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Do STD Clinic Patients Who Consent to Sexual Health Research Differ from Those Who Decline? Findings from a Randomized Controlled Trial with Implications for the Generalization of Research Results

Michael P. Carey, Ph.D.[a], **Theresa E. Senn, Ph.D.**[a], **Peter A. Vanable, Ph.D.**[a], **Patricia Coury-Doniger, FNPC**[b], and **Marguerite A. Urban, M.D.**[b]

a *Center for Health and Behavior, Syracuse University*

b *School of Medicine and Dentistry, University of Rochester*

Abstract

Objectives—This study determined whether patients from an STD clinic who agreed to participate in behavioral research are representative of the overall patient population.

Study Design—Patients attending an STD clinic (*N* = 2694) were invited to participate in sexual risk-reduction research. Those who accepted (Consenters) were compared to those who declined (Non-Consenters) on data obtained from the medical chart.

Results—Overall, 58% of eligible patients consented to participation. Logistic regression analyses indicated that consenting to participate was associated with female sex (OR = 1.86), non-Caucasian race (OR = 2.16), having completed at least some college (OR = 1.70), being a returning patient (OR = 1.21), and having a greater number of sexual partners in the past 3 months (OR = 6.95) (all *p*s < .05).

Conclusions—Patients who agreed to participate had more education, were more familiar with the setting, and were more vulnerable to HIV/STD (as suggested by epidemiologic research). Efforts to enhance participation by an even greater percentage of patients might target these predictors of participation by enhancing risk awareness, and providing pre-emptive reassurances regarding the research process and setting.

Keywords

sexually transmitted disease; HIV; public health; randomized controlled trial; sexual behavior

Behavioral interventions are effective in reducing sexual risk behaviors that lead to STDs and HIV.[1-3] However, studies documenting intervention effectiveness rely upon individuals who volunteer to participate in the research. How representative are the individuals who agree to participate in behavioral research? Do they differ from individuals who decline? Answers to these questions will determine whether the results of behavioral intervention studies generalize to all STD clinic patients.

Rates of participation vary across research studies. In a meta-analysis of sexual risk reduction interventions conducted with patients attending STD clinics, participation rates ranged from 24% to 97%.[3] Studies with lower participation rates are at greater risk of their results being

Michael P. Carey, Ph.D. Center for Health and Behavior 430 Huntington Hall Syracuse University Syracuse, New York USA 13244 −2340 Telephone: (315) 443−2755 Fax: (315) 443−4123 Email: mpcarey@syr.edu.

affected by a non-participation bias. Despite the implications for external validity, comparisons between non-participants and participants are seldom reported, perhaps due to the difficulty of obtaining data from those who decline participation.

A small number of randomized controlled trials (RCTs) conducted with patients attending STD clinics have compared participants and non-participants on demographic characteristics. Generally, patients are more likely to participate if they are women,[4-6] African-American,[5, 7] unemployed,[7] and younger.[8] Comparison of consenters with non-consenters on sexual risk behavior are even rarer, with inconsistent findings. For example, Kamb et al.[4] found participants were more likely to have an STD at enrollment whereas Boyer et al.[5] found that participants were less likely than non-participants to report a previously diagnosed STD; Kalichman et al.[7] found no difference between participants and non-participants in the percentage who had previously been treated at the STD clinic. Reconciling these mixed results is made more difficult because few researchers have reported detailed, multivariate analyses that control for multiple predictors.

The purpose of this study was to determine whether consenters and non-consenters differed on demographic or sexual behavior variables. Our goal was to clarify prior inconsistent findings about the association between study participation and sexual risk behavior by using multivariate analyses that control for demographic differences between these groups.

Methods

This research was conducted at a publicly funded clinic in upstate New York. All procedures were approved the Institutional Review Boards of the participating institutions. Patients who were age 18 or older, not known to be HIV positive, and had not attended the clinic in the past 3 months met with a trained Research Assistant (RA) a private room. The RA asked patients if they would be willing to answer a few questions because they might be eligible for a research study. After asking the screening questions and determining eligibility, the RA explained the study to eligible patients.

Clients were told that participation would involve three sets of activities on that day: (1) a 45-minute baseline survey that assessed health-related behaviors; (2) a clinic visit, including an intake, a physical exam, a rapid HIV test, behavioral counseling and, if indicated, medical treatment; and (3) a 10-minute exit survey. In addition, some patients would be asked to attend (4) a 4-hour educational workshop within two weeks. All participants would also be asked to (5) return to the clinic three times over the next year to complete follow-up surveys and provide a urine sample for STD testing. If they agreed to participate, they would be paid $20 for completing the initial survey, $40 for attending the workshop, and $30 for each follow-up survey they completed. Informed consent was obtained from those who agreed to participate (Consenters). Eligible patients who declined (Non-Consenters) were asked why they chose not to participate, and then thanked for their time. The clinic identification numbers were recorded by the RA.

Data for the current analyses were obtained through clinic records. Demographic data included gender, race, ethnicity (Hispanic vs. non-Hispanic), education (some college vs. high school or less), age, and patient status (new vs. returning clinic patient); sexual risk behavior data included the number of sexual partners in the past 3 months.

To determine the variables on which Consenters and Non-Consenters differed, we conducted initial analyses of variance (ANOVA) for continuous data and Chi-square analyses for categorical data. Variables that were significant in the univariate analyses were included as predictors of consent in a multivariate logistic regression. Outliers were trimmed for the number of partners reported in the past 3 months [values that were more than 3 times the interquartile

range (IQR) from the 75th percentile were trimmed to 3 times the IQR from the 75th percentile + 1.[9] In addition, the number of partners in the past 3 months was transformed using a $\log_{10}(x + 1)$ transformation.

Results

Out of 5768 patients approached, 5614 (97%) agreed to answer the screening questions, and 2694 (48%) were eligible for participation. Out of those eligible, 1562 (58%) consented, and 1132 (42%) declined study participation. Complete clinic data were unavailable for 187 patients, leaving a final sample of $n = 1535$ Consenters, and $n = 972$ Non-Consenters.[1]

Overall, the sample was 59% male ($n = 1469$), 63% African-American ($n = 1569$), and 29% Caucasian ($n = 735$). Patients were, on average, 29.3 years old ($SD = 9.7$ years), and 64% had a high school education or less ($n = 1605$).

The most common reason for declining to participate was a lack of time, reported by 83% of decliners (see Table 1). Other common reasons for declining participation included: child care issues (e.g., had to pick up or be home for a child, or did not want child to wait while completing survey), just wanted to see the nurse or receive treatment, not interested, would not commit to returning for follow-up surveys, psychological reasons (e.g., anxious, preoccupied), would not commit to attending workshop, physical reasons (e.g., feeling ill, tired), concerns about privacy, and did not want to do a survey.

In univariate analyses, consenters were more likely to be female, χ^2 ($N = 2507$) = 36.35, $p < .001$, non-Caucasian race, χ^2 ($N = 2507$) = 54.56, $p < .001$, and have completed at least some college, χ^2 ($N = 2507$) = 7.81, $p < .01$ (see Table 2). Consenters also were more likely to be a returning patient, χ^2 ($N = 2507$) = 15.77, $p < .001$. Consenters reported a greater number of sexual partners in the past 3 months than did Non-Consenters, F (1, 2505) = 41.88, $p < .001$. Ethnicity and age were not related to consent.

Sex, race, education, patient status, and number of partners in the past 3 months were entered simultaneously into a logistic regression. All variables in the logistic regression remained associated with consent status (see Table 3), indicating that female sex (OR = 1.86), non-Caucasian race (OR = 2.16), having completed at least some college (OR = 1.70), being a returning patient (OR = 1.21), and having a greater number of sexual partners in the past 3 months (OR = 6.95) all independently predicted a greater likelihood of consenting to participate in the research.

Discussion

Using a large sample, we found that 58% of the eligible patients attending an STD clinic agreed to participate in a RCT designed to evaluate a risk reduction intervention. This participation rate is similar to the rate obtained by Branson et al.[6] who recruited 996 of 1681 eligible patients (59%) from a STD clinic in Houston. The rate observed in our study compares favorably to rates reported in a number of major RCTs, which have ranged from 33% to 44% in similar clinic settings.[4, 5, 10]

The relatively successful recruitment rate was achieved even though participation was burdensome. Patients who consented to participate were agreeing to disclose sensitive information during a detailed and lengthy baseline assessment, attend a 4-hour workshop, and

[1]Data were unavailable for some patients because: (a) the clinic identification number was recorded incorrectly; (b) the patient left before being seen in the clinic that day; (c) it was later determined that the patient had been seen previously at the clinic under a different name, and the clinic identification number was changed to the original number; or (d) complete data were not available in the clinic database.

return to the clinic three times over the next year, to complete additional follow-up assessments, and provide urine samples for laboratory testing.[2] We believe that this level of participation is noteworthy, given the unexpected nature of the invitation, the immediate demand on the day of their clinic visit, and the socially sensitive and potentially embarrassing nature of the research. The successful recruitment of African-American patients was encouraging, especially given the legacy of the Tuskegee Study and the resultant distrust of governmental and health care institutions.[11]

An important factor in the recruitment rate we observed is the use of financial incentives for participation. We have previously reported the results of a pilot study during which we compared attendance rates at a sexual risk reduction workshop with, and without, financial incentives.[12] In that pilot, we observed much higher attendance rates when an incentive was provided, consistent with several other studies that have reported this effect.[13-15] We believe that participation rates in the current study benefited from a number of other strategies that we used. For example, we employed a friendly and culturally competent staff; obtained a Federal Certificate of Confidentiality for the study (to help allay confidentiality or privacy concerns); provided assistance with child care and transportation; and conducted the research in an accessible, community-based STD clinic that enjoyed a long history of serving the local community.

The most common barrier to participation was time, a finding that has been observed previously.[10] We tried to minimize this barrier by using strategies that would keep the overall clinic visit as brief as possible (e.g., starting to recruit before the clinic officially opened, approaching patients when we knew that they would have to wait due to clinic volume). Many of the patients who declined participation asked if they could come back later to complete the baseline survey; however, our study design required that patients complete the baseline survey before they received counseling in the clinic visit that day. When planning future studies, investigators should attempt to design studies that do not extend the normal visit length, which should have the effect of increasing participation rates.

We examined patient characteristics that were associated with participation, and were especially interested to determine if sexual risk was associated with participation after controlling for known demographic correlates. In this regard, we found that ‘repeat’ patients as well as female and African-American patients, and those who had attended at least some college were more likely to participate. After controlling for these demographic characteristics, study participation remained associated with having a greater number of recent sexual partners. These findings, strengthened by the use of multivariate analyses that controlled for known correlates, corroborate results obtained previously.[4-7]

We hypothesize that female and African-American patients may be more likely to agree to participate because they recognize their enhanced vulnerability to STDs, particularly HIV. For example, women are more vulnerable to STDs due to biological (e.g., a larger genital mucousal surface[16]) as well as relationship (e.g., less power relative to men[17]) factors. African-Americans are disproportionately vulnerable to HIV and other STDs due to a variety of contextual factors (e.g., disassortative mixing by risk status, relatively low ratio of African-American men to women).[18-20] For both women and African-Americans, recognition of their greater vulnerability to STDs may increase participation because these patients see the value of sexual health promotion and risk reduction programs. Relative to men, women are probably also be more likely to participate because they tend to be more comfortable in groups, accept counseling at higher rates, and are generally more health-conscious.[21, 22] If this explanation

[2]Although not the focus of this report, return rates for the follow-up assessments exceeded 70% for the 3-, 6-, and 12-month return assessments.

is correct, then efforts to enhance participation by an even greater percentage of patients might involve strategies to enhance risk awareness, such as motivational interviewing or other personalized feedback approaches.[23]

Finding that education was associated with participation has precedent. For example, among men who have sex with men (MSM), research has found that those men who have more education are more likely to participate in sexual health research.[24, 25] Perhaps individuals with more education, particularly those who have attended some college, are more familiar with the importance of and benefits associated with research; with this knowledge, they are more willing to participate. An implication of this finding is that participation might be enhanced by providing pre-emptive reassurance regarding the research process to reluctant participants. Anecdotally, we have found that research assistants who excel at developing an easy rapport often allay the concerns of prospective participants.

In addition, patients in the present study who had been previously seen at the clinic were more likely to agree to participate. These patients may have been more comfortable with (and more trusting of) the clinic and its staff, and therefore more likely to agree to participate in research associated with the clinic. They may also place more value on the services that the clinic provides, and thus be more willing to participate in a project designed to improve services offered at the clinic. Patients who had been to the clinic before may also have been more comfortable returning to the clinic for workshops and follow-ups, and not viewed their visit at the clinic as an isolated experience. As noted earlier with regard to the educational status of patients, we believe that participation might be enhanced by providing pre-emptive reassurance regarding the research staff and setting. Previous research with other populations suggests that interpersonal trust is important to recruitment of research participants.[26]

Perhaps the most important finding was that sexual risk behavior was related to research participation. Those who agreed to participate in the study reported more sexual partners in the past 3 months than those who did not agree to participate. These results replicate the findings of Vanable et al.[27] who concluded that individuals who participate in sexual behavior research tend to engage in more frequent sexual activity. It is reassuring that sexual risk reduction intervention research is reaching those who are most at-risk of contracting an STD.

These results should be interpreted mindful of the limitations of this study. First, the demographic composition of patients at our setting may not reflect patients seeking care at other settings. Thus, as with any primary-level investigation, this research needs to be replicated in other settings with a wider range of patients to determine the generalizability of the results obtained. Second, participation rates observed in this (or any) research project should not be assumed to generalize to a non-research (e.g., clinical or community) context. It is possible that the additional resources associated with a RCT (e.g., staffing, incentives) as well as the additional burdens of participation (e.g., completing surveys, returning for follow-up visits) may facilitate or impair attendance at risk reduction programs. Nonetheless, research can help to identify patient characteristics and recruitment strategies that might lead to improved participation rates. Indeed, because the magnitude of the participation observed in most RCTs leaves ample room for improvement, we expect that continued research will identify improved recruitment strategies that can lead to enhanced participation rates.

Overall, though, the results of our research reveal that a majority of patients will agree to participate in research, even a demanding project such as ours, if the invitation is presented in a culturally-sensitive and respectful way, with appropriate incentives, and supportive services (e.g., child care). Because the primary reason for declining among our patients was time, efforts to make research participation less burdensome may help to increase participation even further.

Recruiting a representative sample of participants enhances the likelihood that findings obtained will generalize the larger population of STD clinic patients.

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Table 1

Most Common Reasons for Study Declination

Reasons for Study Declination	% of Non-Consenters		
	All	Female	Male
Not enough time to participate	83%	87%	80%
Child care issues	7%	15%	3%
Just wanted treatment or to see the nurse	5%	5%	6%
Not interested	5%	4%	5%
Not willing to return for follow-up assessments	3%	1%	5%
Psychological reasons (anxious, preoccupied)	2%	2%	3%
Not willing to attend the workshop	2%	1%	3%
Physical reasons (ill, tired)	1%	1%	1%
Concerned about confidentiality or privacy	1%	<1%	1%
Not willing to do the (baseline) survey	1%	<1%	1%

Note. Some patients reported more than one reason for non-participation; thus, percentages sum to greater than 100%.

Table 2

Demographic, Patient, and Sexual Risk Behavior Characteristics of Consenters vs. Non-Consenters—Univariate Analyses

	Consenters (*n* = 1535)		Non-Consenters (*n* = 972)			
	n	**%**	***n***	**%**	χ^2	***p***
Sex					36.35	< .001
Female	708	68%	330	32%		
Male	827	56%	642	44%		
Race					54.56	< 0.001
Non-Caucasian	1167	66%	605	34%		
Caucasian	368	50%	367	50%		
Ethnicity					0.77	ns
Hispanic	132	64%	74	36%		
Non-Hispanic	1403	61%	898	39%		
Education					7.81	< .01
Some college	585	65%	317	35%		
High school or less	950	59%	655	41%		
Patient Status					15.77	< .001
Returning	1022	64%	571	36%		
New	513	56%	401	44%		
	M	*SD*	*M*	*SD*	*F*	*p*
Age (years)	29.2	9.6	29.4	9.7	0.40	ns
Number of sexual partners, 3 months	2.5	2.0	2.0	1.4	41.88	< .001

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Table 3

Demographic, Patient, and Sexual Risk Behavior Characteristics of Consenters vs. Non-Consenters—Logistic Regression Analyses

	Log-likelihood	Odds Ratio	Confidence Interval	*p*
Full Model	−1583.12			< .001
Sex (female)		1.86	1.56−2.22	< .001
Race (Non-Caucasian)		2.16	1.77−2.62	< .001
Education (at least some college)		1.70	1.41−2.06	< .001
Patient status (returning patient)		1.21	1.01−1.45	< .05
Number of sexual partners, 3 months		6.95	4.17−11.58	< .001