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A Comparison of Methods and Results in Recruiting White and Black Women into Reproductive Studies: The MMC-PSU Cooperative Center on Reproduction Experience

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Abstract

Establishing a holistic approach for the enrollment of subjects into clinical trials that includes strategies for the recruitment of non-traditional and minority populations has been an elusive task. The existence of such a design, that is understood and embraced by investigators and the target communities, would streamline the current level of commitment of time, energy and resources. This is necessary to successfully encourage individual and community participation in research studies. The Center for Research in Reproduction at Meharry set out to recruit a large number of African American women volunteers of reproductive age into clinical trials. The experience, of recruiting volunteers from the African American community for clinical trials in the Meharry Medical College/ Pennsylvania State University (MMC/PSU)'s Cooperative Center for Research in Reproduction at Meharry, is presented.

Keywords

Recruitment; African Americans; minorities; clinical trials research

1. Background

The Cooperative Center for Research in Reproduction at Meharry was established in 2003 and is a collaborative project between Meharry Medical College (MMC), in Nashville, Tennessee, and Pennsylvania State University (PSU) in Hershey, Pennsylvania. The Center's mission is to create an academic and research milieu that conducts clinically relevant research in gynecologic endocrinology and increase scientific knowledge that will ultimately ameliorate chronic reproductive disease while fostering collaboration among diverse institutions and researchers in women's health.

While African American participation in clinical trials is reported to be less than representative of the population, the literature does not provide comprehensive rationale for such

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observations. [1] The reasons given are conflicting and no model exists that is predictive of success.

Socioeconomic factors such as limited flexibility in jobs held by minorities, lack of trust in the healthcare community in general, and infrastructure that is culturally incompetent and indifferent to minorities and their role in the discovery process have all been suggested for African Americans' lack of participation in clinical trials research. An additional observation has noted the community's perception of unilateral exchange that occurs when academic institutions enlist their participation into clinical trials without feedback, lack of improvement in the community's health, or a failure to sincerely demonstrate concern for its needs. [2].

The focus of the MMC/PSU Center for Research in Reproduction at Meharry is on diseases that manifest significant gynecologic morbidity in women generally but differentially in blacks and whites: uterine leiomyomata, polycystic ovarian syndrome and osteoporosis. Consequently, volunteer subjects were sought between the ages of 12 and 45 years. MMC is located in a metropolitan city in the South with a total population of just over a half million and an African American population of 28%. The city is home to twenty-one colleges, including three historically black colleges and universities. PSU is located in the Northeast with a population that is primarily rural with a county wide population of just over a quarter million that is 75% white. Furthermore PSU enjoys a long and productive history of volunteer recruitment from its community for clinical studies. The two distinctly different demographics (Table 1), facilitated the two institutions partnership to the study racial/ethnic differences in reproductive disorders. Based on the female populations at the two sites, MMC could target approximately 40,000 age eligible African American women (12-45 years) and PSU could target approximately 60,000 White women for recruitment.

With numerous national and institutional initiatives now focusing on strategies to address health disparities, especially in the African American community, all efforts to broaden understanding and facilitate the inclusion of this population into clinical trials is extremely critical. Consequently, the objective of this study was to review our experience in recruiting African American women of reproductive age into clinical trials research at MMC compared to parallel efforts of the collaborating institutions' recruitment of Caucasian women for identical studies at PSU.

2. Methods

Both institutions utilized nearly identical recruitment tools for each strategy that included traditional newspaper, flyer, and radio and television advertisements. The radio media was selected based on its' popularity in the African American community. The Center staff developed printed material and advertisements for use at both sites. Some differences were reflected in printed materials for each site, which were related to the focused recruitment of whites at PSU and African Americans only at MMC. The printed materials and advertisements explicitly extended invitations to African American women only to participate at Meharry. The printed material was race neutral at PSU. The websites conveyed brief synopsis of the research with an invitation to explore participation. Any other differences were minor and dictated by individual institutional Internal Review Boards. PSU did not use television based on previous experience and Meharry abandoned it early on because of ineffectiveness and cost. There were a small number of Hispanic volunteers who showed interest at PSU and they are excluded from this report. Only African American volunteers responded to the targeted advertising of that group at MMC. Participants were provided incentives and free health screenings at both institutions.

The Meharry site enlists a full time equivalent Recruitment Coordinator whose responsibility is to work directly with the community to provide education, information, and encouragement, serve as liaison and advocate, and most importantly assure the participant of confidentiality. Introduction of this position into the community was followed by accelerated and expanded visits to the communities and interaction with community leaders. Billboard and metropolitan bus advertisements were launched and the postcard and flyer distribution on college campuses were intensified. Brown bag luncheon discussions on research and the Center studies were initiated for the faculty and staff. The principal investigators and Center staff members participated regularly on local and minority focused radio programs to discuss the value of research and the importance of minority community involvement in research. Investigator participation at numerous health fairs and women's conferences was expanded. Print materials providing information about the studies were placed in area businesses, churches and clinics. Referrals were requested from campus and area physicians and non-physician professionals. An informational website was created with the ability to schedule appointments online.

The Center utilizes a data system comprised of an electronic medical record and a database developed in Access (Microsoft) that allows compilation and evaluation of medical and study related data on each study participant to include sources of referrals, numbers screened, numbers enrolled, screening failures, and financial costs associated with recruitment. The data evaluated for this study was collected from August 2004 through June 2006.

3. Results

At the conclusion of the first year of recruitment, 2004, a total of 50 volunteers were screened and 21 enrolled for all studies at Meharry. During the same time period, PSU screened 143 and enrolled 44 for all studies. At the conclusion of an additional 22 months, characterized by the more aggressive recruitment strategy employing a full time recruitment coordinator, MMC screened a total of 1054 volunteers and enrolled 132 subjects; PSU screened a total of 660 women and enrolled 106 subjects (Tables 2,3).

The most effective methods overall for screening the target population at MMC were postcards, flyers and brochures, comprising 37% (N=389) of respondents compared to 7% (N=46) at PSU. Radio listeners resulted in 34% (N=359) at MMC and 60% (N=397) at PSU. Referrals by health professionals were also higher for PSU (22%) compared to MMC (10%) (Table 2). The success of enrollment followed the trend of respondents with radio the highest followed by distribution of printed material (Table 3).

A review of the cost per subject enrolled revealed that distribution of print material was the most cost effective method at MMC versus the website at PSU. The newspaper, television and the city Bus advertisements were the least cost effective marketing tools as well as the least effective in enrolling subjects. The estimated cost per subject enrolled was >\$4800 at Meharry and \$1800 at Penn State (Table 4).

4. Discussion

Research to determine the best and most cost effective methods for recruitment of African Americans into clinical trials and for minimizing potential barriers to their participation is sparse. Traditional prospective studies in largely white populations have utilized the media (newspaper, radio and television), public appearances, flyers, and direct solicitation from clinics to market their studies. Though these techniques have not always proven to be as effective when recruiting African Americans, [3,4] the Center was optimistic that established strategies for enrollment would be successful given the prevalence of the disorders under

investigation in the target population. Additionally, all of the investigators at MMC shared racial and ethnic ties to the group being recruited.

Harris has reported that African Americans are more responsive to reactive recruitment scenarios as opposed to proactive ones [4]. Printed advertisements (brochures, flyers, etc.) were well received by MMC's target population. Disappointingly, the number screened to enrolled subjects from churches, health fairs and public housing units were 13:2, 49:1 and 37:1 respectively, which contrasts the prevailing opinion that these sources are most reliable for recruiting African American volunteers into research trials. Convincing the community to assist in this process required considerable effort in time and investment of substantial resources that would not have been possible without extramural support.

Additionally, the recruitment coordinator was instrumental in soliciting participation by building rapport and research value awareness in the community. The coordinator's connection in the community also led to a valuable lesson for interacting with the inner city neighborhoods. There is an absolute need to establish a business-like relationship with the resident counselors in these areas. This was essential in gaining credibility with the residents as this group proved to be the most cautious and needed reassurance of a commitment to their community independent of their commitment to research. Despite this interaction's failure to result in significant enrollment into the studies during this study interval, the Center and its research activities have clearly deepened the ties of the school in the community hopefully leaving a foundation for clinical research efforts in the future.

In conclusion, this experience generated some new perspectives about recruitment in general and specifically of African Americans into clinical trials. *First*, a review of the marketing strategies utilized in this project allowed a site-specific formula for successful recruitment to occur. A better appreciation for what works at MMC has led to the necessary revisions that will positively impact our current and future studies. *Second*, social and economic factors are well established; however equal credence should be given to health related influences that limit enrollment in that significant health related co-factors might impact on African Americans' eligibility for rigid protocols. We found this reason to represent the majority of volunteers (criteria ineligibility in most instances secondary to chronic disease) who were not eligible, in lieu of simply refusing to participate. The second most common reason for non-enrollment of eligible volunteers was the commitment of time required to participate. *Third*, we have found that documented limitations of recruiting African American women are not insurmountable. Clinical trials are quite costly in general and we believe that the costs of this work is cost effective considering much of what we implemented and the strides we made were reflective of a start-up environment for clinical research and recruitment of human subjects. Additionally, we are recruiting for several clinical trials that should make significant contributions to the scientific community. We further concede that such research is not possible without extramural funding support. PSU has a well-established infrastructure for clinical research and this is reflected in their high percentage of physician referral and early, steady enrollment with fewer screening failures.

Cultural sensitivity, which includes awareness of social and economic barriers to participation, is essential. Additionally, careful selection of recruitment methods will also have a significant impact on enrollment success. This correlates with the findings presented by Wendler [5]. *Fourth*, the value of a recruitment coordinator and an amenable clinical referral base cannot be overemphasized.

Finally, we cannot speak to the possible extrapolation of our experience to the African American male, as we have no experience with males in general. However, the impression a research team leaves on any community, positively or otherwise, cannot be revoked. Our goal

should be to promote a sentiment of optimism about the eradication of health disparities that only a mutually respectful partnership with the community can accomplish.

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Table 1**Demographics of Research sites**

	Tennessee Nashville	Pennsylvania Dauphin County
Total Population	553,988	254,176
Female population	284,322	132,420
% White	64.4	75.5
% African American	28.6	17.4
% Age 25+ high school graduate	84.7	88.2

2006 American Community Survey: <http://factfinder.census.gov>

Table 2
 Number of volunteers responding to invitations to participate in clinical trials by year and strategy

Recruitment Strategy/Source	MMC			PSU			Total (%)	Total (%)
	2004	2005	2006	2004	2005	2006		
Radio	0	190	169*	99	253	45	359 (34)	397 (60)
Television	0	8	NU*	NU	NU	NU	8 (1)	NU
Newspaper	0	28	19	1	19	0	47 (4)	20 (3)
Postcard/flyer/brochure	3	281	105	12	23	11	389 (37)	46 (7)
Physician	17	57	35	26	84	37	109 (10)	147 (22)
Non-Physician providers	3	41	33	0	7	11	77 (7)	18 (3)
Other [#]	27	27	5	NU	NU	NU	59 (6)	NU
Website	0	3	3	5	19	8	6 (1)	32 (5)
Total per year	50	635	369	143	405	112	1054	660

* NU (strategy not utilized by site)

[#] Other at MMC site includes self referrals and referrals from health fairs

Table 3
Numbers and percent of volunteer enrollees by referral source or recruitment strategy

Recruitment Strategy/Referral Source	MMC 2004-2006 Number enrolled (%)	PSU 2004-2006 Number enrolled (%)
Radio	34 (26)	45 (42)
Flyer, brochure, postcard	32 (24)	7 (7)
Television	6 (4.54)	NU*
Metropolitan Bus Advertisements	2 (1.5)	NU
Newspaper	1 (0.008)	2 (2)
Website	0	6 (6)
Health Professionals [@]	57 (44)	46 (43)
Total	132	106

* NU (strategy not utilized by site)

[@] Includes self referrals, physicians, non-physician providers, health fairs

Table 4
Cost in dollars per subject enrolled by recruitment strategy

Recruitment Strategy	MMC 2004-2006	PSU 2004-2006
Radio	610	408
Flyer, brochure, postcard	218	218
Television	195	NU
Metropolitan Bus Ad	3820	NU
Website	188	348

* NU (strategy not utilized by site)