



SAFER SEX STRATEGIES FOR WOMEN: THE HIERARCHICAL MODEL IN METHADONE TREATMENT CLINICS

ZENA STEIN, MA, MB, BCh, HELGA SAEZ, MD,
WAFAA EL-SADR, MD, MPH, CHERYL HEALTON, DRPH,
SHARON MANNHEIMER, MD, PETER MESSERI, PHD,
MICHAEL M. SCIMECA, MD, NANCY VAN DEVANter, DRPH,
REGINA ZIMMERMAN, MPH, AND PRABHA BETNE, PHD

ABSTRACT Women clients of a methadone maintenance treatment clinic were targeted for an intervention aimed to reduce unsafe sex. The hierarchical model was the basis of the single intervention session, tested among 63 volunteers. This model requires the educator to discuss and demonstrate a full range of barriers that women might use for protection, ranking these in the order of their known efficacy. The model stresses that no one should go without protection. Two objections, both untested, have been voiced against the model. One is that, because of its complexity, women will have difficulty comprehending the message. The second is that, by demonstrating alternative strategies to the male condom, the educator is offering women a way out from persisting with the male condom, so that instead they will use an easier, but less effective, method of protection. The present research aimed at testing both objections in a high-risk and disadvantaged group of women. By comparing before and after performance on a knowledge test, it was established that, at least among these women, the complex message was well understood. By comparing baseline and follow-up reports of barriers used by sexually active women before and after intervention, a reduction in reports of unsafe sexual encounters was demonstrated. The reduction could be attributed directly to adoption of the female condom. Although some women who had used male condoms previously adopted the female condom, most of

Dr. Stein is Professor of Public Health and Psychiatry, Emerita, Columbia University; Dr. Heulton is Associate Professor of Clinical Public Health and Associate Dean; Dr. Messeri is Associate Clinical Professor; Dr. VanDevanter is Assistant Professor; and Ms. Zimmerman is Research Scientist, Joseph L. Mailman School of Public Health of Columbia University. Dr. Saez and Dr. Betne are Research Scientists, HIV Center for Clinical and Behavioral Studies, New York State Psychiatric Institute. Dr. El-Sadr is Clinical Professor and Dr. Mannheimer is Assistant Professor of Clinical Medicine, Department of Medicine, Columbia University, Harlem Hospital Center. Dr. Scimeca is Director, Department of Addiction Medicine, St. Barnabas Hospital, Bronx, NY.

Correspondence: Zena Stein, MA, MB, BCh, Professor of Public Health, Emerita, Division of Epidemiology, Joseph L. Mailman School of Public Health of Columbia University, 600 West 168th Street, Room PH19-112, New York, NY 10032. (E-mail: zas2@columbia.edu)

those who did so had not used the male condom previously. Since neither theoretical objection to the hierarchical model is sustained in this population, fresh weight is given to emphasizing choice of barriers, especially to women who are at high risk and relatively disempowered. As experience with the female condom grows and its unfamiliarity decreases, it would seem appropriate to encourage women who do not succeed with the male condom to try to use the female condom, over which they have more control.

INTRODUCTION

In endeavoring to provide safer sex strategies for women at presumed high risk for contracting or transmitting human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) and other sexually transmitted infections (STIs), the New York State Department of Health AIDS Institute proposed the use of the hierarchical model.^{1,2} The model accepted that, although the male condom was the device deemed most effective against transmission, many women could not negotiate with their male partners to use it. Rather than leave them without any form of protection, designers of the model recommended that a range of methods should be discussed with women, although the instructor must rank the methods in terms of their presumed efficacy: first, the male condom; second, the female condom; third, a device to cover the cervix (originally, only the diaphragm was mentioned, but in a recent application of the model, the cervical cap was also included); finally, a spermicide, non-oxynol 9. At the end, the instructor was to state emphatically: *never go without protection*. The AIDS Institute created a video to communicate the message, and this model is under testing currently in several settings.³

Since this policy was formulated (in 1992), several arguments for and against its use have been raised. On the positive side, since 1993 this policy has allowed a far more widespread recognition of the need to find efficacious and effective alternatives to the stark message: Be abstinent, use a male condom, or walk away.³⁻⁷ Experience also has demonstrated that the female condom probably will provide as much protection as the male condom (certainly for pregnancy),⁸ and there are occasions when it will be accepted when the male condom will not.⁹ Even more important, the approach of providing women with a choice of both types of condoms (i.e., encouraging rather than discouraging choice) may decrease the number of unsafe encounters.¹⁰ Finally, although the test of the efficacy of non-oxynol 9 against infection with HIV has not survived a major trial, evidence exists that, in appropriate doses, it will provide protection against at least some STIs.⁴

Nevertheless, objections are still raised against the hierarchical model by some health professionals. These objections tend to take two forms. One is based on

an apparently firmly held principle that a single simple message (e.g., "Just say no") is understood better than a more complex one. The second is more of an assumption: If women are offered options other than the male condom, they will be tempted to use one of these other (and probably less effective) options; hence, the overall degree of protection in the population will be less as women resort to the less-safe choices. However, there is little evidence to support either of these objections, and if they are valid, it is likely that they would apply to limited circumstances or populations.

We designed a study to evaluate the hierarchical model in a population of women at risk of HIV/AIDS; subjects were seen in a service setting in which we could ensure a reasonable, if brief, follow-up. The goals of the study were to address the two types of concerns raised above: Is the hierarchical message too complex to be comprehended by women at high risk of infection? Does introduction of options lead women to transfer from their reported use of the male condom (the presumed safest message) to other, less-safe procedures?

To answer the first question, a knowledge test was administered before and after the intervention. To answer the second question, reports of sexual behavior at baseline were compared with reports at follow-up.

The study, to be based on volunteers, was approved by the institutional review boards of Columbia University and Harlem Hospital. The consent form is available on request.

METHODS

STUDY LOCATION: RECRUITMENT

The study was conducted in a single methadone treatment clinic in central Harlem, New York. Invitations to volunteers were posted at the entrance and waiting room of the clinic, and refreshments were advertised as an incentive. All interviews and interventions took place in the basement of the clinic simultaneously with routine treatment sessions. The investigators did not approach clients personally in the waiting room or examination areas, but individual clinic staff actively directed women to the research room. Interested women then volunteered and gave informed consent first to the interview, then to the intervention.

INTERVIEW

The interview included information covering demographic variables, reproductive experiences, knowledge of sexual risk, and individual sexual practices. The

baseline interview also elicited responses to a systematic set of questions on high-risk behavior and use of protective devices or methods. (Questions are available for inspection on request.)

At the initial interview, clients were invited to participate in the intervention, which would also be given during clinic hours in the same location. Participants in the intervention, which took place either at initial enrollment or some days later, were asked the same questions on knowledge of safer sex and protection that had been asked initially, as well as questions on sexual behavior and on clients' understanding of the hierarchy.

Follow-up was conducted at approximately 2 and 4 weeks after the intervention. At each follow-up visit, women were questioned again on their sexual encounters and on their use of protective methods.

At each visit, women described the frequency of their sexual encounters, past and recent. Frequency was coded in three mutually exclusive categories as "rare" (no encounters in the previous 3 months), "occasional" (at least one encounter in the prior 3 months, but none in the last 2 weeks), or "active" (at least one encounter in the prior 2 weeks).

INTERVENTION

The intervention (modeled on that created by Gollub and associates for use in a public clinic for women with sexually transmitted infections)³ included a brief description, which included illustrations, of anatomy and physiology of the reproductive systems in women and men and a demonstration of the methods presently available for women to reduce their risk of infection during sexual encounters. We followed the hierarchical model strictly, beginning with an emphasis on the male condom, moving on to the female condom, followed by the diaphragm and cervical cap, and last the spermicide (non-oxynol 9, the bioadhesive gel known as Advantage 24), illustrating the use of each method with models.

A special video created by the AIDS Institute to reinforce the message was also used; this ends emphatically, as did our intervention, with the same message: use the safest method you are able to use, but *don't go without protection*.

The intervention groups numbered two to six women on each occasion. The duration of the session was usually 45 minutes. There were three instructors, all professionals in public health; two were physicians. In the opening days of the study, one instructor conducted the intervention, while one of the others observed to achieve uniformity across instructors. However, because the sessions were essentially informal and interactive, punctuated by discussion and refreshments, they were not standardized strictly.

At the end of the session, women were provided with male and female condoms and spermicide according to their estimated needs.

STATISTICAL METHODS

From the 63 participants either remaining or returning for the single small-group intervention, the effect of the intervention on knowledge of sexual risk was assessed. The percentage correct responses of the participants on individual items was compared before and after the intervention and tested for significance by the McNemar Test. The mean percentage of correct responses among grouped items also was examined before and after intervention.

Reported changes, if any, in sexual behavior and in protective practices were elicited from each woman individually after each session. Among reported encounters, the percentage unprotected was compared for those sexually active at baseline, for those sexually active at the first 2-week follow-up, and for those sexually active at the second follow-up.

RESULTS

There were 91 women who volunteered to join the study; they were drawn from an estimated 139 who came to the clinic at least once a week over the 6 months that the research team was present. Among these 91 women, 63 agreed to participate in the intervention. Of these, 54 (86%) participated in the 2-week follow-up, and 40 (63%) participated at 4 weeks. All participants were regular clinic attendees. No monetary incentives for attendance were offered.

The 91 women volunteers were compared on baseline demographic variables (age, ethnicity, work status) to the 139 methadone program enrollees. There were no significant differences in these characteristics, either between these two groups or between them and the 63 who received the intervention.

The 63 women who volunteered for the intervention session did so either at the initial visit and baseline interview or within the following 2 weeks.

The characteristics of the 63 women who agreed to participate in the intervention (which usually involved a second visit) were compared with the group of 91 from which they were drawn on a wide range of demographic variables, reproductive experiences, knowledge, and sexual practices. There were very few differences between these two groups on the above characteristics, and none approached significance. Hence, without assuming that the volunteers are representative of the wider group, it seemed apt that the parsimonious tabulations included in this report are based only on the women who participated in the intervention.

The majority of the participants were African-American (73%) or Hispanic

(16%), almost all were on public assistance and were unemployed. Their mean age was 42; only 8% were under 30 years old. In Table I, further descriptive data from the baseline interview are displayed regarding marital status, type of residence, education level, work, and income.

Almost all women reported exclusive relations with a single male sexual partner, 11% with a husband. Partnerships seemed to be long-standing, whether or not exclusive: only a few women reported more than one current partner,

TABLE I Women Clients of a Methadone Treatment Center:
Demographic and Socioeconomic Characteristics of the
63 Study Participants

Characteristics	% Distributions
Marital status	
Married	11
Living with partner	14
Divorced	5
Separated	13
Widowed	14
Never married	43
Residence	
Owens house or apartment	6
Lives with family or friends (does not contribute to rent)	5
Lives with family or friends (contributes to rent)	86
Lives in a shelter	3
Education level	
Grade 8 or less	9
Some high school (grades 9–11)	54
Finished high school or equivalent	24
Vocational/trade/business school	0
Some college or 2-year degree	11
Finished college or more	2
Employment	
Employed full time	0
Employed part time	3
Not employed	94
Not reported	3
Average monthly income	
No income	2
≤\$800	76
\$801–\$1600	13
\$1601–\$2400	2
\$2401–\$3200	3
Missing	5

even over the previous 3 months. Sexual encounters were virtually all vaginal, but 27% reported oral sex in addition. None reported anal sex.

Most women had several pregnancies. At some time in the past, many had used birth control measures, which were divided fairly evenly between hormones only (taken orally) (52%) and barriers (with and without hormones) (92%). In addition, 11% had had a tubal ligation or hysterectomy.

At initial interview, half of all sexual encounters were reported as unprotected against infections.

The baseline responses on selected knowledge items relevant to the relative efficacy of barriers are shown in Table II. Most respondents indicated that the male condom was very effective or somewhat effective. On the other hand, 23% of women believed that use of birth control pills gave some protection from sexually transmitted infections (STIs) and HIV; few knew about Depo-Provera or Norplant. Only 19% (Depo-Provera) and 8% (Norplant), respectively, stated firmly that their use would not protect against STIs. Only one-third to one-half believed that intrauterine devices, tubal ligation, or the rhythm method were ineffective against transmission of infection. Almost half (46%) of the women did not know anything about the female condom.

Relevant to barriers, 20 other knowledge items were tested. Following the

TABLE II Women Clients of a Methadone Treatment Center: Percentage Perceived Efficacy of Contraceptive Methods Against Sexually Transmitted Infection/HIV at First Contact

METHOD (row%)	(N) % Very Effective	(N) % Somewhat Effective	(N) % Not Very Effective	(N) % Not at All Effective	(N) % Don't Know Effectiveness	(N) % Don't Know Method
Men's condom	(26) 41%	(28) 44%	(6) 10%	(2) 3%	(1) 2%	(0) 0
Women's condom	(7) 11%	(13) 21%	(2) 3%	(0) 0	(12) 19%	(29) 46%
Diaphragm	(4) 6%	(18) 29%	(7) 11%	(13) 21%	(12) 19%	(9) 14%
Spermicide	(5) 8%	(12) 19%	(8) 13%	(9) 14%	(7) 11%	(22) 35%
Cervical cap	(1) 2%	(3) 5%	(2) 3%	(6) 9%	(4) 6%	(47) 75%
Birth control pills	(1) 2%	(5) 8%	(8) 13%	(39) 62%	(5) 8%	(5) 8%
Norplant	(1) 2%	(3) 5%	(0) 0	(12) 19%	(5) 8%	(42) 67%
Depo-Provera	(1) 2%	(0) 0	(2) 3%	(5) 8%	(3) 5%	(52) 83%
Intrauterine	(0) 0	(7) 11%	(1) 2%	(29) 46%	(5) 8%	(21) 33%
Withdrawal	(2) 3%	(5) 8%	(5) 8%	(36) 57%	(2) 3%	(13) 21%
Rhythm/calendar	(0) 0	(1) 2%	(3) 5%	(21) 33%	(1) 2%	(37) 59%
Tubal ligation/ hysterectomy	(3) 5%	(3) 5%	(4) 6%	(35) 56%	(3) 5%	(15) 24%

intervention, there were more correct responses on every item of the 20 presented compared to responses given previously; for 19 items, the changes were significant on the McNemar Test at the $<.05$ level (two tailed). The increments in understanding are summarized in Table III. There were substantial gains throughout, most particularly, but not exclusively, in relation to the female condom.

Reported sexual practices, including number of partnerships and frequencies of encounters, did not change significantly between baseline and first follow-up visit. There were a number of individual women who changed from reporting no recent encounters at the first interview to reporting several on the second, and vice versa, hence women categorized as sexually active at baseline and those so categorized at follow-up are not necessarily the same women.

Table IV shows the change in reported use of protective methods over the course of the study. The table covers each visit as a cross-sectional survey of the women who attended and who were sexually active at that time. It does not describe a longitudinal cohort of individual women, which would be difficult to do since the level of sexual activity varied over time. No woman had used or accepted the offer of referral for fitting a diaphragm or cervical cap. Nevertheless, there was a notable reduction, among sexually active women, in the proportion of unprotected sexual episodes. At baseline, among 34 sexually active women, 48% reported using no barriers at all in 84 recent episodes; at the first follow-up, 2 weeks later, among 29 women who were sexually active, 21% reported no use of barriers in 57 recent episodes. At the second follow-up, 4 weeks later, among 24 women who were sexually active, 20% reported no use of barriers in 51 recent episodes. The change could be attributed to the adoption of the female condom rather than to desertion from the male condom; nearly half of the users of the female condom had not reported prior use of the male condom.

TABLE III Women Clients of a Methadone Treatment Center: Knowledge of Risk and Barriers Among 63 Participants Before and After a Single Intervention

Knowledge Categories	Mean Percentage Correct	
	Before Intervention	After Intervention
General knowledge about barriers (2 items)	71	77
About the male condom (5 items)	55	85
About the female condom (4 items)	21	75
About the diaphragm (4 items)	38	75
About the hierarchy of prevention (5 items)	54	75

TABLE IV Sexually Active* Clients of the Methadone Treatment Center: Percentage Protective Devices Used During Vaginal Sexual Encounters in the Latest Three Episodes in Two Weeks Prior to Interview, Before Intervention and at Follow-up

	% Episodes (n = 84)
Before intervention: 34 women having active sex, among 63 respondents	
Used male condom	48
Used spermicide, withdrawal	5
Used nothing	48
% Episodes (n = 57)	
At first follow-up: 29 women having active sex, among 54 respondents†	
Used male condom	46
Spermicide	3
Used women's condom	30
Used nothing	21
% Episodes (n = 51)	
At second follow-up: 24 women having active sex, among 40 respondents‡	
Used male condom	39
Spermicide	4
Used women's condom	37
Used nothing	20

*Sexually active defined as any encounter in the prior 2 weeks.

†23 between 8 and 14 days; 30 at ≥15 days.

‡25 at ≤28 days; 15 at ≥29 days.

DISCUSSION

The results of this study indicate that, after a single group intervention, there was a marked increment in knowledge of barrier methods. The women clearly understood the meaning of the hierarchy in the safer sex strategies displayed to them. The message was not too complex to be comprehended.

The women also reported a reduction in the number of unprotected sexual encounters following the intervention. The increment in protected sexual encounters was due largely to the use of the female condom. The responses suggest that at least some women used the female condom at least once, and that, in many cases, these attempts were made by women who had earlier reported minimal use of the male condom. Thus, this increase in the use of the female condom did not reflect women moving away from the male condom.

A strength of the study is that there was a single defined intervention with an acceptable follow-up. Participants were probably women at high risk of transmitting or contracting HIV through sexual encounters.

There are several important limitations to this study, beginning with its representativeness. Every treatment clinic will have unique characteristics that depend on the population from which it draws. Our choice for location was based on the large numbers of women attending the selected clinic and the helpful attitudes of the responsible staff. Volunteers to the intervention program cannot be assumed to be representative of clinic clients as a whole. The study can be seen as a case history of a single clinic, likely to be exemplary, but certainly not representative of clients of such clinics. An estimated 50% of women attendees at the clinic are HIV positive, and our suspicion is that this is a group at high risk of becoming infected, or of infecting others, through unprotected sexual encounters.

The study has other important limitations. Subjects are all volunteers; it is based on small numbers; and the results on initial behavior and on change depend entirely on self-report.

Another important limitation is the short follow-up. We do not know, because the study did not permit it, whether the reported changes in behavior persisted over a longer period than between visits (3 weeks on average). Adoption of the female condom, for instance, might have been a response to the novelty of the device. Nevertheless, the data do encourage the speculation that the volunteers were women who had the self-efficacy and initiative to use the female condom, and that their male partners were willing to accept it.

In conclusion, this study provides encouraging results from a modest intervention, suggesting that the hierarchical model is a promising approach to reduce unsafe sexual encounters among women at high risk of sexually transmitted infections and HIV. The model certainly can be understood with a single simple explanation. It should be tested widely among diverse populations and locations. In general, prevention programs for women should offer a wider set of alternatives.

ACKNOWLEDGEMENT

We acknowledge the support of the staff of the Harlem Affiliated methadone treatment programs. The research was funded by the New York State AIDS Program, contract SDH-C12149.

REFERENCES

1. New York State Department of Health, AIDS Institute. *Women and HIV Prevention: Methods of Personal Protection. A Policy Statement*. Albany, NY: New York State Department of Health. *Focus on AIDS in New York State* (newsletter); July 1992.
2. Cleary J, Winters S. *Female condom. Efficacy, Acceptability and Relationship to the Women's*

- Hierarchy of Risk Reduction*. Albany, NY: New York State Department of Health, AIDS Institute, Division of HIV Prevention; January 1994.
3. Gollub EL, French P, Latka M, et al. The women's safer sex hierarchy: initial responses to counseling on women's methods of STD/HIV prevention at an STD clinic. Paper presented at: 11th International Conference on AIDS; July 17, 1996; Vancouver International AIDS Conference; Vancouver, British Columbia, Canada. Abstract MoD 583.
 4. Elias CJ, Coggins C. Female-controlled methods to prevent sexual transmission of HIV. *AIDS*. 1996;10(3):S43-S51.
 5. Soper DE, Shoupe D, Shangold GA, Shangold MM, Gutmann J, Mercer L. Prevention of vaginal trichomoniasis by compliant use of the female condom. *Sex Transm Dis*. 1993;20(3):137-139.
 6. Rosenberg MJ, Davidson AJ, Chen JH, Judson FN, Douglas JM. Barrier contraceptives and sexually transmitted diseases in women: a comparison of female-dependent methods and condoms. *Am J Public Health*. 1992;82:669-674.
 7. Gollub EL, French P, Latka M, Stein Z. Reducing women's risk of unwanted pregnancy and repeat STD through use of multiple barrier methods. Paper presented at: 124th American Public Health Association Conference; November 17-21, 1996; New York City.
 8. Trussel J, Sturgen K, Stricker J, Dominik R. Comparative contraceptive efficacy of the female condom and other barrier methods. *Fam Plann Perspect* 1994;26:66-72.
 9. Shervington D. The acceptability of the female condom among low income African American women. *J Nat Med Assoc*. 1993;85:5.
 10. Fontanet AL, Sabha J, Chandeying V, et al. Protection against sexually transmitted diseases by granting sex workers in Thailand the choice of using the male or female condom: results from a randomized controlled trial. *AIDS*. 1998;12:1851-1859.