

Corbie-Smith et al, Arch Intern Med, 2002

- To better understand health disparities, and improve the generalizability of research findings, the Federal Government mandated that women, minorities and children be included in clinical research studies.
- In spite of this, studies do not always do a good job at recruiting minorities.
- Why? Distrust in medicine, rooted in experiences dating back to slavery and recently, Tuskegee.

Study Design

- National telephone survey
- 1997
- Rollins School of Public Health (Emory)
- General population survey (n=500; 27 were African American)
- 500 African Americans in an oversample
- Refusal rate = 50% in both groups

Responses to Items, by Race

	AA	White
If your physician wanted you to participate in research, you trust that he/she would fully explain it to you. (disagree or DK)	42%	23%
You believe that you can freely ask your physician any questions you want. (no or DK)	15%	8%
Your physician would not ask you to participate in research if he/she thought it would harm you. (disagree or DK)	37%	20%
In deciding about treatments, you feel your physician will always try to protect you from risk. (no or DK)	46%	35%

All significant at $p < .01$

Responses to Items, by Race (Cont)

	AA	White
How likely is it that people like you might be used as guinea pigs without your consent? (very likely, somewhat likely or DK)	79%	52%
How often, if ever, do you think physicians prescribe medication as a way of experimenting on people without their knowledge or consent? (very often, fairly often or DK)	63%	38%
Do you believe physicians have ever given you treatment as part of an experiment without your permission? (yes or DK)	25%	8%

All significant at $p < .01$

Discussion Points

- Trust in one's MD is an iterative process
- Trust in medical profession may come from friends, media, public opinion
- Dramatic fall in public opinion, due to negative events (unethical behavior, violations) being broadcast
- To regain public trust, especially in African American community there needs to be:
 - Engagement
 - Dialogue
 - Feedback

Discussion Points (cont)

- Ongoing involvement important
- Community advisory boards
 - STOP CAB in full swing – learn something at every meeting
- Engage members in all aspects from planning, to engagement, to dissemination of data
- At the beginning of the encounter and at the end, try introducing questions like the Trust in Physician's Scale, or the Primary Care Assessment Survey or the Patient Trust Scale
- Be a myth buster everywhere you go

Common Recruitment Mistakes

- Thinking “color” solves your problem – recruiting respondent solely by matching staff by skin color or sex
 - Data show that respondents care about staff being respectful, competent and trustworthy
- Assumptions about respondents’ compliance based on color, gender, drug use
- Assuming people will find us if they need us
- Assuming everybody reads the same papers, listens to the same news, watches the same programs, or lives in the same area
- Assuming everyone has access to your location

Bias in Excluding Hidden Populations

- Post-marketing strategies, clinical trials and other studies that recruit treated populations (professional subjects) miss a significant untreated, often symptomatic, population at risk
- These populations are “hidden” and, in many cases, vulnerable
- These populations are those that need treatment

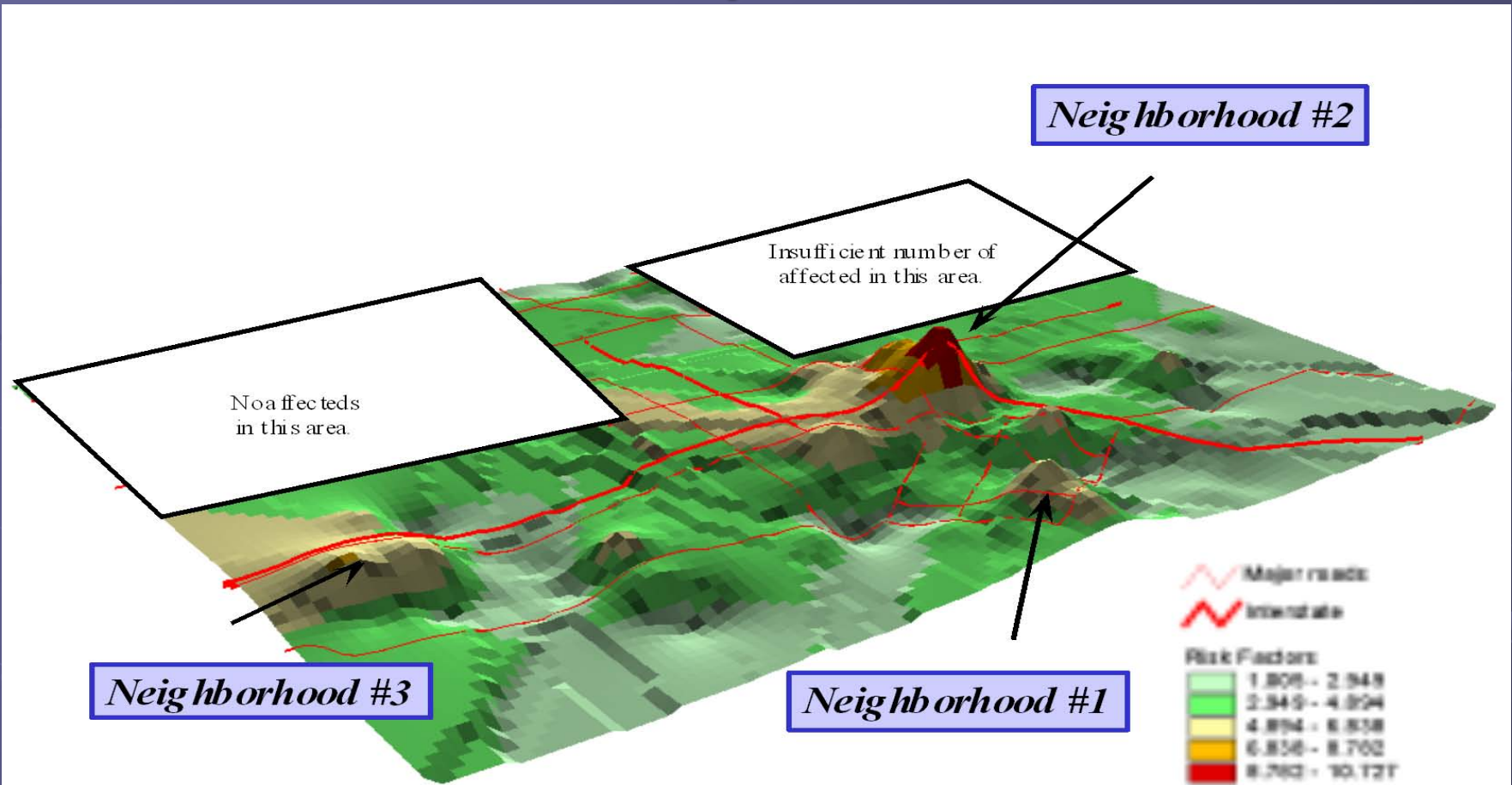


Tip of the Iceberg Phenomenon

Challenges

- Community members might not trust you initially
- Diversity of a team is mandatory
- Community leaders must be won over and then win over their constituents
- Investigators must shed the “ivory tower” image

Total Aggregated Risk Factors Perspective



HealthStreet: A Public Health Collaboration

- The HealthStreet North and South sites are the result of a collaboration between the St. Louis City Health Department and Washington University School of Medicine since 1989
- Common services offered through the sites are food pantry referrals, & housing referrals
- The Washington University Women's Health Studies offered community members the chance to participate in HIV risk reduction efforts by enrolling in research studies conducted at HealthStreet

HealthStreet Sites



Common Outreach Areas

- Bars & clubs
- Beauty shops
- Parks
- Shelters
- Bus stops
- Community agencies
- Churches
- Hot spots from Vice
- Health care facilities
- Tanning parlors
- Fast food
- Grocery stores
- Laundromats
- Nail salons
- Drug Court/Judge
- Tattoo parlors
- Colleges
- Gas stations
- Check cashing
- Head start

Keep Track of Outreach Efforts by Mapping Neighborhood Zones

Sister to Sister/Women Teaching Women Project Voucher

Bring this voucher to HealthStreet for your
Personal Health Screening

4620 Delmar or 7704 Ivory
(314) 286 - 2233

Expiration Date: July 13, 2000 Area: Grand and Holly Hills

CHOW's Initials: LBC Voucher # 1014

Washington University Locator Form

- The Locator Form elicits phone numbers and addresses to locate the respondents throughout the study and into the future.
- It elicits phone numbers and addresses for:
 - “Best Place to Locate”
 - Parents
 - Friends
 - Relatives
 - Church
 - Employer
 - Parole Officer
 - Person contacted if Arrested
 - Place would go if could not stay at current residence

14. If you couldn't stay at your current address any longer where would you go?

Name: _____

Address: _____

Phone: _____

15. How did you find out about the study?

Thanks very much for this information. Now I'd like to get a copy of your drivers license, state ID or other identification.

PHOTOCOPY ANY IDS THE RESPONDENT HAS. PUT STUDY ID# ON THE PAGE.

of IDs Copied _____

I understand that the information I have supplied will be used to locate me for future interviews by this research team. This information will remain confidential, and will not be linked to any other information I provide in an interview.

Signature

Date

Interviewer's Signature

Date

Outreach

- Outreach staff must be comfortable going out into the community and talking to people
- People in the community must be comfortable with the outreach team – you can tell whether they are just by looking!
- That often (but not always) means looking the same or sounding the same

Intensive Follow-Up Experience

- St. Louis Team achieved 96.6% completion at 18 month follow-up
- Elements of success
 - ◆ Creative and persistent team
 - ◆ Phone, system and field tracking
 - ◆ Detailed locator form
 - ◆ Refusal conversion

Cottler LB, Compton WM, Ben-Abdallah A, Horne M, Claverie D. Achieving a 96.6% follow-up rate in a longitudinal study of drug abusers. *Drug Alc Dependence* 1996, 41:209-217.

Final Dispositions of EOTO Sample

Cottler et al. Achieving a 96.6% follow up rate in a longitudinal study of drug abusers. *Drug and Alc. Dependence* 1996;41:209-217.

Status	Interview			
	Baseline		18 Month	
	<i>N</i>	Percent	<i>N</i>	Percent
Full complete	476	99.4%	454	96.6%
Partial complete	2	0.4%	1	0.2%
Breakoff	1	0.2%		
Refusal			3	0.6%
No show			1	0.2%
Locate/no contact			4	0.9%
No locate			7	1.5%
Deceased			9	
Total sample	479	100.0%	470	100.0%

Effectiveness of Street Outreach for Drug Abusers

Recruitment=
Yield
$$\frac{\text{enrolled}}{\text{all screened on the street}}$$

Enrollment=
Yield
$$\frac{\text{enrolled}}{\text{all eligible from the street}}$$

Precision =
$$\frac{\text{all eligible from the street}}{\text{all screened on the street}}$$

Constant Monitoring Necessary

- Monitoring respondents - from contact to final disposition - can inform us of who participates, who is difficult to recruit, retain, etc.
- Can alert us to areas where more outreach efforts are needed
- Enrollment should be monitored during the study, to make corrections, and for retraining, staff changes

Comparison among street contacts, eligible street contracts, and study enrollees

	<u>Street Contacts</u>		<u>Eligible Contacts</u>		<u>Study Enrollees</u>		X^2 (P-value) ^a
	n	%	n	%	n	%	
STS			2272	67	920	55	67.54
WTW			1123	33	751	45	(<0.001)
Combined	5551	100	3395		1671		

^a Compares study of eligible contacts to enrolled contacts.

Recruitment, Precision, and Enrollment Yields

	Recruitment Yield ^a (%)	Enrollment Yield ^a (%)	Precision ^c (%)
STS	16.6	40.5	40.9
WTW	13.5	66.9	20.2
Combined	30.1	49.2	61.2

^a Recruitment yield is the number of study enrollees out of the total screened (5551 cases)

^b Enrollment yield is the number of enrolled out of the number of eligible

^c Precision is the number of eligibles out of the number of screened contacts

Summary

For every 10 people contacted,
expect to enroll 3

Expect to enroll about $\frac{1}{2}$ of all
eligible respondents

For every 5 people contacted,
expect about 3 to be eligible

Maintain Neutral Staff and Trusting Relationship by:

- Use a Certificate of Confidentiality
- Don't let interviewers conduct an interview with a personal friend or associate
- Establish good rapport with the respondent, but not too good rapport
- Maintain privacy in the interview setting
- Ongoing ethics training of staff will help ensure this

Maintain Neutral Staff (cont)

- Discuss with interview staff their biases and the effects of their biases on the outcomes of research.
- PIs: should interact with respondents, and do a research interview every now and then to understand the unique situation these respondents have and to engage them in the study. Tell respondents how important they are to the study.

Frequently Unasked Questions you MUST Answer

- Why do you want me now?
- Why should I trust you?
- How will this help my community?
- Will you give me the data?
- Will it help me? When? How?

The Message Matters

- Use words that your target audience understands
- Don't use words out of context
- Tailor your message to the audience
- Tell respondents why they might want to be in your study in words they understand

Study Names -- Acronyms

- Assume participants will see the name – make sure it is clearly linked to the study and appropriate
- If studying an approved product, avoid using the brand name in the title – it may be considered coercive

<http://www.samedanltd.com/homepage/ict/Summer2006/Rob.pdf>

Key Recruitment Points

- Plan early and revisit the recruitment plan often
- Talk to people who know the community
- Be creative!
- Remember, every study is different!