INVOLVING WOMEN IN HIV VACCINE EFFICACY TRIALS: LESSONS LEARNED FROM A VACCINE PREPAREDNESS STUDY IN NEW YORK CITY

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ABSTRACT This paper identifies the recruitment strategies and human immunodeficiency virus (HIV) risk behaviors of at-risk women in an HIV vaccine preparedness study in New York City, assesses how these behaviors changed over time, and draws implications for women's involvement in HIV vaccine efficacy trials. Noninjecting HIV-1 negative women (N = 89) were recruited into an HIV vaccine preparedness study. An observational cohort study design was used. Women were recruited from clinics and community-based organizations (40%), through other study participants (24%), through newspaper advertisements (20%), and through street outreach (16%). Most women who refused (72%) also came from clinics and agencies. Retention after 12 months was 67%; after 18 months, it was 62%. The proportion of women reporting unprotected vaginal sex in the previous 3 months was 85% at baseline and declined to 70% after 12 months ($P < .05$). There have been no seroconversions detected. Recruitment efforts to include at-risk women in HIV vaccine efficacy trials must be diverse and actively involve community agencies. Successfully retaining these cohorts over time and detecting a high enough HIV seroincidence rate present ongoing challenges that will need to be addressed to ensure women's involvement in future trials in the US.

KEY WORDS Efficacy Trials, HIV, Vaccine Preparedness Study, Women.

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INTRODUCTION

It has been almost 20 years since the acquired immunodeficiency syndrome (AIDS) epidemic began, and there continues to be an urgent need for innovative solutions to prevent the spread of human immunodeficiency virus (HIV). As there is still no cure for HIV disease, the most effective way to curb the spread of infection is through primary prevention. One potentially promising tool is a preventive vaccine. The development of an HIV preventive vaccine is particularly critical for women, whose prevention options are limited. Condom use, a mainstay of prevention, requires male cooperation, and those at highest risk for HIV infection face a host of competing issues, such as poverty, substance abuse, and violence.[1] There is currently no vaccine available that will prevent HIV infection. However, Phase I and II studies with preventive vaccine candidates are ongoing.[2] Two Phase III vaccine efficacy trials are also ongoing, involving mostly gay men in the US and injection drug users in Thailand. Both men and women will be needed to participate in Phase III HIV vaccine efficacy trials in the future.[3]

In anticipation of such trials, Project ACHIEVE (AIDS Community Health Initiative En route to a Vaccine Effort) undertook a vaccine preparedness study of women at risk for HIV transmission through sexual contact with men. Project ACHIEVE conducts a variety of HIV prevention research studies for men who have sex with men and women at heterosexual risk and is sponsored by the New York Blood Center (both men's and women's sites) and the New York City Department of Health (women's site).

This paper describes a "first-generation" vaccine preparedness study conducted in 1995 at our women's site in New York City; the study was designed to focus on recruitment of volunteers, retention of the cohort, and HIV seroincidence. Participants were not told that this was a vaccine preparedness study as data regarding their knowledge, attitudes, and beliefs about HIV vaccines and their motivation and willingness to enroll in vaccine trials were not collected. However, this information was collected in a subsequent multisite vaccine preparedness study in which Project ACHIEVE participated, and those results are reported elsewhere.[4] In this paper, we describe the strategies used to recruit and retain women, present the characteristics of the women at baseline, assess risk behaviors over time, and discuss implications for enrolling women in HIV vaccine efficacy trials.

METHODS

PARTICIPANTS

From May to December 1995, women were recruited at a clinic located in a health department building in the South Bronx section of New York City. Recruitment

initially relied on flyers in the building, approaching patients in a public health sexually transmitted disease (STD) clinic, and receiving referrals from community-based organizations. Later, recruitment expanded to include referrals from study participants, outreach by staff, word of mouth through friends, and advertisements in citywide newspapers.

Women were screened for eligibility using a brief screening questionnaire and, if eligible, were invited to enroll. To be eligible, women had to be between 18 and 60 years of age and test HIV antibody negative. Because the study was part of a vaccine preparedness study, behavioral risk criteria were selected to create a cohort that was high risk and thus might be suitable for a vaccine efficacy trial. These criteria included reporting two or more male sexual partners in the previous 3 months, diagnosis with an STD (syphilis, gonorrhea, genital herpes, pelvic inflammatory disease, trichomonas, chancroid, genital warts, or chlamydia) in the past year, ever using crack cocaine or exchanging sex for money or drugs, or currently in a sexual relationship with a high-risk partner. A high-risk partner included a man who was known to be HIV positive or to have AIDS, a man who had sex with other men or injected drugs since 1977, or a man who was known to have had an STD in the past year. Because the study was designed specifically to focus on women at elevated risk for HIV through sexual contact with men, those who reported injection drug use in the previous 3 years were not eligible to enroll.

The study schedule consisted of visits every 3 months over a period of 18 months. Follow-up visits were every 3 months to enhance retention and to minimize the potential bias involved in recalling events in the preceding months, and in the event of a seroconversion, to be able to link, if possible, specific risk behaviors with this event.

Each visit consisted of a structured interview, HIV pretest counseling, risk reduction counseling, and blood sampling for HIV antibody testing. Participants were asked to return in 2 weeks to receive their test results and to have post-test counseling. The HIV pre- and post-test counseling was conducted by counselors trained according to the New York State guidelines. Referrals for social services were given as necessary. Participants were also offered transportation, small gifts such as cosmetics or perfume samples, a modest stipend as reimbursement, and prevention supplies such as male and female condoms and lubricants.

Retention strategies varied. At enrollment, participants were expected to give their name, address, phone number (if available), and if possible, the names, addresses, and phone numbers of two contacts who did not live with them. To remind participants of their appointments, a letter was sent 3 weeks before a

visit was due, and a reminder phone call was made to the participant (or her phone contacts if she did not have a phone) the day before the visit. Missed visits were followed up with phone calls within 24 hours. Women without phones were mailed letters rescheduling their appointments; if that subsequent appointment was missed, visits were made to participants' homes. Home visits served to verify an address, and hand delivering a letter was intended to signal to the participant that her appointment was important enough for us to seek her out. If home visits to participants were unsuccessful, home visits to contacts' homes were also done when possible. In the event that a participant was located in the field, the outreach worker attempted to bring the participant back to the office for her appointment. In the few instances when women were unable to visit the study site (e.g., due to a high-risk pregnancy), visits were conducted at a participant's home.

Structured interviews were used to gather data on demographics and risk behaviors at baseline and to assess how these risk behaviors changed over time. Participants were asked about the types of sexual behavior in which they had engaged, the HIV serostatus of their male partners, and their use of male and female condoms in the previous 3 months. Women were also asked about their drug history, use of alcohol, and history of pregnancy and STDs. At each follow-up visit, questions about the risk behaviors of the women and the risk profile of their partners in the previous 3 months were repeated.

As part of the visit, participants also received HIV counseling. Following standard pretest counseling, client-centered risk reduction counseling was conducted. The aim was to develop an individually tailored risk reduction plan with emphasis on increasing condom use. The correct use of both male and female condoms was demonstrated using anatomical models. At subsequent visits, the plan was revised and modified to reflect the participant's current risk situation. The purpose of this process was to help women identify areas in which they were having difficulty lowering their risk and to equip them with the skills and tools needed to enable them to do so. The overall goal, consistent with what would be the case in an efficacy trial[5], was to assist these at-risk women in remaining HIV antibody negative.

Statistical Analysis

The data were analyzed in several steps. The first step involved examining cross-tabulated data of the cohort at baseline according to demographic characteristics, sexual behavior, and substance use. Comparisons were made between those who

enrolled and those who refused and between those who enrolled, but were subsequently lost to follow-up. Cross tabulations using the chi-square statistic were also used to examine the relationship between how women were recruited and their demographic and risk profile. The characteristics of women who completed the 12-, 15-, and 18-month visits and those who did not were also compared.

The second step in the analysis involved examining changes in behavior over time using the data of those completing the 12-month visit because just under two-thirds of the original cohort remained in the sample on study completion at 18 months. To look at changes over time, we first compared the sexual and condom use behaviors of women at baseline and at 12 months by creating 2×2 tables and using the McNemar test for matched samples. Women who were intending to get pregnant were not included in this analysis, although women with either single or multiple sex partners were. We then looked at behavior change by grouping women according to whether the number of their sexual partners increased, decreased, or remained the same over 12 months, and then we compared the risk behaviors of each of these subgroups of women.

RESULTS

Baseline Characteristics

Of the 205 women who were screened and found to be eligible, 89 (43%) enrolled in the study, and 116 (57%) refused (Table I). Most women who enrolled were either African-American (65%) or Latina (29%). A third of women (34%) reported having an STD in the past year, and slightly more than a third (39%) reported ever smoking crack. A quarter of them (22%) had exchanged sex for drugs, and almost one-fifth of them (18%) reported a partner with an STD in the last year. Refusers differed significantly from those who enrolled only in terms of how they were recruited. Almost three-quarters of women who refused were approached in clinics or referred by community-based organizations (72%) compared to 40% of the women who enrolled. Enrollees were significantly more likely to have been recruited by referrals from study participants or through newspaper advertisements ($P < .001$).

Women differed in several ways according to how they were recruited into the study (Table II). Compared to others, those recruited through other participants were less likely to be high school graduates ($P < .01$), whereas those who were recruited through clinics and community agencies were younger ($P < .05$) and less likely to report crack use ($P < .05$). Women recruited through agencies were also less likely to have completed the 12-month visit compared with those

TABLE 1 Characteristics of Women Enrollers and Refusers, Project ACHIEVE, New York City

	Enrolled		Refused	
Characteristics	n	(%)	n	(%)
Total	89	(43)	116	(57)
Ethnicity				
African American	58	(65)	75	(65)
Latina	26	(29)	33	(28)
White	0	(0)	3	(3)
Other	5	(6)	5	(4)
Recruitment method				
Clinics/community-based organizations	36	(40)	84	(72)
Study participant	21	(24)	11	(10)*
Newspaper advertisements	18	(20)	5	(4)
Street outreach	14	(16)	16	(14)
Risk profile				
Sexually transmitted disease in the last year	30	(34)	50	(43)
Partner had a sexually transmitted disease in the last year	16	(18)	38	(33)†
Ever had sex for money or drugs	20	(22)	20	(17)
Ever injected drugs	4	(4)	12	(10)
Ever smoked crack	34	(39)	34	(29)

*$P < .001$.
†$P < .10$.

recruited elsewhere ($P < .05$). Whether women completed the 15-month and 18-month visits was not associated significantly with how they were recruited into the study, although agencies had a lower follow-up rate.

The retention rate of this cohort on study completion at 18 months was 62%. Those who completed the study did not differ from those who were lost to follow-up except in terms of employment and age. Those who were employed ($P < .05$) and those who were younger ($P < .10$) were significantly less likely to complete the study than others. However, no significant differences in reported risk behaviors were found between those who completed the study and those who did not. When the study was completed, no HIV seroconversions had been detected based on 122 person-years observed (95% confidence interval 0–3.13%). The probability of observing zero seroconversions when the true conversion rate is 0.015 is .16.

After a year of follow-up, 60 of the 89 women enrolled at baseline completed their 12-month visit, resulting in a retention rate of 67%. Women who failed to remain in the cohort after 1 year were younger ($P < .05$) and more likely to be

TABLE II Characteristics of the Women by Recruitment Source, Baseline Visit, Project ACHIEVE, New York City (N = 89)

	Advertising (N = 18)		Clinics/ Agencies (N = 36)		Participant (N = 21)		Outreach (N = 14)	
Characteristics	n	(%)	n	(%)	n	(%)	n	(%)
Age (years)								
18–24	6	(33)	14	(39)	5	(24)	2	(14)
25–34	4	(22)	16	(44)	4	(19)	3	(21)
>34	8	(44)	6	(17)	12	(57)	9	(64)*
Ethnicity								
African-American	12	(67)	22	(61)	14	(67)	9	(64)
Latina	5	(28)	12	(33)	7	(33)	4	(29)
Other	1	(6)	2	(6)	0	(0)	1	(7)
Education								
Less than high school	4	(22)	19	(53)	16	(76)	6	(43)
High school graduate	14	(78)	17	(47)	5	(24)	8	(57)†
Income								
Less than $10,000	12	(67)	29	(81)	19	(90)	10	(71)
$10,000–$19,999	4	(22)	3	(8)	2	(10)	2	(14)
$20,000 and more	2	(11)	4	(11)	0	(0)	2	(14)
Employed	8	(44)	13	(36)	5	(24)	2	(14)
Sexual partners in the last 3 months								
High risk partner‡								
Yes	3	(17)	1	(3)	3	(14)	2	(14)
No	9	(50)	22	(61)	6	(29)	5	(36)
Don't know	6	(33)	13	(36)	12	(57)	7	(50)
Paying partner	3	(17)	1	(3)	1	(5)	2	(14)
Sexual behavior in the last 3 months								
Unprotected vaginal sex	14	(78)	31	(86)	19	(90)	11	(79)
Unprotected oral sex	9	(50)	19	(53)	7	(33)	4	(29)
Anal sex	3	(17)	6	(17)	3	(14)	4	(29)
Unprotected anal sex	1	(6)	4	(11)	3	(14)	1	(7)
Drug use in the last 3 months								
Crack	8	(44)	8	(22)	8	(38)	9	(64)*
Cocaine	9	(50)	14	(39)	9	(43)	9	(64)
Heroin	4	(22)	1	(3)	4	(19)	4	(29)
Marijuana	10	(56)	20	(56)	15	(71)	11	(79)
Retention								
Completed the 12-month visit	13	(72)	18	(50)	18	(86)	11	(79)*
Completed the 15-month visit	12	(67)	17	(47)	16	(76)	10	(71)
Completed the 18-month visit	12	(72)	17	(47)	14	(67)	11	(79)

*$P < .05$.

†$P < .01$.

‡A high-risk partner included a man who was known to be HIV positive or have AIDS, had sex with other men, or injected drugs in the last 3 months.

employed ($P < .10$) compared to those who completed 12 months of follow-up. Baseline risk behaviors did not differ significantly between those who completed 1 year of follow-up and those who were lost.

Changes Over Time

Significant changes in sexual risk behaviors over time were observed (Table III). Although 85% of women reported unprotected vaginal sex when they enrolled, 12 months later this percentage dropped to 70% ($P < .05$). For unprotected oral sex, this proportion was reduced from 45% at baseline to 26% after 12 months of follow-up ($P < .05$). Sexually transmitted diseases in the last 3 months appeared to decline over time as well, from 25% reported at baseline to 11% reported after 12 months. Changes in the frequency of condom use over 12 months were

TABLE III Changes Over Time: At Baseline and at the 12-Month Follow-up Visit, Project ACHIEVE, New York City* (N = 53)†

	Baseline		12-Month visit	
	n	(%)	n	(%)
Sexual behavior in the past 3 months				
Vaginal sex	50	(94)	49	(92)
Unprotected vaginal sex	45	(85)	37	(70)‡
Unprotected oral sex	24	(45)	14	(26)‡
Anal sex	8	(15)	5	(9)
Unprotected anal sex	5	(9)	3	(6)
Sexually transmitted disease	13	(25)	6	(11)§
Condom use in the past 3 months				
Male condoms				
Always	6	(11)	14	(26)
Sometimes	21	(40)	18	(34)
Never	23	(43)	16	(30)
Female condoms				
Always	0	(0)	1	(2)
Sometimes	4	(7)	8	(15)
Never	46	(87)	39	(74)
No partners in the past 3 months	3	(6)	5	(9)

*No significant differences in demographic or risk behaviors except age and employment were found between those who completed the 12-month visit and those who were lost to follow-up.

†Excludes 7 women who were droppped from the analysis because they were trying to get pregnant.

‡$P < .05$.

§$P < .10$.

observed as well. At baseline, only 11% of women reported always using male condoms compared to 26% after 12 months, and almost a third of women (30%) continued to report never using condoms after a year of study participation.

The analysis that examined changes in the number of partners a woman reported revealed that half of women (52%) reported a single partner at baseline and after 12 months, 27% reported a decrease in the number of partners over 12 months, and 21% reported an increase in number of partners over 12 months (data not shown). Of the women who reported a single partner at both visits, it is not clear whether the partner was the same at baseline and 12 months later. However, 59% of these women reported at baseline that they never used a condom. A third of women who decreased their number of partners (33%) and 42% of those who increased their number of partners over 12 months also reported never using condoms at baseline.

DISCUSSION

This study of at-risk women in New York City highlights some of the challenges that lie ahead if women are to participate successfully in HIV vaccine efficacy trials. Conducting successful Phase III trials of preventive HIV vaccine candidates that will yield the data necessary to answer questions about vaccine efficacy requires at minimum three key components. First, recruiting sufficient numbers of high-risk individuals who are willing to participate is needed.[6] Second, the successful retention of study cohorts over the course of the trial is essential.[7] Third, a high enough HIV seroincidence rate in the study population is also required to maximize the ability to detect an effect between the vaccine and placebo groups while keeping the overall sample size feasible.[8] Although vaccine preparedness studies by their very nature are not able to present all the issues that trial participants may confront, such as randomization, blinding, possible social harms, and vaccine-induced HIV seropositivity, they do provide essential information about HIV seroincidence, and they shed light on the recruitment and retention process.

Findings from this vaccine preparedness study suggest that the recruitment of women into HIV vaccine trials will need to employ a number of diverse strategies. Study participants, outreach efforts, and newspaper advertisements were each found to be important recruitment sources, and none appeared to compromise the risk profile of this cohort. However, more than half of the women who were eligible did not choose to enroll, resulting in a small sample size; this might be a cause for concern. Because this study offered HIV testing, it may be that these women, like many others at elevated risk, do not realize their risk or

seek information until there is an issue or confrontation that compels them to be tested.[9]

Most of the participants who enrolled in this cohort came from clinics and community-based organizations; yet, women at these sites were also more likely to refuse participation and to withdraw from the study once enrolled. Recruitment strategies that appeared to be successful in bringing in high-risk women included street outreach and newspaper advertisements. Given the sample size and the number of multiple comparisons examined by recruitment source, the low number (four) of significant results detected suggests that these results reflect true differences in women across recruitment sites and are less likely to be due to chance. Given this, the high rate of nonparticipation among women from the less successful recruitment sites points to the need to increase the awareness of HIV prevention research, particularly the importance of vaccine trials, at the community level. This will require the assistance of community agencies in preparing for large-scale vaccine trials. By encouraging and incorporating community input into the way trials are implemented, the participation of women and men in HIV prevention research efforts can be supported and enhanced.[10] Involving community-based organizations in this process can also help researchers to understand and overcome community-defined perceptions of the risks and benefits of study participation that result from the unique historical experiences particular groups have with scientific research.[11]

A vaccine preparedness study of participants recruited from eight cities across the US found that a large proportion of the women at high risk of HIV infection expressed a willingness to enroll in future HIV vaccine efficacy trials.[4] This is encouraging, although we do not know the proportion of those who would choose to enroll in an actual trial if given the chance.[6] Recruiting study volunteers from communities that actively support HIV vaccine trials will form an integral part of the pipeline needed to ensure that, among those who are willing, some (perhaps many) actually will choose to enroll.

Once enrolled, the retention of cohorts over time is critical in any longitudinal study, and this proved to be a limitation of this study. After a year, one-third of the original sample was lost to follow-up despite our efforts. Unfortunately, at the outset, many who enrolled were reluctant to give us the name and address of two contacts, which left us with less-than-adequate locator information when a participant moved. However, this type of retention rate is not unlike that of other studies with similar populations,[12] and those lost to follow-up did not differ with respect to baseline risk behaviors from those who enrolled.

Nevertheless, retention rates of women in HIV vaccine efficacy trials will have

to be considerably higher than those found here. Strategies that enhance retention include collecting extensive locator information at baseline, frequent contacts with study participants, incentives, an effective tracking system, and the active involvement of community advisory boards.[7] We have since utilized many of these strategies, and a cohort of 164 women subsequently recruited at our site in 1998 had a follow-up rate of 92% after 12 months, largely due to more extensive outreach efforts. In clinical trials for HIV treatment, successfully recruiting and retaining African-Americans who live in poverty-stricken urban areas has also required a multilevel support system, which included attractive and accessible recruitment materials, adequate numbers of outreach staff, transportation, child care assistance, and support groups.[13] Such ancillary services are recommended highly if the recruitment and retention of high-risk women in HIV vaccine efficacy trials is to be taken seriously. The need for this additional support is clear. Extreme poverty is evident in this cohort, in which most of the women reported an annual income of less than $10,000. Furthermore, women who enrolled in a larger, national vaccine preparedness study that included this site presented with a number of issues, including substance abuse, inadequate housing, and domestic violence, that threatened to interfere with their ability to keep subsequent appointments.[14] At a minimum, case management services and local referral systems will need to be in place to support the long-term involvement of women who participate in HIV vaccine efficacy trials. Modifications to the protocol,[11] such as building in more study visits to maintain sufficient participant contact, may also be needed to retain women in such studies successfully.

Just as important as recruitment and retention is the HIV seroincidence rate of the study population. A minimum seroincidence rate of 1% to 3% is required to conduct modest size HIV vaccine efficacy trials ($N < 10,000$) that will yield significant results within a few years.[15] Smaller incidence rates can be tolerated if larger trials are conducted, but of course, this has major cost implications. In this cohort, after 18 months of follow-up, no seroconversions were detected. Given that our initial sample size was small ($N = 89$), it is possible that we did not recruit a sample large enough to measure seroincidence over the study period of 18 months. It is also possible that any seroconversions that occurred were among women who were lost to follow-up. However, since the probability of observing no seroconversions is only 16% when the true incidence may be 1.5%, the most plausible explanation is that we did not recruit a population that was at high enough risk of HIV infection. In the future, we would need to use stricter eligibility criteria than we did here. Adjusting the eligibility criteria can yield a higher HIV seroincidence rate, as observed elsewhere.[16]

Not detecting any seroconversions over the study period should not minimize the HIV risk status of this cohort, however. Though women were involved in regular risk reduction counseling sessions and their reported sexual risk behaviors did decrease over time, almost three-quarters reported unprotected vaginal sex after 12 months. Furthermore, although half of the women in this cohort reported a single partner at baseline and after 12 months, most of these women reported never using a condom. By reporting unprotected sex with a man in a metropolitan area with high HIV seroprevalence, these women are by definition at risk for HIV infection.[17] Their at-risk status underscores the need for a wide range of HIV prevention strategies, in addition to an HIV vaccine, that women can use.[18]

This vaccine preparedness study points out some of the key issues that need to be considered in the participation of high-risk women in HIV vaccine efficacy trials in the US. Enrolling women in such trials will not be without some major challenges. The first HIV vaccine efficacy trial to be conducted in the US began in June 1998, and while it focuses on men who have sex with men, a small proportion of women at risk through sex with men have also been enrolled.[19] It is anticipated that this will be the first of a number of HIV vaccine efficacy trials to be conducted in this country. The successful and broader participation of women in future trials in the US will hinge on available data regarding their HIV seroincidence and on the provision of resources and support needed to ensure adequate recruitment and retention rates.

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