The Effect Of Condoms On Std Reinfection Rates In Women In Washington Heights/Inwood

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A. Introduction

Sexually Transmitted Disease (STD's) continue to be a large contributor to morbidity and mortality in women in the United States and worldwide. Millions of dollars are spent on STD treatment and prevention. While treatment and medical knowledge about this series of diseases has been documented for decades, the incidence of STD's continue to climb. With the emergence of HIVAIDS in the 1980's and it's association with sexually transmitted disease, we as health care professionals have renewed incentive to attempt to eradicate this group of infectious diseases.

Women in the Washington Heights/Inwood neighborhoods of New York City are at high risk for contracting STD's as well as HIV. There has been a significant degree of medical literature discussing various modes of reducing STD infection rates in high risk populations. The crux of the literature, however involves the adolescent population. Those trials who specifically target adult populations focus primarily on behavioral and educational techniques to effect change. It is well documented in the medical literature that consistent and correct use of latex condoms can significantly reduce spread of sexually transmitted disease, including HIV. While nearly all the recent studies targeting reduction in STD infection rates included education about condom use in their protocols, few have employed direct interventions involving condoms (i.e. adequate access to condom for study populations).[1] It is our belief that direct access to condoms to women in Washington Heights and Inwood would significantly decrease reinfection rates of all sexually transmitted diseases. (not including HIV).

B. Subjects

Women between the ages of 18 years and 45 years, residing in the Washington Heights/Inwood neighborhood would be eligible for this study. Participants would need to have capacity to give informed consent to enter the study, be financially eligible for Medicaid and have completed more than two years of college.

Women who have not had any sexual activity for year, are currently participating in any other medical study would be ineligible for this study.

We believe that given the ethnic breakdown in this community the study will have a more than adequate number of traditionally underrepresented ethnic groups in our recruitment pool.

C. Study Design

The primary endpoint of the study is to compare reinfection rates of STD's in our study population after being randomly assigned to two different treatment arms.

The study protocol will progress as follows:

The study participants will be followed for approximately one year.

Three - six months before the onset of the trial community physicians and local community boards will be contacted to discuss the upcoming trial and to begin to inform the population. Two weeks to one month before enrollment we would post local advertisements in the community using flyers and radio announcements. Screening for the study would consist of door to door communication in addition to

[1] Except in series which studied prostitutes/sex workers as patient population

participants who respond to the aforementioned ads. Except for initial screening all testing will be performed at Columbia Presbyterian Medical Center in the AIM clinics.

Patients would first be asked to fill out or answer a questionnaire.[2] They would subsequently be screened for a series of STD's using urine testing, portable vaginal swabs, blood sampling, and +/- full gynecological evaluation. (If patients are screened at home, they will be given the opportunity for full gyn evaluation and blood sampling when they visit the AIM clinic for follow-up.) Patients would call in for results or contacted if positive results in one week. All patients with positive results will be referred to AIM clinic for treatment. Patients who were screened at home would be given a full gynecological exam at this time to screen for ulcerative diseases. For patients with primary MD, he or she would be notified of results, of treatment, and (later) whether or not their patient decided to enroll in the study. All patients with a primary MD will be encouraged to discuss the study with their physician prior to enrollment. All patients with primary MD's would be encouraged to continue to follow up with their primary physicians for other medical problems and at the end of the study.

Once arrived at AIM clinic patients would be offered enrollment into the study. If agreed, they would have detailed discussion re: study objectives, design, risks and benefits, confidentiality and ability to discontinue participation in the trial at any point. Patients would be paid a small fee for their participation in the study, and refunded for costs of transportation.

Participants would then be randomized to one of two groups: Group A - patients would be given condoms at each visit and ID card t obtain condoms form AIM clinic at any time for one year. Group B would receive no condoms. Both groups would be treated for all STD's diagnosed at screening and at first visit. Both groups would be enrolled in behavioral modification classes and provided with education about STD's and condom use.[3]

Patients enrolled in the study would have quick follow-up visits at AIM every three months. Patients would be tested for reinfection. Group A patients would have condoms renewed. Patients Group A would be questioned in detail about sexual activity and condom use. Group B would be questioned re: sexual activity.

Patients who decline participation in the study will be given appropriate referrals for treatment.

D. Statistical Analysis

This will be a randomized prospective trial. Patients will be randomized using a standard randomization table (but grouped). We have determined that to attain statistically significant results using and 01- of .05 and a Power of 80% each arm of the study will require 112 women. We have assumed the following: the reinfection rate of STD's in this community is approximately 8%[4] - and that the compliance with condom use is at most 20%[5] (range 12 - 18%). In addition we have assumed that of the se in the general population is at most 20%- group with reinfections only at most 1% will be reinfection even while using condoms. We expect that the expected change between groups with our intervention to be about 50%.[6]

Assuming a prevalence of STD's of 30%[7] in similar populations we need to screen approximately 746 women. Once all data'is collected results will be analyzed using chi-square analysis. There will be no crossing over of subjects.

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[2] brief questionnaire re: gyn/medical and sexual history; name of primary MD; mode of contact for test results. Questionnaires will be available in English, Spanish, Russian

[3] Behavioral modification and Education will be provided through a standardized protocol using lectures, videos, role playing and reading materials

[4] Data from NYC Department of Health

[5] Rosenbera, MJ, Commentary: methods women can use that may prevent sexually transmitted disease, including HIV, American Journal of Public Health, Nov. 92 Vol. 82 (11)

[6] see footnote 5

[7] see footnote 5

E. Medical Devices

There are no investigational devices used in this study. We will provide commercially available latex condoms. All medical kits for diagnosis will be those routinely used in medical practice at CPMC

F. Bibliography

to follow