

MINORITY INCLUSION IN CLINICAL RESEARCH:

Techniques for Recruiting a Diverse Sample

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Public Law PL 103-43, 1997, 2001

- women and minorities must be included
- cost NOT an acceptable reason for exclusion
- NIH obligated to support outreach efforts to recruit and retain women, minorities, and their subpopulations in clinical studies

Can researchers comply?

Barriers and challenges



Barriers to recruitment: Concerns of potential enrollees

- history of clinical research--Tuskegee, Sims procedure
 - Savitt TL. The use of blacks for medical experimentation and demonstration in the old south. *J South Hist* 1982;48:331-48.
- failure of trust—suspicion of MDs & medical system
 - Cooper-Patrick L, Gallo JJ, et al. Race, gender and partnership in the patient –physician relationship. *JAMA* 1999; 282,6: 583-589.
- fear of consequences, especially if undocumented
- burdens of participation, especially if low income
- unclear benefits of participation, if no sub-analysis

Advertising a study:

Potential barriers to recruitment

- PI may be unfamiliar with neighborhood info channels
 - media, churches, grocery stores, advocacy groups
- PI may lack personal contacts
 - community leaders, outreach workers, social workers, probation officers
- PI may experience language & cultural barriers
 - even a study name may resist translation

On-Site Enrollment Challenges

- Profiling problem
 - Patients may feel singled out for screening
- Privacy problem
 - Waiting room versus bedside
- Trust issues
 - Staff skills: engagement and rapport
- Language barriers

Literacy & Limited English Proficiency (LEP)

- reading & writing: forms to fill vs oral interview
- medical literacy: the medical knowledge base
- spoken English proficiency
- LEP: data accuracy is affected
 - across generations (using family)
 - with untrained (unrelated) interpreters
 - with trained interpreters

Strategies to address challenges

NIH recommendations

- hire minority staff
- collaborate formally with minority communities
- identify communication channels prior to initiation
- reimburse adequately & provide transportation
- address cultural beliefs, ie involvement of family
- work with institutions around CLAS standards
- pilot instruments and procedures for validity and acceptability among minority populations
- monitor data for differences in enrollment & f/u rates

Project Link: Brief Motivational Interview in the Clinical Setting To Reduce Cocaine and Heroin Use

- 23,669 patients screened 5/98-11/00
- 1232 eligible
- 1175 enrolled (95% of eligible)
- Composition: 62% Black, 24% Hispanic, 14% white
- 82% follow-up rate

The Job Description for LINK

Characteristics of Peer Research Assistants

- recruited from the communities we serve
 - people skills -- warmth, enthusiasm and confidence
 - flexibility -- adaptability to clinical setting
 - team approach -- work well with clinic staff
 - detail-oriented for data quality & completeness
 - bilingual
 - people in solid recovery encouraged to apply

Staff Training to Promote Recruitment

- establishing rapport, and asking permission
- human subjects protections and informed consent
- scripted introduction of study
- check list for consent
- adherence monitored by audio/video tapes of role plays and direct observations of screening and informed consent process

Project Link: Recruitment Logistics

- screen administered face to face by bilingual peers
 - eligibility questions embedded in health survey
 - privacy assured (in office at UCC & exam rooms)
- everybody got something
 - survival guide (info & resources)
 - reimbursement for time and effort
 - appreciation meals provided during study
- co-PI worked on site
- clinic staff oriented to study but did not refer
- no delay or interference with patient care

Studies in Progress

- Project RAP (Reaching Adolescents for Prevention)
 - a randomized, controlled trial of a peer intervention to reduce drinking, marijuana use and associated consequences among 14-21 y.o. BMC Pediatric ED patients
(NIAAA Youth Alcohol Prevention Center)

- Project Safe
 - a randomized controlled trial of a peer intervention to reduce the rate of sexually transmitted diseases among ED patients who use heroin and cocaine (NIH, NIDA)

Recruitment Lessons Learned



- community participation promotes peer research staff recruitment

- peer researcher and the community in-reach model may lead to greater minority inclusion and enrollee trust and participation

- active collaboration with clinic staff and space are critical to facilitate patient access and recruitment