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ENROLLMENT OF MINORITY WOMEN AND THEIR MAIN SEXUAL PARTNERS IN AN HIV/STI PREVENTION TRIAL

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There is a paucity of empirical reports that quantitatively assess the success of recruitment strategies in randomized clinical trials (RCTs) using sampling units other than the individual. As innovations in HIV and sexually transmitted infection (STI) preventive intervention protocols and targets of change evolve, there is a need to examine the efficacy of attendant adaptations to recruitment protocols and strategies in the enrollment of study participants. This article examines factors related to enrollment of women and their main, male sexual partners in an RCT of a relationship–based HIV/STI preventive intervention conducted from 1997 to 2001. Among eligible participants (N = 388), findings indicate that race/ethnicity, employment status, marital status, and language preference were significantly associated with enrollment among eligible, potential participants. Additionally, being HIV–positive and having a past or current STI were significantly associated with enrollment. These findings underscore the need to ensure sufficient representation of all risk groups in RCTs, especially those testing innovative HIV/STI preventive intervention approaches or using novel enrollment strategies.

Scientifically rigorous trials of HIV/STI preventive interventions rely on the randomized clinical trial (RCT) to estimate and demonstrate efficacy. With the growing emphasis on ensuring that women, racial/ethnic minorities, and other socioeconomically disadvantaged groups are represented in clinical research (National Institutes of Health, 2001; Varmus, 1994) and that targets of intervention expand beyond the individual to couples (El–Bassel, Witte et al., 2003; Musaba, Morrison, Sunkutu, & Wong, 1998; Padian, O'Brien, Chang, Glass, & Francis, 1993; Remien, Wagner, Dolezal, & Carballo–Dieguez, 2001; Voluntary HIV–1 Counseling and Testing Efficacy Study Group, 2000), there is a need for development of innovative and novel recruitment strategies designed to identify potential, eligible participants and enroll them in research studies. Examining the retention of potential participants from eligi-

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bility determination to enrollment and randomization in an RCT is important not only to qualify and quantify the extent of generalizability of study findings but also to maximize the accuracy of estimates of treatment effects. This article examines factors related to enrollment in Project Connect, an RCT testing the efficacy of an HIV and sexually transmitted infection (STI) preventive intervention where the sampling unit of heterosexual couples were enrolled by screening women at risk of HIV/STI transmission and working with them to enroll their main sexual partner in the study.

Project Connect tested the efficacy of a six–session relationship–based HIV/STI preventive intervention designed to decrease sexual risk behavior among heterosexual couples at elevated risk for HIV and/or STI transmission (El–Bassel, Witte et al., 2003; Sormanti, Pereira, El–Bassel, Witte, & Gilbert, 2001). The relationship–based intervention was developed in response to the need for innovative approaches to prevent heterosexual transmission of HIV/STIs, especially among Latina and African American women (El–Bassel, Gilbert, Rajah, Foleno, & Frye, 2001; Harvey, 2000; Wingood & DiClemente, 1995). The efficacy trial required recruitment and enrollment of women and their primary, long–term, male sexual partners. Because efforts to recruit minority women and their partners in HIV prevention RCTs is a unique endeavor at the time of this writing, we sought to examine whether characteristics of the women who enrolled in Project Connect with their main partner differed from eligible women who did not enroll.

The growing literature on RCT recruitment and enrollment highlights barriers to participation and enrollment, as well as factors associated with participation and enrollment. Most of the reports are descriptive, and the few reports quantitatively analyzing empirical data are drawn from data in which the individual was the sampling unit. Those studies found that participation in RCTs has been shown to be related to age (Chang et al., 2002; Corbie–Smith et al., 2003; de Graaf, Bijl, Smit, Ravelli, & Vollebergh, 2000; Goldman et al., 1982; Whiteman, Dunne, & Burnett, 1995; Wilson & Webber, 1976), gender (Wilson & Webber, 1976), race/ethnicity (Aylward, Hatcher, Stripp, Gustafson, & Leavitt, 1985; Gifford et al., 2002; McCann et al., 1997; Psaty et al., 1994), employment status (Orr, Blackhurst, & Hawkins, 1992), and marital/relationship status (Vaughn, Sarrazin, Saleh, Huber, & Hall, 2002). However, various other clinical trials, including those focused on HIV prevention, report no significant association with many of these sociodemographic variables. For example, the NIMH Multisite HIV Prevention Trial (1997) found race/ethnicity to be a significant factor associated with retention, with Latinos/as being more likely to drop out of the study compared with African Americans. However, Brown–Peterside et al. (2001) found no difference in race/ethnicity when accounting for attrition rates in their HIV prevention and vaccine trials with urban, minority women.

Studies showed that enrollment in a disease–related RCT was found to be related to participants' concern or perceived risk of disease (Vollmer et al., 1998; Whiteman et al., 1995) and behavioral or physiological risk (Aylward et al., 1985; de Graaf et al., 2000; Jordhoy et al., 1999; McCann et al., 1997; Orr et al., 1992; Psaty et al., 1994; Wilson & Webber, 1976); in general, findings indicate greater participation correlated with greater risk. However, reports on two HIV/STI–related studies found no significant association between retention and either behavioral or physiological HIV/STI–related risk factors (Brown–Peterside et al., 2001; NIMH Multisite HIV Prevention Trial, 1997). Neither of these studies described tested the association between psychological variables, such as perceived risk, and participation in the HIV/STI clinical study.

In examining the existing literature reviewed above, issues of participation generally have combined participation/attrition during recruitment, intervention delivery, and follow–up. The paucity of empirical reports that quantitatively assess the success of recruitment strategies is well noted (Hatchett, Holmes, Duran, & Davis, 2000; Lovato, Hill, Hertert, Hunninghake, & Probstfield, 1997; Swanson & Ward, 1995). Furthermore, as innovations in intervention protocols and targets of change continue to be developed—such as in Project Connect's HIV prevention with women and their primary male partners that targets relationship dynamics—there is a need to examine, understand, and test the efficacy of attendant adaptations to recruitment protocols and strategies (e.g., recruiting couples via the female partner). To our knowledge, there are no quantitative reports regarding recruitment of women and their primary male partners in RCTs. This article examines sociodemographic and HIV/STI–related risk factors associated with enrollment into an HIV/STI preventive intervention study by comparing these factors among all women approached, screened, and determined eligible for the study to those women who actually enrolled in the study.

METHODS

RECRUITMENT

As part of a larger RCT of a relationship–based HIV/STI preventive intervention study conducted from 1997 to 2001(El–Bassel, Witte et al., 2003), potential study participants were recruited from outpatient clinics at a large New York City hospital. In four of the six neighborhoods served by the hospital, over 40% of the residents live in poverty; 35% of the residents are African American and 48% are Latino. In several of the neighborhoods served by these outpatient clinics, the AIDS prevalence is two to three times higher than in New York City as a whole (New York City Department of Health, 2000).

Because Project Connect's intervention was designed to address the increasing proportion of African American and/or Latina women at risk of HIV and/or STIs via heterosexual transmission, intense preparation and efforts were dedicated to the design and implementation of recruitment procedures for women and their main, male sexual partners (for a full description, see Witte, El–Bassel, Gilbert, Wu, & Chang, 2004). Briefly, all female patients entering the outpatient clinic were approached by project staff, handed a flyer describing the parent study, and invited to complete a brief screening questionnaire to determine eligibility for the parent study. Interested women were invited into a private office, where they completed the 10–minute, face–to–face screening, administered by a female interviewer. Eligible women were offered several strategies for partner recruitment. A "brokering" strategy (Preloran, Browner, & Lieber, 2001) was employed/offered to each woman in which she would describe the project to her partner—including using study invitation flyers provided to the woman by study staff—and engage his participation on her own. Alternatively, "co–recruitment" strategies (Preloran et al., 2001) were offered in which (a) the woman would introduce the study to her partner, as in the brokering approach, but to have the invitation letter sent directly to her partner's mailing address from the study staff; (b) the woman would call her partner from the study office to extend an invitation to participate, with either a male or female staff member standing by to answer any questions or to provide details about the study to her partner (choice of gender of staff member determined by the woman); or (c) the woman would ask her partner to come by the study office (with or without her) to discuss the project with a study staff member in more detail. In all cases, male staff offered to role–play with women each of

the above strategies that she could use to motivate partner participation, with emphasis on motivational statements highlighting potential benefits such as the altruistic role of participation, financial compensation, and the potential to strengthen relationship skills.

All individuals (both male and female) were compensated for each activity they completed: $3 for the screening interview, $25 and $40 for the baseline and each of the two follow–up assessment interviews, and $20 for each intervention session attended. Protocols for this study were approved by the institutional review boards of both the research institution and the hospital at which recruitment took place.

ELIGIBILITY CRITERIA

The data presented in this article come from the 388 screening interviews completed by women meeting study eligibility criteria for the parent study. The screening interviews were conducted in either English or Spanish, according to the preference of the participant. A woman was eligible for the parent study if she (a) was between 18 and 55 years old; (b) had a regular, male sexual partner whom she identified as a boyfriend, spouse, or lover (i.e., hereinafter referred to as the "primary male partner"); (c) had been involved with this partner for at least 6 months; (d) was confident that she would stay with this primary partner for at least 1 year; (e) had at least one episode of unprotected vaginal or anal sex with this partner in the past 30 days; (f) did not report any life–threatening abuse by this partner within the past 6 months (according to selected questions from the Revised Conflict Tactics Scales (Straus, Hamby, Boney–McCoy, & Sugarman, 1996); and (g) was a patient at one of the hospital's primary care clinics. The parent study also required that the participant had to report knowledge or suspicion that her male partner met at least one of the following HIV/STI risk–related criteria: (a) He had sex with other men or women in the past 90 days; (b) he had been diagnosed with or exhibited symptoms of an STI in the past 90 days; (c) he had injected drugs in the past 90 days; and/or (d) he was HIV-positive. Of the 2,416 women screened, a total of 388 met all eligibility criteria and, thus, represent the sample for the analyses presented in this article.

MEASUREMENT

Sociodemographic data collected included a woman's age, race/ethnicity, employment status, and marital status with her primary male sexual partner.

Sexual HIV/STI risk–related behaviors were measured using responses from selected items of the Sexual Risk Behavior Questionnaire (SRBQ). The SRBQ was developed by the investigators and used in several prior studies with over 1,500 female and male participants recruited from a range of settings, including drug treatment, STI clinics, primary health care and emergency departments (El–Bassel et al., 2001; El–Bassel, Gilbert, & Wu, 2003; Gilbert, El–Bassel, Schilling, Wada, & Bennet, 2000). The selected items included the woman's self–report about number of sexual partners in the preceding year, history of having an STI, and condom use consistency during instances of sex with the primary sexual partner during the prior 3 months.

Participants were also asked if they had knowledge that primary sexual partners had a risk factor placing them at risk for HIV infection. Positive responses were coded if the woman indicated that she had knowledge or suspected that her primary partner had sex with another man or women recently (i.e., within the last 90 days), a recent STI diagnosis or symptoms (e.g., pain during urination, sores on the penis), injection drug use, or an HIV–positive diagnosis.

In addition, perceived HIV risk was assessed by asking the participant to answer "How worried are you that you might already have or in the future get HIV, the virus that causes AIDS?" using responses from a Likert scale (0 = "not at all worried," 1 = "a little worried," 2 = "somewhat worried," and 3 = "very worried").

Women were considered "enrolled" in the parent study if they met two criteria: They provided consent to enroll in the randomized clinical trial, and they attended a baseline assessment interview with their main, male sexual partner. (Note: Random assignment to treatment or control arms was carried out immediately following the baseline interview.) Eligible women who did not meet both enrollment criteria were categorized as "not enrolled."

DATA ANALYSIS

Binary logistic regression analyses were performed using the sociodemographic data and HIV/STI risk variables as the predictor (i.e., independent) variables and enrollment as the criterion (i.e., dependent) variable. Unadjusted and adjusted odds ratios (ORs) are reported with 95% confidence intervals (CIs). To avoid confounding HIV/STI risk with background variables, estimated ORs for each HIV/STI risk variable were adjusted by controlling for sociodemographic variables.

RESULTS

SOCIODEMOGRAPHICS

The sociodemographic characteristics of the 388 women who met study eligibility criteria, comprising the sample for this study, are summarized in Table 1. The majority of the sample of eligible women was African American and/or Latina and unemployed. Less than 10% preferred to converse in Spanish. Most of the women were single, never married, with the remainder identifying (in descending order of proportion) as separated or divorced, married, or widowed. Of the 388 women who met study eligibility criteria, 217 (56%) enrolled in the RCT. The distribution of sociodemographic characteristics of enrolled women is also given in Table 1.

Table 1 (right-most columns) also presents the results from analyses exploring differences in the sociodemographic characteristics between those who enrolled in the parent study and those who were met eligibility criteria but did not enroll. African American women were almost twice as likely to enroll compared with Latinas. Unemployed women were more than twice as likely to enroll compared with employed women. Spanish–speaking women were 20 times less likely to enroll compared with English–speaking women. After controlling for potentially confounding relationships (e.g., ethnicity and preferred language), all of the significant relationships remained at the 95% confidence level. In addition, women who met study eligibility criteria whose marital status was "widowed" were significantly less likely to enroll in the parent study compared with eligible women who reported being "married."

HIV/STI RISK

HIV/STI risk–related factors among the sample of eligible women are summarized in Table 2. More than one third reported having more than one sexual partner in the preceding year. Three quarters of the women who met eligibility criteria never used condoms during intercourse with their primary male partner in the preceding 90 days. Among the sample of women meeting eligibility criteria, over one fourth reported knowing that their primary male partner had a risk factor for HIV. Almost one half of this sample reported that they have or had an STI, and almost one sixth were

TABLE 1. Sociodemographic Characteristics of Eligible Women and Enrolled Women

	Eligible (388 women)	Enrolled (217 women)	Odds Ratio (95% CI) for Enrollment (N = 388)	
	n (%)	*n* (%)	Unadjusted	Adjusted [a]
Age (years)	$\bar{x}$ = 36 (*SD* = 9.5)	$\bar{x}$ = 37 (*SD* = 8.2)	1.0 (1.0, 1.1)	1.0 (1.0, 1.1)
Race/ethnicity				
Latina	180 (46)	79 (36)	—	—
African American	180 (46)	123 (57)	2.8 (1.8, 4.2)	2.0 (1.2, 3.1)
Other	28 (7.2)	15 (6.9)	1.5 (.66, 3.3)	1.0 (.44, 2.3)
Unemployed	324 (84)	193 (89)	2.2 (1.3, 3.9)	2.2 (1.2, 4.1)
Marital status				
Married	52 (13)	30 (14)	—	—
Single, never married	229 (59)	131 (60)	.98 (.53, 1.8)	.68 (.33, 1.4)
Separated/divorced	89 (22)	48 (22)	.86 (.43, 1.7)	.55 (.25, 1.2)
Widowed	18 (4.6)	8 (3.7)	.59 (.20, 1.7)	.23 (.07, .74)
Spanish screening	30 (7.7)	2 (0.9)	.05 (.01, .20)	.05 (.01, .23)

[a]Each odds ratio is adjusted for all of the other sociodemographic variables listed.

TABLE 2. HIV/STI Risk Factors of Eligible Women and Enrolled Women

	Eligible (388 women)	Enrolled (217 women)	Odds Ratio (95% CI) for Enrollment ($N = 388$)	
	n (%)	*n* (%)	Unadjusted	Adjusted[a]
>1 partner in last year	145 (37)	90 (42)	1.5 (.99, 2.3)	1.0 (.73, 1.8)
Condom use consistency				
More than half of the time	43 (11)	29 (13)	—	—
Half of the time	26 (6.7)	15 (6.9)	.66 (.24, 1.8)	.57 (.20, 1.6)
Less than half of the time	32 (8.2)	18 (8.3)	.62 (.24, 1.6)	.66 (.24, 1.8)
Never	287 (74)	155 (71)	.57 (.29, 1.1)	.71 (.34, 1.5)
Partner with known HIV risk–related factor	108 (28)	67 (31)	1.4 (.91, 2.2)	1.5 (.92, 2.6)
Have/had an STI	185 (47)	122 (66)	2.2 (1.5, 3.3)	1.7 (1.1, 2.7)
HIV–positive	57 (15)	42 (19)	2.5 (1.3, 4.7)	2.1 (1.1, 4.1)
Perception of HIV risk[b]				
Not at all worried	68 (21)	33 (19)	—	—
A little worried	71 (21)	35 (20)	1.0 (.53, 2.0)	.86 (.41, 1.8)
Somewhat worried	61 (18)	38 (22)	1.8 (.87, 3.5)	1.3 (.60, 2.8)
Very worried	131 (40)	69 (39)	1.2 (.66, 2.1)	1.1 (.55, 2.1)

[a]Adjusted for age, race/ethnicity, employment, martial status, and language of the screening interview. [b]Only women who were not HIV–positive ($N = 331$) were included for perception of HIV risk.

HIV–positive. Among the subsample of eligible women who did not report having an HIV–positive diagnosis, 79% reported some concern about being infected by HIV. To allow comparison between eligible enrollees and eligible nonenrollees, the third and fourth columns in Table 2 also summarize the HIV/STI risk–related factors among the subsample of those who enrolled in the parent study.

Table 2 (right-most columns) also provides findings exploring the relationship between HIV/STI risk–related factors and enrollment. Women who have or had an STI were more likely to enroll in the parent study compared with women with no history of having an STI. Compared with those who reported being HIV–negative, women who self–reported being HIV–positive were more than twice as likely to enroll. These relationships remained significant after controlling for sociodemographics.

Various post hoc analyses were carried out in order to examine the robustness of the estimates between sociodemographic and HIV/STI risk variables and enrollment, as well as to examine key findings in more detail. Several relevant examples are discussed below, and results from all analyses involving interaction terms and/or comparing results conducted with different subgroups are available upon request. In some cases, the association between STI history and HIV status with enrollment did not achieve significance with 95% confidence. However, in these instances, as well as the vast majority, estimates changed by less than 10%. Thus, we posit that the essential relationships, and thus our conclusions, remain unchanged and that the lack of significance observed is due to the decrease in power stemming from the smaller sample sizes of each subgroup. One potential exception was observed when models were run separately for African Americans and Latinas: the association between knowing that one was HIV–positive and enrollment was larger among African Americans (adjusted OR = 4.8, 95% CI = [1.4, 17.0]) compared with Latinas (adjusted OR = 1.2; 95% CI = [.46, 3.1]). These findings prompted us to examine enrollment among Latinas in more detail. Among eligible Latinas, bivariate analyses indicated that compared with Dominican women (n = 15), Puerto Rican women (n = 113) enrolled at significantly higher rates ($\chi^2 = 11.0$; $df = 2$; $p < .01$). Unfortunately, the small sample size prohibited meaningful multivariate analysis to further investigate this and other possible differences within the Latina subgroup of the sample.

DISCUSSION

To our knowledge this is the first study that examines factors associated with enrollment in an HIV/STI RCT for women and their primary sex partners. The findings indicate that race/ethnicity, English language ability/preference, not being widowed (yet having a current sexual partner), and being unemployed were related to study enrollment among women screened. Eligible participants who had tested positive for HIV and/or a different STI were significantly more likely to enroll in our HIV/STI RCT compared with those with no history of HIV or STI infection.

Although the recruitment protocol implemented in this study aimed to address such barriers and recruiters were trained and monitored in problem–solving recruitment barriers, the findings showed that African American women were almost twice as likely to enroll compared with Latinas. Reasons for lower enrollment rates among Latinas at the institutional level may be related to the fact that although Latinos/as constitute a majority of the community and patient population, most clinic staff are English speaking only and most clinic documentation and signage is in English only. As a result, Spanish–speaking women may feel more disenfranchised and less likely to

return or further engage in activities at the institution. Furthermore, there may be differences between subpopulations often grouped together, as suggested by differences in enrollment among Dominicans versus Puerto Ricans in this study. On both the individual and community levels, there may be differences among ethnic/racial groups or subgroups regarding what is perceived as beneficial (e.g., some groups/cultures may be more motivated to participate in an HIV preventive intervention study by "improving the health in our relationships and families" while other may be more motivated by "protecting our communities from HIV"). Comfort with discussions about sexuality and sexual behavior, especially the notion of such discussions being initiated by a female partner to her male partner, may also differ or reflect different gender norms within different racial and ethnic groups. Thus, additional research is needed to identify effective strategies for enrolling Latinas and Latina subgroups, in order to ensure that they are represented in the RCT literature.

Despite our efforts to provide flexibility in the timing of assessment and intervention appointments (Witte et al., 2004), unemployed women were more than twice as likely to enroll compared with employed women. Clearly, more research on innovative recruitment strategies for employed women are needed. The finding that employment and marital status significantly predict enrollment may be an indication that at–risk women may be balancing multiple needs (e.g., economic/financial needs, childcare) and concluding that meeting financial, household, or other obligations may take priority over concern about HIV and/or STIs. Clearly, additional data regarding at–risk women's other obligations and living situations would shed greater light on this issue.

The finding that history of STI or HIV infection (indicating firsthand experience of the negative associated consequences) significantly predicts enrollment is interesting in light of results that did not find significant associations between enrollment and engagement in risk behavior (i.e., sex without condoms, having multiple sexual partners), having a risky partner, and/or perceived risk. Many HIV/STI prevention efforts are predominantly based on theories, such as the Health Belief Model (Rosenstock, Strecher, & Becker, 1994) and the AIDS Risk Reduction Model (Catania, Kegeles, & Coates, 1990), which include emphasis on perceived vulnerability and susceptibility to infection. Greater emphasis on the actual, negative consequences associated with HIV/STI infection based on reported risk behaviors in the screening assessment might also improve likelihood of participant enrollment.

Eligible participants' responses to questions that directly ask about reasons for enrolling or not enrolling in the RCT would be very useful in understanding the findings from this study. In this RCT, which sought to enroll women and their primary male intimate partners, we did not obtain data from the partners' of the eligible women who did not enroll. It may be that more important differences lie with the characteristics of these male partners, i.e., some male partners may be more open or likely to participate in the RCT compared with others. For example, the fact that a woman with at least one diagnosed STI, including HIV, was more likely to enroll may reflect an underlying dynamic about disclosure: if she disclosed such information, her male partner may have been more motivated to enroll with her, whereas if disclosure had not occurred, he may have been less motivated to participate. Finally, we were also unable to assess the impact of important process variables (e.g., consent procedures, information given to participants) because they were held constant and/or not measured throughout the course of recruitment and enrollment. Future research should articulate recruitment strategies and include recruitment process—both quan-

titative and qualitative—and outcome evaluation components to track and evaluate the efficacy of such strategies.

Despite these limitations, the findings from this study provide important information on barriers to recruitment and enrollment of women and their main, male partners into an HIV/STI relationship–based intervention. The findings highlight the continuing need for HIV/STI prevention researchers to reduce barriers to study recruitment (e.g., flexible study hours and/or alternatives to monetary compensation to increase participation among potential participants who are employed). Understanding barriers to couple recruitment and enrollment into RCTs would improve the external validity of the research findings and also increase the inclusion of women who tend to be overlooked in clinical research. Moreover, these findings have special importance because this RCT involved a relationship–based intervention for women and their sex partners, an HIV/STI research topic and approach that is innovative and in the relatively early stages of maturation. The findings may be useful to HIV researchers who are conducting or plan to conduct research involving women and their main sex partners.

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