Maya Vijayaraghavan, PGY-2

The Role of Basic Primary Care and Physician-Guided, Patient-Specific Counseling in Reducing High-Risk Behaviors in Homeless Women

A. Study Purpose and Rationale

This study aims to assess the efficacy of consistent access to primary care and physician-guided counseling in decreasing high-risk behaviors in women's shelters.

1. Specific Aims

AIM 1: To test the efficacy between consistent access to a physician, as defined by holding weekly clinic sessions at the shelter versus sporadic access to primary care in 1) decreasing the incidence of sexually transmitted infection (STI) and HIV, 2) changing substance abuse behaviors to favor decrease abuse

AIM2: To compare the efficacy of physician-guided, patient-specific counseling of high-risk behaviors to the standardized NIDA HIV-prevention counseling sessions in 1) decreasing the incidence of sexually transmitted infection (STI) and HIV, 2) changing substance abuse behaviors to favor decrease abuse

2. Background and Significance

Homelessness compounded with mental illness and substance abuse serves as the perfect medium for acquiring sexually transmitted infections (STI) and HIV. The prevalence of STI, HIV and substance abuse varies widely in the urban homeless and is estimated from cross-sectional data. A study conducted in two urban shelters in Birmingham, Alabama reported a prevalence of 12.9% and 19.9% respectively for STI, averaging out to 16.4% among sexually active participants (1). A study in San Francisco, California reported a prevalence of 10.5% for HIV in the homeless and marginally housed communities, and ranged anywhere between 1-21.1% depending on the geographical areas, populations being studied and the sampling method (2). The prevalence of substance abuse disorders in the homeless population ranges from 30-40% (3).

Women bear the brunt of the epidemic. The effect of unstable housing situations in rendering women vulnerable to commercial sex-work, drug offences and incarceration is well established. In most scenarios, women seek help too late when after multiple emergency room visits for STI they become infected with HIV. Each emergency room visit serves as a failed opportunity in restoring consistent access to healthcare and counseling to an at-risk population.

While medical resources are often harnessed after the infection, adequate counseling on prevention of high risk behaviors by healthcare professionals often lags behind. A survey of 154 emergency room healthcare providers in a Northeastern county caring for people with STI reported only 55% educating patients with STI on their HIV risk and only 10% of those encouraging patients to get tested for HIV (4). The rationale for not offering HIV counseling or testing included lack of appropriate

follow-up, insufficient time, and inadequate training to provide counseling and testing (4). Primary care physicians are in the unique position of seeing a diverse and sometimes marginalized population in which high-risk behavior may be rampant, and more importantly have the infrastructure to provide continuity of care. Even so, data collected to date have outlined some of the barriers and physician biases of HIV screening in routine primary care settings (5,6). Part of the problem arises from lack of standardized instruments in assessing high-risk sexual and substance abuse behaviors and physician subjectivity on whom to screen. As a result, efforts are devoted to training primary care physicians to ask probing questions on specific sexual and drug use practices and also to offer HIV screening to all patients as part of their routine health care maintenance.

Despite these measures, what remains to be quantified is the efficacy of the physician-patient interaction in preventing HIV risk behaviors in a well-established, high-risk population like that of a women's shelter. Studies have shown that health-care utilization by those in temporary housing situations is marginal in comparison to those who are permanently housed (7). While enabling access to care by providing a physician at the shelter at regular intervals, the current pilot study aims to determine if consistent access to primary care and counseling against high-risk behaviors directly impacts the frequency of such behaviors. The model is akin to that of the intervention proposed for tobacco cessation where the noted success with frequent physician contact where smoking was addressed superseded that of any other short term pharmacologic or self-help courses (8).

While healthcare resources are expensive to establish in a shelter setting, the role of the current study is to determine the feasibility of such an endeavor and also to highlight the need for providing a much-needed clinical service to our underserved communities.

B. Study Design and Statistical Analysis

The study will be a randomized-controlled trial conducted in single, women's shelters in New York. The shelter system in New York is divided into the temporary adult assessment shelters and the more permanent single women's or men's and family shelters. The first three months of the study will be devoted to establishing primary care, collecting background data on sexual and drug use practices, and prevalence rates of STI and HIV at the shelter.

HIV negative women will be enrolled in the study. A prior history of STI and substance abuse does not preclude them from enrolling in the study. However, women with an active STI will first be treated prior to enrollment. A woman who has a positive urine toxicology screen will be enrolled in the study, and the change in drug use behaviors will be assessed at each follow-up interval. The physician-guided, patient-specific counseling intervention will begin after the first three months of the study. The control arm will be assigned to the standard NIDA HIV-prevention program currently utilized in shelter settings. The intervention will take place for a period of one year, with the total study time being one-and-a-half years.

The primary outcome measure is a composite score of the number of new STI and HIV infections. The secondary outcome is the change in substance abuse behaviors measured by urine toxicology screens.

Based on the event rate of STI and HIV in urban shelters of approximately 20%, and assuming that the proposed physician-guided intervention will decrease the event rate to 10% the number of subjects needed in the control and intervention groups are 220. This was obtained using the chi-square analysis for categorical data for two groups. Given the transient nature of the patient population, the conservative estimate would likely be 300 individuals in each arm to account for the high attrition rate and to achieve 80% power at a p value of 0.05.

Three or four women's shelters will be targeted to obtain a sample size large enough to see an effect. Within each shelter, women will be randomized by bed numbers to either the intervention or control arms.

The study will use an intention-to-treat approach for the efficacy analysis. The chi-square test for categorical data will be utilized for the power analysis and determining if there is a primary difference between the two groups. The efficacy analysis will calculate a relative risk with 95% confidence intervals. Thereafter, a relative risk reduction, absolute risk reduction and number-needed-to-treat will be calculated to determine the clinical efficacy of the target intervention. To account for confounders such as age, race, income, education level, presence or absence of mental illness, traumatic life events, support network, history of childhood trauma, logistic regression analysis will be conducted.

C. Study Procedure

The study will use the ora-sure rapid HIV test with positive results confirmed by western blot. Pre and post-test counseling will be offered and the turn around time for the results will be approximately 1 week. Urine for nucleic acid amplification or cervical swab will be utilized for STI. Where possible, a cervical swab will be used for testing STI as it has greater sensitivity than the urine based analysis. A urine toxicology screen will be utilized to monitor substance abuse. Each clinic session will last anywhere between a half-hour to an hour, including the time needed for administering the tests, primary care and patient-specific counseling. The women will be scheduled to see the physician at 4-week intervals for primary care and counseling following the initial three-month observation and setting up period.

Women will have a urine toxicology screen and be tested for STI and HIV at the initial visit prior to the start of the intervention and then at 3, 6 and 12-month intervals. Additionally, qualitative surveys that touch upon self-reported sexual and drug use practices will be administered at the start of the study and then at 3, 6 and 12- month intervals. Anyone who tests positive for HIV will be referred to the nearest AIDS treatment center. Any women with a STI will be treated with antibiotics and systems will be set in place to ensure partner notification. Any women with a positive drug screen will be referred to drug rehabilitation programs.

The duration of the study will be 1.5 years, with the duration of the intervention being 1 year. Given that the intervention is taking place at a shelter with a transient population, the anticipated duration of participation by an individual may range between 3 months to 1 year. There will likely be a high attrition rate, and therefore the number needed in each arm is a slight overestimation to account for the attrition rate.

D. Study Questionnaires

The topics to be addressed in the questionnaire will include:

- self-reported STI
- number of drug encounters
- number of unprotected sexual encounters
- number of hospital visits for substance abuse or consequences for other high-risk behaviors
- traumatic events during study participation

E. Study Subjects

Inclusion Criteria

- HIV negative women between the ages of 18-60
- Any women with a prior STI
- Any women with a history of prior or current substance abuse

Exclusion Criteria

- HIV positive women between the ages of 18-60
- Women with a current STI will first be treated for the infection and when negative will be enrolled in the study

The focus of the current study is to test the efficacy of primary care and patient-specific counseling in reducing high-risk behaviors in homeless women living in shelters. The proposal will be submitted to the IRB of the Department of Homeless Services (DHS) to ensure the safety of the women being studied. Stringent procedures will be set in place to maintain confidentiality and promote the wellbeing for shelter inhabitants.

F. Recruitment of Subjects

The clinic will be set up at the shelter premises. Any patient who attends the clinic will be notified of the study. Subjects will also be recruited with the use of: 1) flyers, 2) information sessions held by shelter officials, and 3) allotted time with clinic staff to answer questions pertaining to the study.

G. Confidentiality of Study Data

Patient will be assigned a unique code that will utilize numbers starting from 1. Since women in shelters are a particularly vulnerable population, stringent procedures will be set in place to ensure that their drug use, HIV or STI status is not divulged to other members of the shelter. Each physician will record data in a designated study laptop computer that will be stored at the clinician's office outside the shelter facility. Patient's medical charts will have to be kept at the shelter and will be stored in a locked filing cabinet in a locked room at the shelter.

H. Potential Conflict of Interest

There is no perceivable conflict of interest. There may be a potential source of friction between the standard NIDA HIV-prevention intervention model and the physician-guided counseling program if the two are seen as competitors. However,

the study may highlight that both social and clinical interventions are needed in a shelter setting in order to effect change in high-risk behaviors.

I. Location of the Study

The study will be conducted in medium-sized (200 individuals) shelters in the New York area. Three or four shelters will be solicited to enroll approximately 600 subjects. The selection of the shelters will be done in concert with the guidance of the DHS.

J. Potential Risks

The perceivable risk includes the psychological impact to the women if they do seroconvert during the course of the study. Adequate psychological and psychiatric referral services will be set up in the event women test positive for HIV. The referrals will take place outside the shelter premises to maintain anonymity. Furthermore, if women test positive then adequate measures will be taken to notify partners anonymously.

K. Potential Benefits

The benefits of the study are five fold: 1) women in the shelter will have consistent access to care, 2) immediate medical needs will be addressed which may reduce emergency room utilization, 3) a beneficial therapeutic alliance could evolve between the patient and the physician with frequent visits and patient-centered counseling such that patient's try to implement changes in their high-risk behavior, 4) increase in the patient's knowledge base on the impact of high risk behaviors on HIV and STI disease transmission, 5) highlight the need for a much-needed service in shelter settings to promote the allocation of monetary and humanitarian resources.

L. Compensation to Subjects

Since women will not have to travel outside the shelter, they will not be compensated for attending clinic or the counseling sessions. For filling out the surveys at the four intervals, women will be compensated $10 each, for a total amount of $40.

M. Costs to Subjects

Patients will attend the clinic and counseling sessions at no cost. The cost of the antibiotics, basic medical care and investigational studies will initially be incurred by the grant that supports the project for 1.5 year. In the future, however, perhaps Medicare or Medicaid could help subsidize some of the costs of the clinic. However, women with no insurance will not be denied care.

N. References

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