Recruitment and Retention in Clinical Research

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Why engage the community in clinical research?

- It takes an average of 17 years for only 14% of new scientific discoveries to enter day-to-day clinical practice (Balas and Boren).
- Americans only receive 50% of the recommended preventive, acute, and chronic health care (McGlynn et al.).
  - Just over 50% of eligible Americans have received appropriate colorectal cancer screening.
  - While the beneficial effect of beta-blockers in acute myocardial infarction was discovered 25 years ago, the variation in use is great, and they’re still underutilized.
Why we need women and minorities in research studies . . .

- For many years, researchers did not include women in medical research studies because they believed it would make the studies too complicated.

- Medical researchers assumed that if it worked for men, then it would work the same way for women (Society for Women’s Health Research).

Source: [www.womancando.org](http://www.womancando.org); Mills, 2004
Main Goal of Recruitment and Retention of Underrepresented Groups:

Study patients who mimic the population of those likely to be treated with the new medicine

Source: Geba, 2006; http://www.dfhcc.harvard.edu/minority_initiatives/index.asp
Challenges to Recruitment, Retention . . .

- History
- Personal Behaviors
- Culture
- Physical Environment
- Genetics
- Education
- Income
Attitudes of Minority Participants Towards Research

• For example--attitudes and beliefs of African Americans toward participation in medical research:
  • Mistrust of doctors, scientists, and the government was consistently reported by focus group participants.
  • Many described concerns about the ethical conduct of clinicians and investigators.

Source: Corbie-Smith, Thomas, Williams, & Moody-Ayers, 1997; Yancey et al., 2006.
Attitudes of Minority Participants Towards Research

- Many focus group participants cited exploitation as supporting evidence for their mistrust of the medical establishment.
- Few participants understood the concept of Informed Consent.
- Participants saw signing the document as relinquishing their autonomy and as a legal protection for the investigator.

Source: Corbie-Smith, Thomas, Williams, & Moody-Ayers, 1997.
Attitudes of Minority Participants Towards Research

- Fear of being “guinea pig”
- Data used to advance researcher’s careers, portray community in unfavorable light
- Researchers “take the data and run”
- Bias is evidenced when researchers exclude minorities on the claim that, “they are hard to reach”
- Researchers don’t look like the targeted population--small number of minority researchers

Source: Swanson and Ward, 1995; Yancey et al., 2006.
NIH Policy on Inclusion in Clinical Research

• Mandated by Congress, 1993 PL 103-43
  • Women and Minorities **must** be included in all clinical research studies.
  • Women and Minorities **must** be included in Phase III clinical trials and trials must be designed to permit valid analysis.

• During Scientific Review: unacceptable recruitment plans **must** be reflected in the priority score.
NIH Policy on Inclusion in Clinical Research

- An application with an unacceptable recruitment plan **cannot** be funded. The applicant **must** revise the recruitment plan.

- Cost is **NOT** allowed as an acceptable reason for exclusion.

- NIH supports outreach efforts to recruit and retain women, minorities, and their subpopulations in clinical studies.
NIH Policy on Inclusion in Clinical Research

- NIH funding components will not award any grant, cooperative agreement, or contract or support any intramural project that does not comply with this policy.

- For research awards that are covered by this policy, awardees will report annually on enrollment of women and men, and on the race and ethnicity of research participants.
Recruitment & Retention Goals in Clinical Research

- Increased representation of minorities and women in research that would increase the generalizability of research data and allow for valid analyses of differences in subpopulations.
- Getting the message out: being in a clinical research study is advantageous to participants regardless of the final research study results.
Recruitment & Retention Goals in Clinical Research

- Instead of telling minorities that participation in research is good for them, the research community should focus on understanding what minority communities want from clinical research and then tailor the message to meet this need.

- Persuasive arguments to promote long-term increased representation of minorities in clinical research must come from within minority communities.
Establishing academic/community relationships:

Involving community in research means rethinking “business as usual” at the proposal development/research design stage:

- *Who* needs to be at the table
- *What* needs to change as a result of research
- *How you get* community people involved
Who needs to be involved in community-based research:

- Groups historically underserved by health services
- Groups facing geographic or linguistic barriers to care
- Prevention & Early Intervention (PEI) priority populations
- Local priority populations
- Groups with high uninsurance, underinsurance and/or poverty rates
Data sources:

- UCDHS CTSC Community Engagement website (http://www.ucdmc.ucdavis.edu/ctsc/areas/engagement.html)
- Census data
- Statewide and local reports
  - California Health Interview Survey (CHIS)
  - Kaiser Family Foundation
  - The California Endowment
  - Public School data
  - First 5 Children and Families Commission data
- Trends of penetration rates
- Department of Public Health data
- Data resources within communities such as United Way, NGOs, etc.
What needs to change:

- Back to the beginning: who are the beneficiaries/stakeholders in this research?
- Are they involved in formulation of research questions?
- Can you jointly envision what might change as a result of your findings?
  - Getting stakeholders involved in the beginning
  - Keeping them informed
  - Sharing results as you go along
How to maximize minority recruitment: active (face-to-face) and passive (media-based) strategies

- Mixing and matching
- Criteria for deciding on strategies
“Passive” Recruitment Strategies:

- Health system (Public Affairs, physician networks)
- Newspapers, magazines
- Flyers
- Advertisements
- Radio, PSAs
- Mailings

Source: Yancey et al., 2006.
Example--passive recruitment

- Nutrition and physical activity effects on body composition among African American women:
  - Local zip codes of purchased black women’s magazine subscriber list
  - Lots of participants--recruitment discontinued one year before intervention began for final cohort.
  - Why? Opportunity to contribute to success of African-American physician-researcher; perception they were deriving less benefit from tax dollars spent on research, a result of lo African-American study participation

Source: Yancey et al., 2006
Criteria for deciding between active, passive strategies

- Long term interest in community/academic partnership?
- Degree of risk/marginality associated with a particular population/community?
- Number of eligibility criteria likely within population?

The greater the interest in partnerships, the higher at risk the population, the higher the number of eligibility criteria, the greater the necessity for active recruitment strategies.
“Active” Recruitment Strategies:

1. Define the target population:

   - Understand medical, epidemiological and sociological basis of disease;
   - Obtain information on health beliefs and behaviors relevant to participation in clinical trials;
   - Seek collaboration from leaders in the target community, involving community groups that have the trust of the target population (religious and social organizations, education institutions, medical institutions, athletic groups).

   - Source: Geba, 2006; http://www.dfhcc.harvard.edu/minority_initiatives/index.asp
2. Bring project staff directly into contact with prospective participants (phone, face-to-face meetings *in community*)

- Use multiple recruitment strategies for each population (one-on-one discussions, posters, using existing structure within the community such as exercise groups and meal sites, direct phone calls).
- Seek collaboration from leaders in the target community, involving community groups that have the trust of the target population (religious and social organizations, education institutions, medical institutions, athletic groups).
3. Hire and train diverse recruitment staff:
   - Recruit study staff from the target populations;
   - Ensure that recruitment staff have cultural competency skills;
   - Include investigators or staff on your research team that have an understanding of the target populations.
4. Recognize potential barriers/develop strategies to address:
   - Sociocultural barriers
     - Language barriers
     - Cultural beliefs or myths about a specific disease;
   - Economic barriers
     - Cost of participation; transportation
     - Lack of insurance;
   - Individual barriers
     - Denial or underestimation of risk
5. Test recruitment strategies:

- Ensure strong communication with patient’s primary care team.

- Use multiple recruitment strategies for each population (one-on-one discussions, posters, using existing structure within the community such as exercise groups and meal sites, direct phone calls).

- Understand and incorporate individuals’ cultures, traditions, beliefs, practices, lifestyle into promotional materials (key-informant interviews, focus groups are helpful).
6. Address barriers in regard to the study design:
   
   - Complex and technical forms
   - Complicated study procedures
   - Frequent visits to health care setting

   - Utilize focus groups and key informant interviews to identify and understand potential barriers and seek solutions

   - Hire bilingual staff and/or utilize medical interpreters
     
     - Especially relevant for Hispanic and Asian populations

   - Ensure that translated materials are both linguistically and culturally appropriate.
Advantage of active strategies:

Building trust and long term relationships, in addition to recruitment
Further findings from Yancey study:

1. Mass mailings effective in recruiting African Americans with middle, higher SES to clinical and prevention trials. However personal contact most effective, especially for recruiting higher-risk participants to prevention studies.

2. Eligibility affects recruitment: Reactive/passive strategies most likely to produce higher randomization yields when study-eligibility rates in target population are high; proactive strategies associated with higher recruitment yields when eligibility is rare.
3. Community involvement by project staff may be more critical to retention than to initial recruitment of African Americans and Latinos.

4. Face-to-face recruitment produced highest yield of eligible, willing participants among African Americans, Mexican and Central Americans, and whites.

5. Impersonal or media-based strategies tend to engage more affluent, less marginalized populations.
Important for retention…

- Use intensive follow-up and contact
- Use same interviewers and field staff over time, particularly staff from targeted community
- Provide social support
- Have accessible locations for data collection, interventions
- Use regular phone reminders, toll-free numbers to reach project staff
- Use timely incentive payments
Budget issues for community researchers

- Translators and interpreters
- Honoraria for community participants
- Travel time, mileage, meals, lodging
- Teleconference
- Meeting space
References
