A Randomized Trial of HIV Counseling and Testing Among Out-of-Treatment Injection Drug Users in Portland, Oregon

by

Brian W. Weir

A Thesis

Presented to the Department of Public Health and Preventive Medicine

and the Oregon Health Sciences University

School of Medicine

in partial fulfillment of the degree of

Master of Public Health

May 2004

School of Medicine

Oregon Health Sciences University

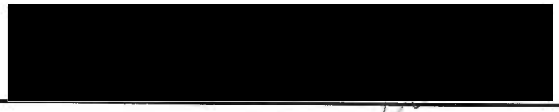
CERTIFICATE OF APPROVAL

This is to certify that the master's thesis of

Brian W. Weir

has been approved

Donald F. Austin, M.D., M.P.H.



Dongseok Choi, Ph.D.

Michael J. Stark, Ph.D.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ACKNOWLEDGEMENTS

I thank the members of my thesis committee. Don Austin, my thesis advisor, has provided me with invaluable help throughout the development of my thesis. I am very grateful to Dongseok Choi for leading me to the use of Poisson distribution for modeling HIV-related risk behavior. Mike Stark has provided me with the opportunity to work on this study. I am most grateful to Dr. Stark for the ten years that I have been working with him. His support and guidance and the opportunities he has provided me have lead to the development of my appetite and abilities for public health research.

The completion of my thesis would have been much more difficult without the support of my colleagues at Program Design and Evaluation Services and the Portland Women's Health Study. In particular, I would like to thank Ronda Bard for her support and Julie Maher for allowing me to bend her ear on analytic issues.

The contributions of many different people allowed for the completion of this study. The vision of Michael Stark, Haiou He, Jeanne Gould, and David Fleming contributed to the development of this study. This study would not have been possible without the dedicated program staff and support staff of the Portland site of the NIDA Cooperative Agreement.

My advancement through the OHSU MPH program has been protracted, with several stops and starts. I am grateful to Katie Riley for bringing me back into the fold and shepherding me through the MPH graduate program.

Finally, I would like to thank my friends and family for their support.

ABSTRACT

HIV counseling and testing has been advocated as an effective intervention for reducing needle risk behavior among injection drug users (IDUs). This randomized controlled trial of HIV counseling and testing with seronegative out-of-treatment IDUs was conducted to evaluate the effectiveness of HIV counseling and testing in reducing needle sharing.

Methods: Subjects were recruited in Portland, Oregon to participate in a "health study" as part of a NIDA-sponsored Cooperative Agreement to reduce HIV among out-of-treatment drug users. Subjects were at least 18 years old, injected drugs in the last 30 days, and had no drug treatment in past 30 days. Intervention subjects received HIV counseling and testing in an initial session and returned two weeks later to receive test results and post-test counseling. Controls received a brief risk assessment only. Subjects returned in six months to complete a follow-up risk behavior assessment, after which all subjects were offered HIV counseling and testing.

Results: Of the 226 IDUs enrolled in this study, 62% were male 55% white, 36% African American, and the mean age was 37 years (range 18 to 61 years); 153 (68%) successfully completed the follow-up assessment. In multivariable negative binomial regression, among subjects who injected at follow-up, the number of injections with a shared needle was almost three times higher in the intervention group than the control group (IRR = 2.94, 95% CI = 1.18, 7.35). In multivariate logistic regression, among subjects who injected at follow-up, subjects in the intervention subjects were over two and a half times as likely to have injected with a shared needle at follow-up than control subjects (OR =

2.56, 95% CI = 1.03, 6.38).

Conclusions: This randomized trial found no evidence that HIV counseling and testing is significantly associated with reductions in needle sharing among seronegative out-of-treatment IDUs. Possible explanations for the higher level of risk behavior among intervention subjects than control subjects at follow-up are discussed.

INTRODUCTION

Injection drug users (IDUs) are at high risk of becoming infected and infecting others with HIV through sharing of injection equipment and through unprotected sex. Injection drug use, either directly or indirectly, has accounted for 36% of the AIDS cases in the U.S. since the epidemic began, and 28% of AIDS cases in 2000 (CDC, 2002). In 2001-2002, 19% of AIDS cases and 20% of new HIV diagnoses in Oregon were among injection drug users or injection drug-using men who have sex with men (Oregon Department of Human Services, 2002). Reducing high-risk behavior among IDUs has been a critical issue in the nation's HIV prevention agenda.

Over the course of the epidemic, HIV counseling and testing has been proposed and implemented as a means of altering risky behaviors among individuals who are at risk of HIV infection and transmission (CDC, 1985; 1987; 2001). The purported benefits of HIV counseling and testing for clients are twofold. First, as a diagnostic tool, individuals infected with HIV are made aware of their status and are able to initiate medical treatment that can enhance and prolong life, and sex or injection drug using partners can be made aware that they may have been exposed to the virus and offered HIV counseling and testing. Second, as a health intervention HIV counseling and testing provides a teachable moment for the counselor to educate the client about HIV transmission and prevention, engage the client in a personal risk assessment, and provide options for reducing high-risk behaviors. The efficacy of HIV counseling and testing is

based on the assumption that knowledge of HIV status, combined with pre- and post-test counseling, should motivate individuals to initiate or maintain reductions of high-risk behavior (CDC, 1987; 2001).

HIV counseling and testing has come to be recognized as a standard of care for HIV prevention. In 1995 the National Institute on Drug Abuse (NIDA) developed a policy encouraging NIDA-funded researchers to provide HIV counseling and testing to their subjects to help reduce HIV risk behaviors and infections in drug users (NIH, 1995). In 1991, the Panel on the Evaluation of AIDS Interventions (Coyle, Boruch, & Turner, 1991) recommended the use of randomized experiments of standard HIV counseling and testing versus alternative interventions to determine 'what works better.' NIDA initiated the 29-site National AIDS Demonstration Research project in 1987 and the 23-site Cooperative Agreement for AIDS Community-Based Outreach/Intervention Research Project in 1990. The goal of both projects was to develop interventions to reduce HIV-related risk behavior among out-of-treatment IDUs and crack users.

NIDA Cooperative Agreement

In the NIDA Cooperative Agreement, individual sites developed Enhanced Interventions and compared them in randomized trials to the Cooperative Agreement Standard Intervention of HIV counseling and testing. HIV counseling and testing in the Standard Intervention was based on the Health Belief Model, fear arousal theory, and other theories of behavioral change (Coyle, 1993). The central themes of these theories are that for individuals to change their behaviors, they must perceive their own

vulnerability to serious risk as well as their ability to protect against risk, and that fear messages about risk function effectively to motivate behavior change so long as they are carefully linked to instruction about new behaviors that a client can adopt. Individual sites developed Enhanced Interventions and compared them to the Standard Intervention in randomized trials. Significant findings from these HIV counseling and testing interventions for out-of-treatment drug users include: reduced frequency of injecting drugs, reduced sharing of cookers and cotton, reduced renting or borrowing of needles, increased use of new needles, and increased needle cleaning (Neaigus et al., 1990; Stephens et al., 1993; Friedman et al., 1992; Booth & Wiebel, 1992; Colon et al., 1993; Simpson et al., 1994; Camacho et al., 1995; Deren et al., 1995). A review of studies from NIDA CA sites (Coyle, Needle, & Normand, 1998) showed that at follow-up 26% of IDUs stopped injecting, injection frequency declined by nearly 40%, and needle reuse declined by 20%. While many studies have found significant reductions in risk behaviors for both Standard and Enhanced Interventions (Stephens et al., 1993), limited differences have been observed between Standard and Enhanced Interventions (Weddington & Brown, 1989; Gianstefano et al., 1994; Rhodes & Humfleet, 1993; Longshoure, 1992; Coyle, 1998; CSR, Incorporated, 2001).

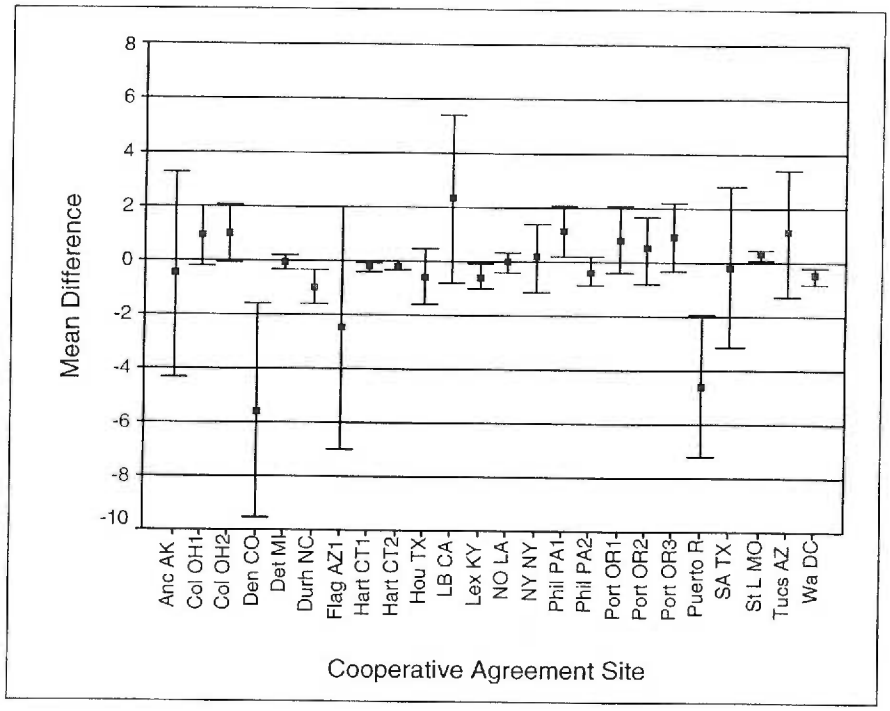
Similar results were found at the Portland site of the NIDA Cooperative Agreement in a study examining the efficacy of encouraging IDUs to enter drug treatment or participate in self-help meetings (He et al., 1996). In this randomized trial, IDUs and crack users received HIV counseling and testing only, HIV counseling and testing plus

assistance and incentives to attend drug treatment, or HIV counseling and testing plus assistance and incentives to attend self-help meetings. At the six-month follow-up, clinically and statistically significant decreases in any injection drug use, frequency of injection drug use, and use of non-new needles were found for all groups. The reductions in risk behavior did not differ between standard and enhanced groups.

The general lack of intervention effects for the Enhanced Interventions at the Portland site and other sites of the NIDA Cooperative Agreement is evident from data from the Final Analytic Report (CSR, Incorporated, 2001). Figure 1 provides a comparison of risk behavior at follow-up for subjects in the Standard and Enhanced Interventions at each of the Cooperative Agreement sites. The figure shows the mean differences (Standard minus Enhanced) and 95% confidence intervals for episodes of injecting with a needle that had been used by someone else in the last 30 days.[1] The majority of the confidence intervals for each of the sites overlap zero, with similar numbers showing negative and positive mean differences between the Standard and Enhanced Interventions.

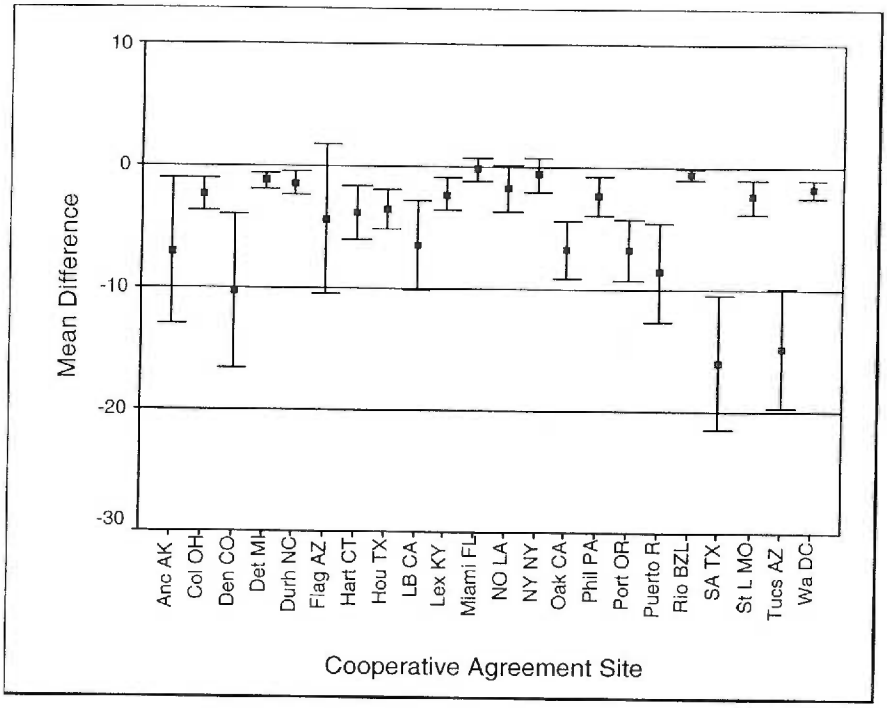
1 Figures 1-2 were created from unadjusted data adapted from Table 4 (p. 91-95) and Table 5 (p. 98-101) of the Final Analytic Report: NIDA Cooperative Agreement Program (CSR, Inc., 2001).

Figure 1. Mean differences in episodes of needle sharing at follow-up for the Standard and Enhanced Interventions of the NIDA Cooperative Agreement by site, with 95% confidence intervals.



Data from the Final Analytic Report of the Cooperative Agreement also demonstrate the reductions in risk behavior among subjects receiving the Standard Intervention. Figure 2 shows the changes in risk behavior from baseline to follow-up for the Standard Intervention at each of the Cooperative Agreement sites. The figure shows the mean differences (follow-up minus baseline) and 95 % confidence intervals for episodes of injecting with a needle that had been used by someone else in the last 30 days. Significant reductions were observed for episodes of needle sharing at 20 of the 23 sites.

Figure 2. Mean differences in episodes of needle sharing from baseline to follow-up for the Standard Intervention of the NIDA Cooperative Agreement by site, with 95% confidence intervals.



Based on observed reductions in risk behavior among subjects receiving HIV counseling and testing, many researchers have concluded that HIV counseling and testing is an effective HIV prevention intervention (Stephens et al., 1993; Coyle, Needle, & Normand, 1998; Compton, 2000). The effectiveness of HIV counseling and testing has also been proposed several times as an explanation for the lack of differences between the Standard and Enhanced Interventions: "A possible explanation for the small effect sizes [for the Enhanced versus Standard Interventions] is that the Standard Intervention alone is an effective, comprehensive program that leads to substantial change so that additions to it may not have had much impact. (CSR, Incorporated, 2001, p.18)"

Studies of HIV Counseling and Testing

Several meta-analyses have been conducted to determine whether HIV counseling and testing is indeed an effective intervention. In a meta-analysis of the effects of HIV counseling and testing on sexual risk behavior, Weinhart et al. (1999) found significant decreases in unprotected sex and number of sex partners and an increase in condom use among individuals who had tested positive for HIV. No significant changes in unprotected sex, number of sex partners, or condom use were found among individuals who had tested negative for HIV. The majority of studies conducted among homosexual men, pregnant women and other heterosexuals who have received a negative HIV test result have shown that counseling and testing has little impact on reducing risk behavior (Fox et al., 1987; Higgins et al., 1991; Wenger et al., 1991; Ickovics et al., 1994). Some researchers have even hypothesized that the receipt of a negative test result after engaging in high-risk behavior may reinforce the behavior as not risky (Fox et al., 1987; Wenger et al., 1991; Rosser & Ross, 1991).

In their review of psychosocial HIV prevention interventions, Gibson, McCusker and Chesney (1998) were only able to identify two studies that employed a randomized design to evaluate the effectiveness of HIV counseling and testing. In a study with IDUs in methadone maintenance, Caslyn et al. (1992) found that subjects assigned to a wait-list reduced their risk behavior as much as subjects receiving AIDS education and optional HIV testing. In a study with IDUs in heroin detoxification, Gibson et al. (1998; 1999) randomized subjects to receive experimental counseling or educational brochures.

Sizable reductions in risk behavior were evident in both groups at follow-up, but no difference was found between the groups. While these two studies indicate that HIV counseling and testing is not associated with reductions in risk behavior, they are dissimilar from the NIDA Cooperative Agreement studies. Both of these studies were with in-treatment IDUs, and the counseling methods employed were not those of the NIDA Cooperative Agreement Standard Intervention.

Study goals

Can the observed reductions in needle sharing among Cooperative Agreement subjects receiving the Standard Intervention be attributed to the effects of HIV counseling and testing? To examine the impact of HIV counseling and testing as a stand-alone HIV prevention intervention on needle risk behavior among out-of-treatment IDUs, a randomized trial of HIV counseling and testing with a delayed treatment control group was conducted at the Portland site of the NIDA Cooperative Agreement. Risk behavior was assessed at baseline and at a six-month follow-up appointment.

The specific hypotheses of this study are: among subjects who continued to inject drugs at follow-up, subjects in the intervention group will inject less frequently with a shared needle at follow-up than subjects in the control group; and among subjects who continued to inject drugs at follow-up, fewer subjects in the intervention group will report any needle sharing at follow-up than the control group. Cessation of injection drug use in the two groups and changes in needle sharing within the two groups from baseline to follow-up will also be examined.

An additional aim of this study is to examine the appropriateness of Poisson and negative binomial regression for modeling episodes of needle sharing at follow-up. The use of Poisson-family distributions for modeling count data is well established but is uncommon in the analysis of HIV-related risk behaviors. Myers et al. (2003) used Poisson regression to model predictors of sexual risk as measured by a sex risk scale. Hutchinson et al. (2003) used Poisson regression to model predictors of number of sex partners, number of episodes of intercourse, and number of episodes of unprotected intercourse among inner-city adolescent females. Brisson et al. (1999) used negative binomial regression to model factors associated with lifetime number of sex partners of the sexually active population of Quebec. Guo et al. (2002) examined the association between adolescent substance use and number of sex partners through negative binomial regression. No examples have been found in the literature of the use of Poisson or negative binomial distributions to model needle sharing.

In HIV prevention studies, a variety of types of metrics of risk behavior have been used (Schroeder, Carey, & Vanable, 2003) including frequency or count (e.g., episodes of injecting with a shared needle), relative frequency (e.g., proportion of injections that were with a shared needle), and dichotomies (e.g., any versus no injections with a shared needle). A variety of analytic techniques have also been employed in HIV prevention studies. For count and relative frequency outcomes, ANOVA, ANCOVA, and ordinary linear regression are typically employed, and for dichotomous outcomes, logistic regression is commonly employed (Schroeder, Carey, & Vanable, 2003). The use of

ordinary linear regression models for count data is often problematic, as frequencies of HIV risk behavior usually follow a highly left-skewed distribution, with a high number of zero scores and low counts and a low number of extremely high scores. Non-normal distributions are often redressed through transformations or through the categorization of data into an interval, likert-type scale.

Poisson regression was developed specifically for the modeling of counts of events, which are limited to non-negative integer values (Cameron & Trivedi, 1998). An advantage of Poisson and negative binomial regression over ordinary linear regression for modeling frequency of risk behavior is that these log-linear methods can model untransformed frequencies with a high number of zero scores and low counts and a low number of extremely high scores (Cameron & Trivedi, 1998). In contrast, hypothesis tests in ordinary linear regression of count data depend on assumptions of the variance of the error terms that are unlikely to be met (Gardner, Mulvey, & Shaw, 1995), and estimates may be inefficient, inconsistent, and biased (Long & Freese, 2001).

In this study, the use of Poisson and negative binomial regression will be extended to modeling episodes of needle sharing at follow-up. These models will be used to test hypotheses about the association between HIV counseling and testing and reductions in risk behavior. In addition, an evaluation of these models will provide important information on the appropriateness of Poisson and negative binomial regression for modeling HIV-related needle risk behavior.

This study was developed in 1994 by the research team at the Portland site of the

NIDA Cooperative Agreement, which included Michael J. Stark, PhD (Principal Investigator, Multnomah County Health Department [MCHD]), Jeanne Gould, MBA (Director HIV/STD Services, MCHD), David W. Fleming, MD (Oregon State Epidemiologist, Oregon Health Division [OHD]), Haiou He, MBA (Research Analyst, MCHD), and Brian W. Weir, BA (Research Analyst, OHD). This study was reviewed and approved by the joint Institutional Review Board for the MCHD and the OHD (IRB-94-7).

METHODS

Subjects

Out-of-treatment IDUs and crack users were recruited through word-of-mouth and flyers inviting participation in a "health study" sponsored by the Multnomah County Health Department. Geographic areas of Portland with concentrations of IDUs and crack users were identified through key informants, previous outreach efforts, and HIV risk-related databases (Watters & Biernacki, 1989). These databases were used to identify geographic areas with high concentrations of syphilis and hepatitis cases, illicit drug use in women giving birth, deaths due to drug overdose or where drugs contributed to death, drug abuse among clients visiting the local health department and hospitals, and drug-related arrests.

In earlier studies at the Portland site, indigenous outreach workers actively recruited subjects. To avoid the possibility that subjects would participate in the study with the expectation that they would receive HIV counseling and testing, no references to HIV or AIDS were made during subject recruitment. While the most desirable strategy for testing the effectiveness of HIV counseling and testing would be to randomize drug users seeking HIV counseling and testing into intervention and no-treatment control groups, such a study would not be ethical; the Panel on the Evaluation of AIDS Interventions (Coyle, Boruch, & Turner, 1991) concluded that 'in the context of a deadly epidemic, it is indefensible to withhold this treatment in the interests of conducting an

experiment from any individual who *desires* it. [italics added] (p. 114-115)' Using a subject population not actively seeking HIV counseling and testing allows for an ethical randomized trial with a control group that was not offered HIV counseling and testing until after a follow-up risk assessment. Furthermore, control subjects were not denied access to HIV counseling and testing during participation in the study. They were free to seek counseling and testing at all venues previously available to them.

Subjects were enrolled in this study from November 1994 through February 1996. During a three-month period (March through May, 1995), subject enrollment was suspended for this study, and subjects were enrolled in a special NIDA Cooperative Agreement multi-site study. To be eligible for enrollment, subjects had to: 1) have injected drugs or smoked crack within 30 days prior to recruitment, confirmed by fresh track marks and/or positive urinalysis; 2) not have participated in formal drug treatment in the last 30 days; and 3) be 18 years of age or older. The analyses in this study are limited to subjects who reported at the baseline assessment that they used injection drugs in the last 30 days and that they have never been told that they were infected with HIV. Follow-up analyses are limited to subjects who completed the follow-up assessment five to nine months after the baseline assessment, which is the standard follow-up assessment window for NIDA Cooperative Agreement studies.

Preliminary Procedures

Participants in the HIV risk reduction project were informed of the procedures, benefits and risks of the study and gave consent prior to participation. Each subject

provided information about where he or she could be reached by study staff as well as three verified contacts who could assist in contacting the subject to schedule the follow-up assessment. Drug use was confirmed for all subjects by examination for fresh track marks or by positive urinalysis for opiates, cocaine, or amphetamines.

Randomization

A table of group assignments with equal numbers of intervention and control group assignments randomly ordered within blocks of 30 was created using SPSS for Windows 11.0. Subjects were randomized into either the intervention group or the control group. When cohabitating individuals were enrolled in the study, they were both assigned to the same group. This was done to reduce diffusion of any intervention effect. Data from the Final Analytic Report of the Cooperative Agreement (CSR, Incorporated, 2001) show that subjects who reported more risk behavior were more likely to be randomized into the Enhanced Interventions than the Standard Intervention at several Cooperative Agreement sites, indicating that randomization procedures may not have been followed. To reduce the likelihood of mis-randomization in this study, the person randomizing a subject needed to obtain the group assignment from the project site manager or the lead interviewer.

Assessment

Intervention subjects were administered the standard risk behavior assessment questionnaire (RBA) for the NIDA Cooperative Agreement, and control subjects were administered an abridged version of the RBA. Questions in the RBA address

demographics, current living situation, employment and income, current and past use of injection and other drugs, drug treatment history, current sexual behaviors and sexual history, HIV and STD testing history, and criminal justice involvement. A short version of the RBA was administered to subjects in the control group to minimize feedback about risk behaviors provided during the assessment process. (Behavior change observed in previous studies may have resulted from feedback about risk behaviors provided to subjects by in-depth baseline assessments.) The assessment instruments differed little in questions regarding injection behavior, but differed markedly in questions regarding sexual risk behavior. The RBA administered to intervention subjects took an average of 27 minutes to complete (SD = 12 minutes), and consisted of 354 possible questions. The abridged RBA administered to control subjects was not timed, and consisted of 166 possible questions.

The RBA was administered in private, one-on-one sessions by trained interviewers. All subjects were given information about social services available to them, including public clinics that offer HIV counseling and testing. Control subjects were asked to return in six months for a follow-up session. Intervention subjects received HIV counseling and testing and were asked to return in two weeks for their HIV test results and post-test counseling and in six months for a follow-up session. All subjects received $25 compensation for participation in the baseline session.

HIV Counseling and Testing

HIV counseling and testing in the Standard Intervention of the NIDA Cooperative

Agreement was developed using several theoretical models. In accordance with communications theory (Shannon & Weaver, 1949), the prevention message came from a credible source (i.e., trained interventionists) and was tailored to the educational levels of the subjects so that individuals could understand the threat of HIV infection. Counseling staff needed to be culturally sensitive in order to develop rapport with the subjects. To this end, the intervention staff included members of the target community and former drug users. In accordance with the Health Belief Model (Becker, 1974), the counseling was designed to help subjects perceive their vulnerability to HIV infection and their ability to protect themselves from infection. Fear arousal theory (Blumburg, 2000) was utilized through the juxtaposition of fear messages with safer behaviors that subjects adopt. Social learning theory (Bandura, 1977), which suggests that behaviors can be learned through observation and copying, was employed through the demonstration of harm reduction behaviors and the rehearsal of the behaviors by the subjects.

The pretest session utilized cue cards to inform and engage the client about: the scope of HIV infection, AIDS cases and AIDS deaths in the U.S.; mortality rates for select populations, including women and IDUs; the course of HIV disease; modes of HIV transmission; and false myths about HIV transmission. Injection drug using subjects were given information about how to protect themselves from contracting or spreading HIV through adopting safer injection practices, including: cessation of injection drug use, using a brand new needle for each injection, not sharing needles or other injection equipment, and cleaning needles with bleach before sharing. The counselor gave a

demonstration of proper needle cleaning, which was demonstrated in turn by the subject. The counselor provided information to all subjects about risk-taking and immunosuppression associated with non-injection drug use. The counselor provided a list of ways to reduce sex risk including condom use, abstinence, non-penetrative sex, mutual masturbation, and reducing number of sex partners. The counselor gave a demonstration of how to properly put on a condom using a dildo as a model, which was in turn demonstrated by the subject. Subjects were offered free condoms and free bottles of bleach and rinse water.

The post-test session occurred approximately two weeks after the pre-test session. The post-test session included provision of test results, the meaning of the test results, and a review of the issues discussed in the pre-test session.

Follow-up Assessment

Follow-up assessments were conducted between 5 and 9 months after the baseline assessment. All subjects were administered a full follow-up risk behavior assessment, and injection drug use was confirmed by visual inspection for tracks and/or urinanalysis. At the follow-up session, all subjects were offered HIV counseling and testing, as previously described. All subjects received $25 compensation for participation in the follow-up session.

Measurement

The analysis for this study examined the data from the baseline and follow-up RBA. The RBA has been shown to be both reliable and valid (Needle et al., 1995;

Weatherby et al., 1994). In this study both count and dichotomous outcomes were employed. While count data more accurately reflect risk of infection, dichotomous outcomes are more frequently used in HIV prevention research. Two different outcomes examined include episodes of injecting with a shared needle in the last 30 days at follow-up and any injections with a shared needle in the last 30 days at follow-up. The outcome was measured at baseline and follow-up with the following question: "How many times in the last 30 days did you inject using works (needle/syringes) that you know had been used by someone else?" Independent baseline variables examined in these analyses include group assignment, age, gender, race/ethnicity, level of education, employment status, days had intercourse in the last 30 days, number of sex partners in the last 30 days, crack use in the last 30 days, injection frequency in the last 30 days, and frequency of injecting with a shared needle in the last 30 days. The codings of the independent baseline variables differed depending on the analysis conducted, and are described below.

Preliminary Analyses

Baseline variables were examined for associations with group assignment among subjects enrolled in the study and among subjects who completed the follow-up assessment. Attrition bias will was evaluated by comparing baseline variables for subjects who did and did not complete the follow-up assessment. Logistic regression analysis was used to examine for differences in the two groups in cessation of injection drug use at follow-up. The non-parametric Mann-Whitney U test was used to characterize differences in the frequency of injecting and needle sharing between the two

groups at baseline and follow-up among subjects who injected at follow-up. The non-parametric Wilcoxon signed ranks test was used to characterize changes in the frequency of injecting and needle sharing within groups from baseline to follow-up.

Primary Analyses

Several different analytic models were employed, including Poisson regression and negative binomial regression for episodes of needle sharing at follow-up (Cameron &Trivedi, 1998; Long, 1997; Long & Freese, 2001) and logistic regression for any needle sharing at follow-up (Hosmer & Lemeshow, 2000). An assumption of the Poisson regression model is that the conditional variance is equal to the conditional mean: $\text{Var}(y|\mathbf{x}_i\beta) = \exp(\mathbf{x}_i\beta) = \mu_i$. In practice, the variance is often overdispersed relative to the mean. The negative binomial regression model is a standard generalization of the Poisson model that includes an overdispersion parameter (Cameron & Trivedi, 1998). The negative binomial regression model was explored as an alternative to the Poisson regression model.

Separate Poisson, negative binomial, and logistic regression models were developed to examine the association between each of the independent variables and needle sharing at follow-up while controlling for needle sharing at baseline. This was done as the associations between predictors and the dependent variable may only be evident after adjusting for baseline risk. Variables associated with sharing at follow-up at $p < .25$ in these preliminary regression models were considered potential covariates for full and reduced multivariable Poisson, negative binomial, and logistic regression models.

Poisson regression analysis used robust standard error estimates (Cameron & Trivedi, 1998). A full Poisson regression model was produced containing all baseline variables identified as candidate covariates. This full model had the smallest conditional variance of Poisson models that were considered, and was used to determine whether overdispersion will make Poisson regression models unsuitable. Overdispersion was examined visually through plots of observed proportions and predicted mean probabilities of counts of episodes of needle sharing at follow-up to determine how well the model fit the observed data (Cameron & Trivedi, 2001). A full Poisson regression model with an overdispersion factor was produced (i.e., a negative binomial regression model). Whether significant overdispersion existed was formally tested through the likelihood ratio test comparing the models with and without the overdispersion factor (Long & Freese, 2001).

Reduced Poisson regression models were produced by removing predictor variables (other than group) from the full Poisson model. The reduced Poisson regression model was compared with the full Poisson regression model with the likelihood ratio test. Tests for differences in the rate of risk behaviors in the intervention and control groups were conducted using the associated z-statistic.

A full negative binomial regression model was developed in similar fashion. A reduced negative binomial regression model was produced through backward stepwise negative binomial regression using the likelihood ratio test for excluded variables. The reduced negative binomial regression model was evaluated through goodness-of-fit statistics, comparisons of the full and reduced models using the likelihood ratio test, plots

of the observed proportions and predicted mean probabilities of counts, and plots of deviance residuals (Cameron & Trivedi, 1998). The reduced and full Poisson and negative binomial regression models were compared through plots of observed proportions of counts minus predicted mean counts for each of the models.

Analyses conducted with dichotomized outcomes followed a similar pattern to the Poisson and negative binomial regression analyses. Analyses began with univariate tests of association between group and other independent variables and the dependent variable using the Pearson chi-square statistic or the Mantel-Haenszel chi-square statistic, as appropriate. All potential independent variables were examined individually in logistic regression models of any needle sharing at follow-up with any needle sharing at baseline as a covariate. A full logistic regression model of any needle sharing at follow-up was developed containing all baseline variables identified as good candidates for covariates. A reduced model was produced through backward step-wise logistic regression. The reduced model was compared with the full model using the likelihood ratio test. Tests for differences in the odds of risk behaviors in the intervention and control groups were conducted using the associated Wald statistic.

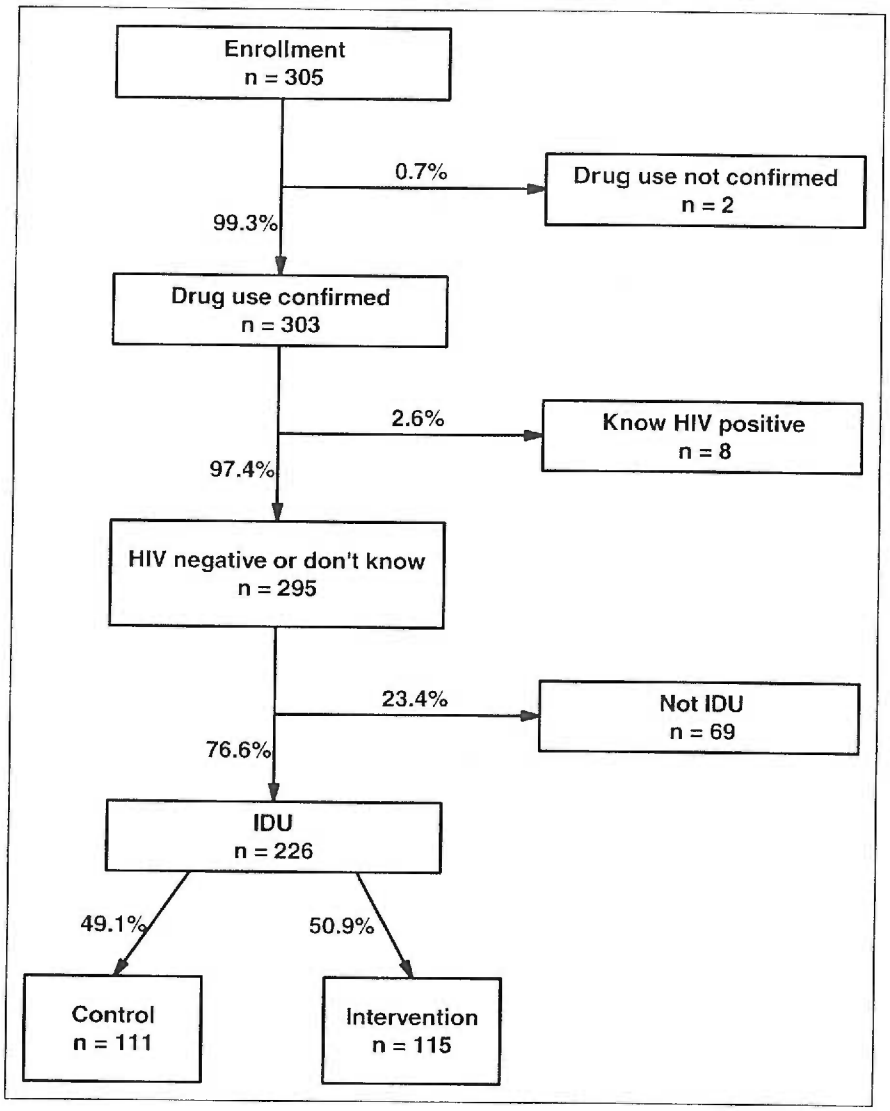
Stata 7.0 (StataCorp, 2001) was used for conducting the Poisson and negative binomial regression analyses, with additional commands written by Long and Freese (2001). SPSS 11.0 (SPSS Statistical Software, 2001) was used for all other analyses.

RESULTS

A total of 305 IDUs and crack users were enrolled from 11/94 to 2/95 and from 5/95 to 2/96. Drug use at baseline could not be confirmed through positive UA or fresh track marks for one intervention and one control subject. These two subjects were excluded from analysis (see Figure 3). During the baseline assessment, eight (two intervention and six control) subjects reported being told that they were infected with HIV. Of the 295 remaining subjects, 226 (76.6%) reported injection drug use in the last 30 days at the baseline assessment. One hundred and eleven (49.1%) were randomized into the control group and 115 (50.9%) into the intervention group. The subjects were 62% male; 55% white, 36% African American, 3% Hispanic, 2% Asian or Pacific Islander, and 3% Native American; 70% had completed high school education; 21% were employed; and the mean age was 37 years (range 18 to 61 years). Two subjects completed the interviews in Spanish, and the remainder in English.

Of the 226 subjects, 155 completed the follow-up assessment. Two subjects (both from the intervention group) completed the follow-up assessment outside of the predefined assessment window of five to nine months since baseline assessment, and were treated as lost to follow-up. Of the 226 subjects with acceptable baseline data, 153 (68%) had acceptable follow-up data.

Figure 3. Subjects meeting inclusion criteria and randomization into intervention and control groups.



Group Differences at Baseline and Attrition

In a comparison of all control and intervention subjects who entered the study, no differences were found on demographic variables (all $p>.20$) with the exception of education level (see Table 1). Subjects in the intervention group were more likely to have

at least a high school education (76%) compared to subjects in the control group (64%) ($\chi^2_{(1)} = 4.27$, p=.03). Subjects in the control group were somewhat more likely to have had multiple sex partners in the last 30 days (26%) than subjects in the intervention group (26%) ($\chi^2_{(1)} = 2.30$, p=.13).

Of the 115 intervention subjects and 111 control subjects, 82 (71%) and 71 (64%) completed the follow-up assessment, respectively. The difference in follow-up rate between the two groups was not statistically significant ($\chi^2_{(1)} = 1.39$, p = 0.24). No significant differences were found between subjects who did and did not complete the follow-up on any of the demographic or baseline risk variables (data not shown).

Among subjects with follow-up data, subjects in the intervention group were somewhat more likely to have completed high school (77%) than subjects in the control group (65%) ($\chi^2_{(1)} = 2.69$, p = 0.10) (see Table 2). No other significant differences were found on the demographic or baseline risk variables.

Table 1. Baseline characteristics of subjects in the control and intervention groups.

	control		intervention		Total	
	n	%	n	%	n	%
Gender						
Male	69	62.2%	76	66.1%	145	64.2%
Female	42	37.8%	39	33.9%	81	35.8%
	111		115		226	100.0%
Race/Ethnicity						
African American	28	25.2%	24	20.9%	52	23.0%
White	70	63.1%	81	70.4%	151	66.8%
Hispanic	4	3.6%	3	2.6%	7	3.1%
Asian/Pacific Islander	3	2.7%	1	0.9%	4	1.8%
Native American	3	2.7%	3	2.6%	6	2.7%
Other	3	2.7%	3	2.6%	6	2.7%
Total	111		115		226	100.0%
Age						
18-24	7	6.3%	9	7.8%	16	7.1%
25-34	37	33.3%	34	29.6%	71	31.4%
35-44	48	43.2%	56	48.7%	104	46.0%
44+	19	17.1%	16	13.9%	35	15.5%
Total	111		115		226	100.0%
Completed High School/GED*						
No	40	36.0%	27	23.5%	67	29.6%
Yes	71	64.0%	88	76.5%	159	70.4%
Total	111		115		226	100.0%
Employed						
No	90	81.1%	89	77.4%	179	79.2%
Yes	21	18.9%	26	22.6%	47	20.8%
Total	111		115		226	100.0%
Crack Use at Baseline						
No	44	39.6%	50	43.5%	94	41.6%
Yes	67	60.4%	65	56.5%	132	58.4%
Total	111		115		226	100.0%
Sex last 30 days						
No	34	30.6%	45	39.1%	79	35.0%
Yes	77	69.4%	70	60.9%	147	65.0%
	111		115		226	100.0%
Number of partners						
0-1	87	78.4%	99	86.1%	186	82.3%
2+	24	21.6%	16	13.9%	40	17.7%
Total	111		115		226	100.0%
Sex with IDU						
No	58	52.3%	64	55.7%	122	54.0%
Yes	53	47.7%	51	44.3%	104	46.0%
Total	111		115		226	100.0%
Injected with shared needle						
No	60	54.1%	67	58.3%	127	56.2%
Yes	51	45.9%	48	41.7%	99	43.8%
Total	111		115		226	100.0%

*p<.05.

Cessation of Injection Drug Use

Of the 82 intervention and 71 control subjects with follow-up data, 66 (80.5%) and 53 (74.6%) injected drugs at follow-up, respectively ($\chi^2_{(1)} = 0.75$, p = 0.39; OR = 1.40, 95% CI = 0.65, 3.01). None of the baseline variables were significantly associated with injection drug use at follow-up (see Table 3). Individuals who used crack cocaine at baseline were somewhat less likely to inject drugs at follow-up than subjects who did not use crack ($\chi^2_{(1)} = 3.58$, p = 0.06; OR = 0.45, 95% CI = 0.19, 1.04). Of the 91 subjects used crack at baseline, 66 (72.5%) injected in the last 30 days at follow-up. Of the 62 subjects who did not use crack at baseline, 53 (85.5%) injected in the last 30 days at follow-up.

Table 3. Baseline characteristics of subjects who did and did not inject drugs at follow-up.

		Injection drug use at follow-up					
		No		Yes			
Baseline variable		N	(%)	N	(%)	chi-sq	p-value
Group	Control	18	(25.4)	53	(74.6)	0.75	0.39
	Intervention	16	(19.5)	66	(80.5)		
Gender	Male	22	(22.7)	75	(77.3)	0.03	0.86
	Female	12	(21.4)	44	(78.6)		
White	No	13	(25.0)	39	(75.0)	0.32	0.55
	Yes	21	(20.8)	80	(79.2)		
Age	18-24	2	(16.7)	10	(83.3)	3.95	0.27
	25-34	10	(20.0)	40	(80.0)		
	35-44	20	(28.6)	50	(71.4)		
	44+	2	(9.5)	19	(90.5)		
Completed high sch./GED	No	11	(25.0)	33	(75.0)	0.28	0.60
	Yes	23	(21.1)	86	(78.9)		
Employed	No	25	(20.8)	95	(79.2)	0.62	0.43
	Yes	9	(27.3)	24	(72.7)		
Crack use	No	9	(14.5)	53	(85.5)	3.58	0.06
	Yes	25	(27.5)	66	(72.5)		
Sex last 30 days	No	11	(20.4)	43	(79.6)	0.17	0.68
	Yes	23	(23.2)	76	(76.8)		
Number of partners	0-1	25	(20.2)	99	(79.8)	1.61	0.20
	2+	9	(31.0)	20	(69.0)		
Sex with IDU	No	18	(22.2)	63	(77.8)	0	1.00
	Yes	16	(22.2)	56	(77.8)		
Used shared needle	No	18	(20.7)	69	(79.3)	0.27	0.60
	Yes	16	(24.2)	50	(75.8)		

A multivariable backward stepwise logistic regression ($p_{Enter} = 0.10$, $p_{Remove} = 0.20$) was conducted with group assignment forced into the model and with other baseline variables associated with injection drug use at follow-up at $p < 0.30$, including crack use ($p = 0.06$), age as a nominal variable ($p = 0.27$), and multiple sex partners ($p = 0.20$). The

final model, containing group assignment and crack use at baseline is presented in Table 4. The adjusted odds ratios in the multivariable model differed little from the odds ratios in the univariable models. Injection drug use at follow-up does not appear to be associated with group assignment.

Table 4. Parameter estimates, significance levels, and odds ratios with 95% confidence intervals for reduced logistic regression model of injection drug use at follow-up.

Baseline variable	Coef.	Std. Err.	z	p	OR	LB	UB
Group	0.310	0.395	0.62	0.433	1.363	0.629	2.954
Crack use	-0.790	0.431	3.36	0.067	0.454	0.195	1.057
constant	1.606	0.413	15.10	0.000	4.983		

Frequency of Injecting and Needle Sharing at Baseline and Follow-up

The mean frequency of injecting and needle sharing at baseline and follow-up among intervention and control subjects who injected at baseline and follow-up are presented in Table 5. The mean number of injections did not differ between subjects in the intervention and control group at baseline (Mann-Whitney U = -0.28, p = 0.78) or at follow-up (Mann-Whitney U = -0.34, p = 0.74). While the mean number of episodes of needle sharing at baseline appears dramatically higher among control subjects than intervention subjects, no significant difference was found between the groups in the non-parametric test for frequency of sharing at baseline (Mann-Whitney U = -1.24, p = 0.22) or at follow-up (Mann-Whitney U = -1.20, p = 0.23).

Table 5. Mean frequencies and standard deviations of injecting and needle sharing at baseline and follow-up among control and intervention subjects who injected at baseline and follow-up.

Variable		Control (n=53)	Intervention (n=66)
Injection frequency			
Baseline	mean	80.0	82.9
	(SD)	(11.0)	(11.0)
Follow-up	mean	58.4	60.1
	(SD)	(73.1)	(64.6)
Sharing frequency			
Baseline	mean	14.8	5.8
	(SD)	(37.7)	(19.8)
Follow-up	mean	4.9	6.2
	(SD)	(14.2)	(19.2)

The Wilcoxon signed ranks test was employed to examine changes in behavior from baseline to follow-up within groups. Among injectors at follow-up, frequency of injection was significantly lower at follow-up than baseline for the intervention group (z = -3.27, $p < 0.001$) and the control group (z = -2.01, $p = 0.04$); frequency of injecting with a shared needle was significantly lower at follow-up than baseline for the control group (z = -2.00, $p < .05$) but not for the intervention group (z = -0.62, $p = 0.54$).

Figures 4 and 5 show scatterplots of times shared at follow-up by times shared at baseline for subjects in the control and intervention groups, and Figures 6 and 7 show the distributions of needle sharing at baseline and follow-up for the two groups when the frequencies of needle sharing are categorized.

Figure 4. Scatterplot of episodes of injecting with a shared needle in the last 30 days at baseline and follow-up by group among subjects who injected at baseline and follow-up.

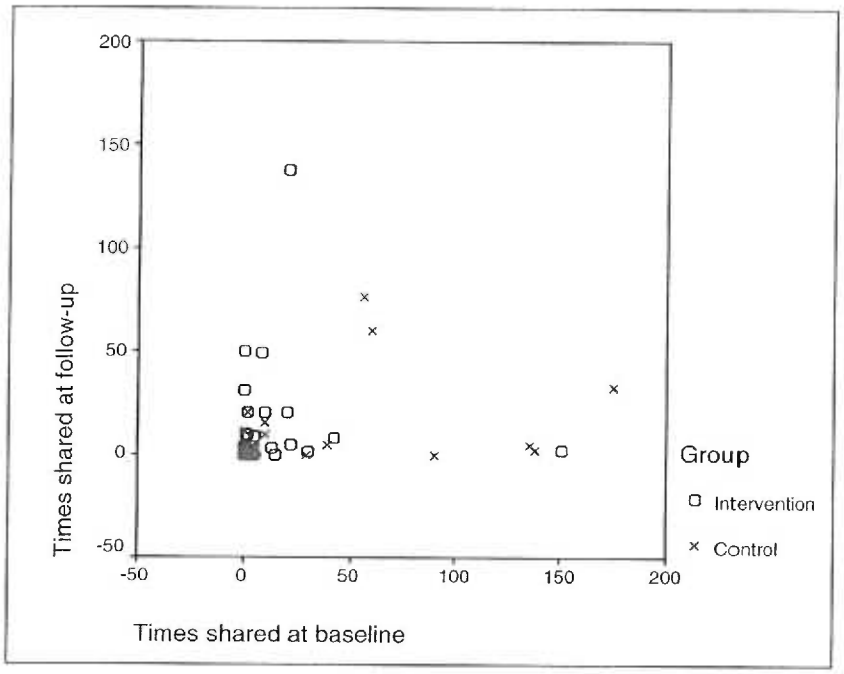


Figure 5. Scatterplot of episodes of injecting with a shared needle in the last 30 days at baseline and follow-up by group among subjects who injected at baseline and follow-up limited to subjects who injected 50 or fewer times at baseline and follow-up.

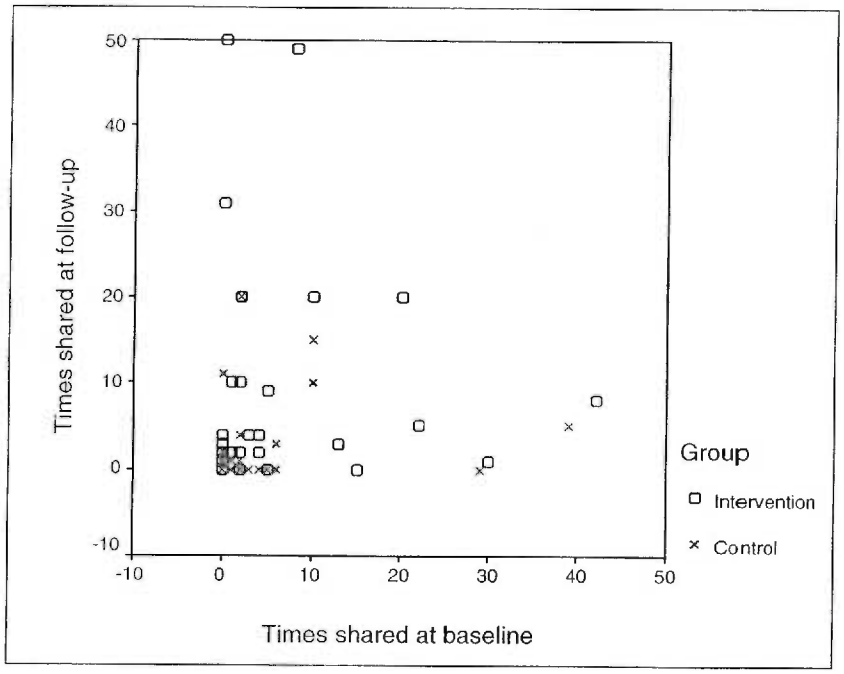


Figure 6. Percent of subjects who injected with a shared needle 0, 1, 2, 3 to 5, 6 to 20 and 21 or more times in the last 30 days at baseline by group among subjects who injected at baseline and follow-up (n = 118).

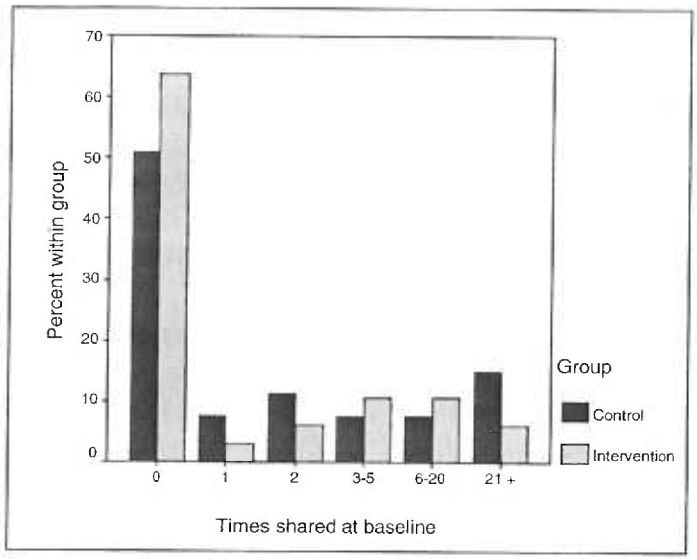


Figure 7. Percent of subjects who injected with a shared needle 0, 1, 2, 3 to 5, 6 to 20 and 21 or more times in the last 30 days at follow-up by group among subjects who injected at baseline and follow-up (n = 118).

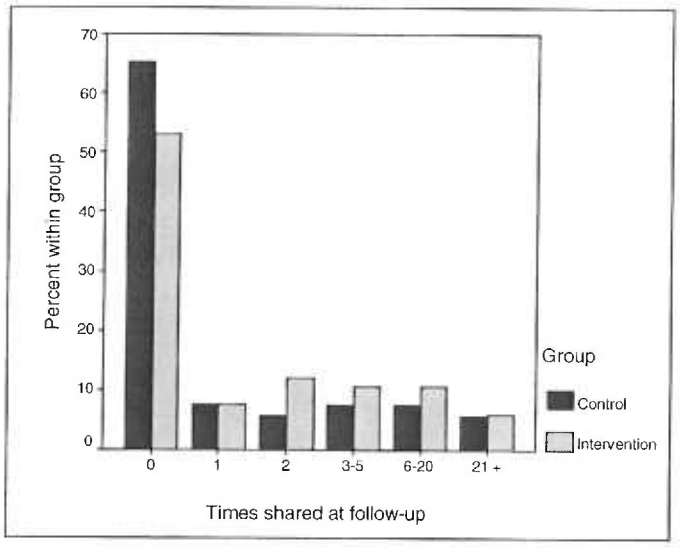


Figure 4 shows more subjects with high frequencies of needle sharing at baseline

Table 6. Coding of independent variables for modeling of episodes of needle sharing at follow-up.

Baseline variable	Levels
Group assignment	control/intervention
Gender	male/female
Ethnicity	White/non-White
Age group	18-24 / 25-34 / 35-44 / 45+
High school education	yes/no
Employed	yes/no
Used crack	yes/no
Days had sex	count
Number of sex partners	0 / 1 / 2 / 3 / 4 / 5+
Sex with an IDU	yes/no
Times injected	count
Times shared	count

Table 7. Regression coefficients of each of the baseline variables, controlling for episodes of needle sharing at baseline, in separate Poisson regression models of episodes of sharing at follow-up using robust standard errors with standard errors, significance levels, and incidence rate ratios (expB) with 95% confidence intervals.

Baseline variable	Coef.	Std. Err.	z	p	expB	LB	UB
Group	0.491	0.550	0.89	0.37	1.63	0.56	4.80
Gender	0.767	0.503	1.53	0.13	2.15	0.80	5.77
White	0.581	0.471	1.23	0.22	1.79	0.71	4.50
Age	-0.550	0.441	-1.25	0.21	0.58	0.24	1.37
Education	-0.261	0.691	-0.38	0.71	0.77	0.20	2.99
Employment	0.468	0.550	0.85	0.39	1.60	0.54	4.69
Crack use	-0.086	0.639	-0.14	0.89	0.92	0.26	3.21
Days had sex	0.045	0.020	2.23	0.03	1.05	1.01	1.09
Number partners	0.339	0.092	3.68	0.00	1.40	1.17	1.68
Sex with IDU	1.376	0.575	2.39	0.02	3.96	1.28	12.21
Times injected	0.000	0.002	0.00	1.00	1.00	1.00	1.00

Variables significantly associated with episodes of needle sharing at follow-up in these analyses included days had sex at baseline, number of sexual partners at baseline, and sex with an IDU at baseline. Group assignment was not associated with episodes of needle sharing at follow-up when controlling for episodes of needle sharing at baseline. A full Poisson regression model was constructed using all baseline variables identified in

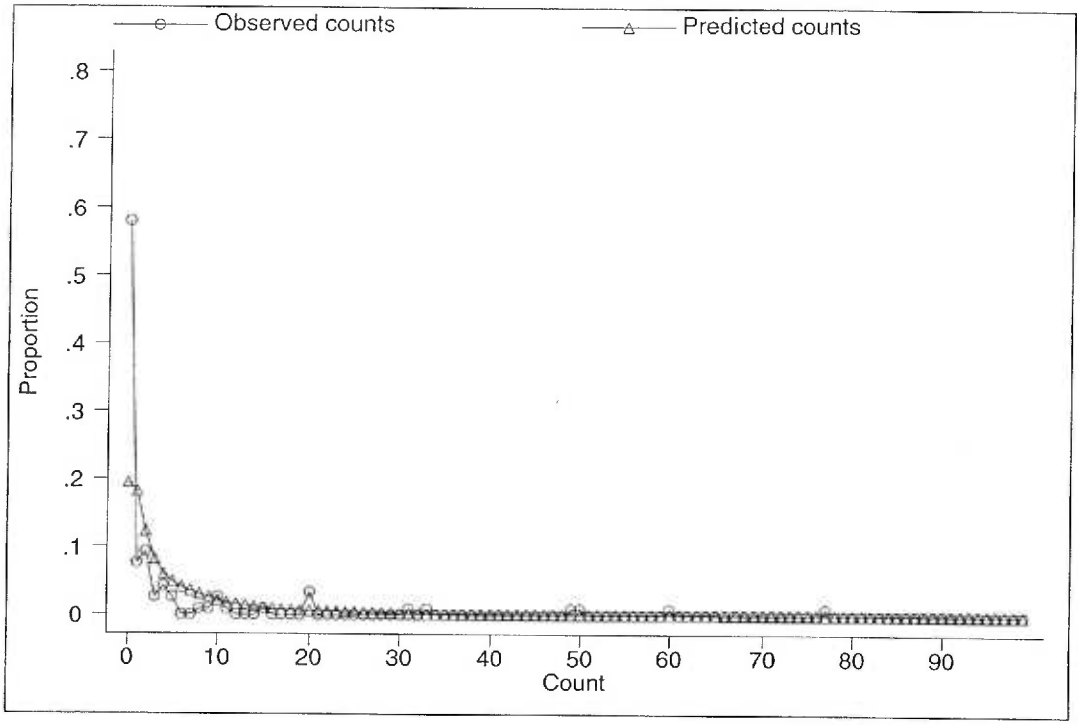
these analyses as associated with injection drug use at follow-up at $p < 0.25$ (see Table 8). The deviance of the full Poisson regression model was 1716.52. In the full Poisson regression model the same variables, needle sharing at baseline, number of sexual partners at baseline, and sex with an IDU at baseline, remain significantly associated with episodes of needle sharing at follow-up. Controlling for the other variables in the equation, the regression coefficient for group assignment is not significant.

Table 8. Regression coefficients of the full Poisson regression model of episodes of needle sharing at follow-up with standard errors, significance levels, and incidence rate ratios (expB) with 95% confidence intervals.

Baseline variable	Coef.	Std. Err.	z	p	expB	LB	UB
Group	0.773	0.522	1.48	0.14	2.17	0.78	6.03
Gender	0.740	0.505	1.47	0.14	2.10	0.78	5.64
White	0.689	0.546	1.26	0.21	1.99	0.68	5.80
Age	-0.328	0.339	-0.97	0.33	0.72	0.37	1.40
Days had sex	0.008	0.031	0.25	0.80	1.01	0.95	1.07
Number partners	0.392	0.188	2.08	0.04	1.48	1.02	2.14
Sex with IDU	1.271	0.461	2.76	0.01	3.56	1.44	8.80
Times shared	0.013	0.004	3.38	0.00	1.01	1.01	1.02
Constant	-0.872	1.430	-0.61	0.54	0.42	0.03	6.89

The observed proportions and the mean predicted probability for each count from zero to 99 are presented in Figure 8. The full Poisson regression model of episodes of needle sharing at follow-up is a poor fit. Zero counts are under-estimated, and low counts are over-estimated, indicating that overdispersion may be present in the data.

Figure 8. Observed proportions of counts and Poisson full-model predicted mean counts of episodes of needle sharing at follow-up.



A reduced Poisson regression model was produced by removing terms that were not associated with episodes of needle sharing at follow-up at $p < 0.20$ (see Table 9).[2] The deviance of the reduced Poisson regression model was 1794.41. In the reduced Poisson model increased counts of needle sharing at follow-up are significantly associated with being female, having had more sex partners at baseline, having had sex with an IDU at baseline, and higher counts of needle sharing at baseline. While subjects in the intervention group shared more frequently at follow-up than subjects in the control group, the difference did not reach significance (incidence rate ratio [IRR] = 2.51, 95% CI = 0.81, 7.82).

2 Stata does not allow for stepwise Poisson regression when using robust standard error estimates.

Table 9. Regression coefficients of the reduced Poisson regression model of episodes of needle sharing at follow-up with standard errors, significance levels, and incidence rate ratios (expB) with 95% confidence intervals.

Baseline variable	Coef.	Std. Err.	z	p	expB	LB	UB
Group	0.922	0.579	1.59	0.11	2.51	0.81	7.82
Gender	1.050	0.527	1.99	0.05	2.86	1.02	8.02
Number partners	0.387	0.153	2.53	0.01	1.47	1.09	1.99
Sex with IDU	1.412	0.514	2.75	0.01	4.10	1.50	11.23
Times shared	0.013	0.004	3.68	0.00	1.01	1.01	1.02
Constant	-2.080	1.303	-1.60	0.11	0.12	0.01	1.60

Negative Binomial Regression of Episodes of Needle Sharing at Follow-up

Based on the possibility of overdispersion in the data, negative binomial regression analyses were conducted. Each baseline variable was modeled individually against number of episodes of needle sharing at follow-up while controlling for episodes of needle sharing at baseline (see Table 10). Baseline variables significantly associated with episodes of needle sharing at follow-up after controlling for sharing at baseline include group assignment and having had sex with an IDU at baseline. Other baseline variables associated with episodes of needle sharing at follow-up at $p < 0.20$ include age as an ordinal variable, employment status, days had sex in the last 30 days, and number of sex partners in the last 30 days.

A full negative binomial regression model was constructed using all baseline variables identified in these analyses as associated with injection drug use at follow-up at $p < 0.25$ (see Table 11). Variables significantly associated with the number of episodes of needle sharing at follow-up include group, sex with an IDU at baseline, and episodes of sharing at baseline, with the coefficient "ln(alpha)" representing the natural log of the overdispersion parameter.

Table 10. Regression coefficients of each of the baseline variables, controlling for episodes of needle sharing at baseline, in separate negative binomial regression models of episodes of sharing at follow-up with standard errors, significance levels, and incidence rate ratios (expB) with 95% confidence intervals.

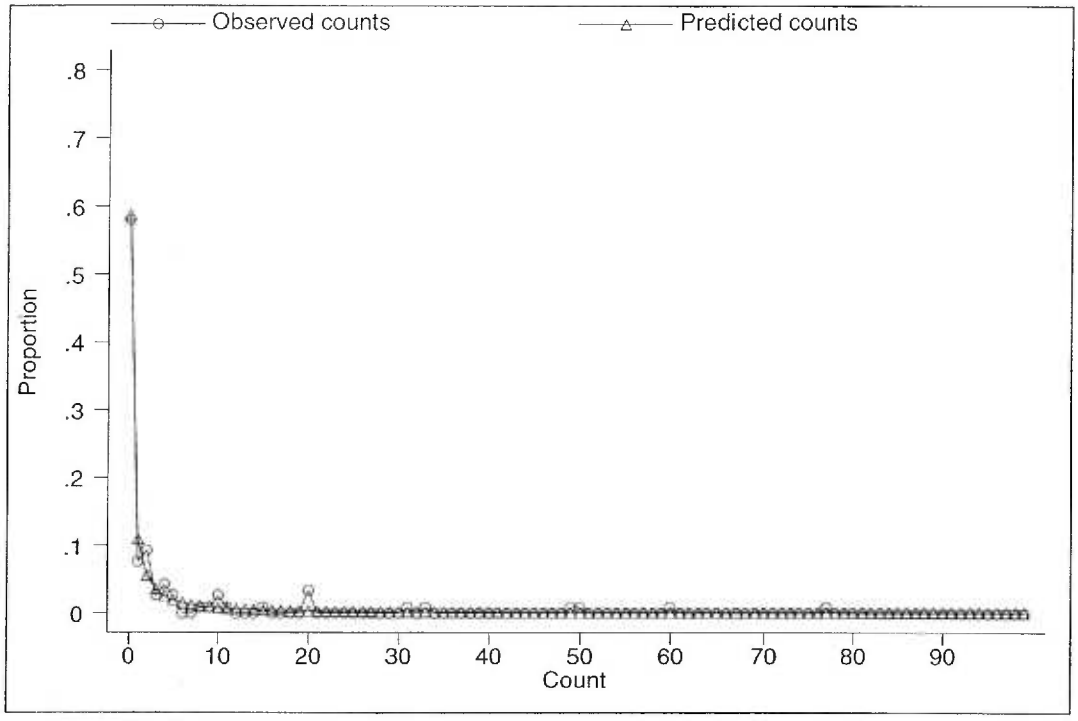
Baseline variable	Coef.	Std. Err.	z	p	expB	LB	UB
Group	1.105	0.477	2.32	0.02	3.02	1.19	7.68
Gender	0.491	0.530	0.93	0.35	1.63	0.58	4.62
White	0.212	0.527	0.40	0.69	1.24	0.44	3.47
Age	-0.426	0.253	-1.69	0.09	0.65	0.40	1.07
Education	-0.295	0.528	-0.56	0.58	0.74	0.26	2.10
Employment	0.901	0.592	1.52	0.13	2.46	0.77	7.86
Crack use	0.369	0.478	0.77	0.44	1.45	0.57	3.69
Days had sex	0.043	0.032	1.33	0.18	1.04	0.98	1.11
Number partners	0.626	0.339	1.85	0.06	1.87	0.96	3.63
Sex with IDU	1.710	0.444	3.85	0.00	5.53	2.32	13.20
Times injected	0.002	0.003	0.48	0.63	1.00	1.00	1.01

Table 11. Regression coefficients of the full negative binomial regression model of episodes of needle sharing at follow-up with standard errors, significance levels, and incidence rate ratios (expB) with 95% confidence intervals.

Baseline variable	Coef.	Std. Err.	z	p	expB	LB	UB
Group	1.054	0.465	2.27	0.02	2.87	1.15	7.14
Age	-0.322	0.240	-1.34	0.18	0.72	0.45	1.16
Employment	0.892	0.540	1.65	0.10	2.44	0.85	7.03
Days had sex	0.028	0.034	0.82	0.41	1.03	0.96	1.10
Number partners	0.251	0.236	1.07	0.29	1.29	0.81	2.04
Sex with IDU	1.806	0.428	4.22	0.00	6.08	2.63	14.08
Times shared	0.033	0.014	2.36	0.02	1.03	1.01	1.06
Constant	-0.381	1.045	-0.36	0.72	0.68	0.09	5.29
ln(alpha)	1.429	0.188					

The deviance of the full negative binomial regression model was 443.43. The likelihood ratio test comparing the full negative binomial and Poisson regression models showed that the negative binomial is a significantly better fit ($X^2_{(1)} = 1366$, $p < .0005$). The observed proportions and the mean predicted probability for each count from zero to 99 are presented in Figure 9. The full negative binomial regression model of episodes of needle sharing at follow-up appears to be a better fit than the Poisson regression model.

Figure 9. Observed proportions of counts and negative binomial full-model predicted mean counts of episodes of needle sharing at follow-up.



A reduced model was produced through backward stepwise negative binomial regression with the significance level set at $p_{Enter} = 0.10$ and $p_{Remove} = 0.20$. The final reduced negative binomial regression model is presented in Table 12. Terms in the final reduced model included group, employment status, number of sex partners, sex with an IDU, and episodes of injecting with a shared needle. The deviance of the reduced negative binomial regression model was 445.48. Controlling for the other variables in the model, the number of injections with a shared needle among subjects in the intervention group who injected at follow-up were almost three times higher than control subjects who reported injection drug use at follow-up (IRR = 2.94, 95% CI = 1.18, 7.35). Higher counts of needle sharing were reported among subjects who were employed at baseline, had

more sex partners at baseline, had sex with an IDU at baseline, and had injected more often with a shared needle at baseline. Examination of second-order interaction terms among the variables in the reduced negative binomial regression model revealed no significant interactions. The likelihood-ratio test comparing the full and reduced negative binomial regression models showed no significant difference in the variance accounted for in the two models ($\chi^2_{(2)} = 2.05$, p=.36).

Table 12. Regression coefficients of the reduced negative binomial regression model of episodes of needle sharing at follow-up with standard errors, significance levels, and incidence rate ratios (expB) with 95% confidence intervals.

Baseline variable	Coef.	Std. Err.	z	p	expB	LB	UB
Group	1.08	0.47	2.31	0.021	2.94	1.18	7.35
Employment	1.08	0.54	2.00	0.045	2.95	1.02	8.52
Number sex partners	0.39	0.19	2.04	0.041	1.48	1.02	2.16
Sex with IDU	1.82	0.43	4.20	0.000	6.14	2.63	14.34
Times shared	0.04	0.01	2.77	0.006	1.04	1.01	1.07
Constant	-1.60	0.51	-3.17	0.002	0.20	0.07	0.54
ln(alpha)	1.46	0.19					

For counts zero to 20, the differences between the observed proportions of counts and the mean predicted probability for counts was calculated for the full and reduced Poisson and negative binomial regression models. Plots of the observed proportions minus predicted probabilities show that the reduced negative binomial model produces almost identical predictions to the full negative binomial model, and that the negative binomial models produce more accurate predictions than the Poisson models (See Figure 10).

For the reduced negative binomial regression model, predicted probabilities of counts zero through nine for episodes of needle sharing were calculated for each of the

groups while holding other variables in the model at their mean values. The plots of these predicted probabilities (see Figure 11) show higher predicted probabilities for counts zero through two for the control group and higher predicted probabilities for counts three through nine for the intervention group.

Figure 10. Observed proportions of counts minus predicted probabilities of counts for full and reduced Poisson and negative binomial (NBR) models of episodes of needle sharing at follow-up.

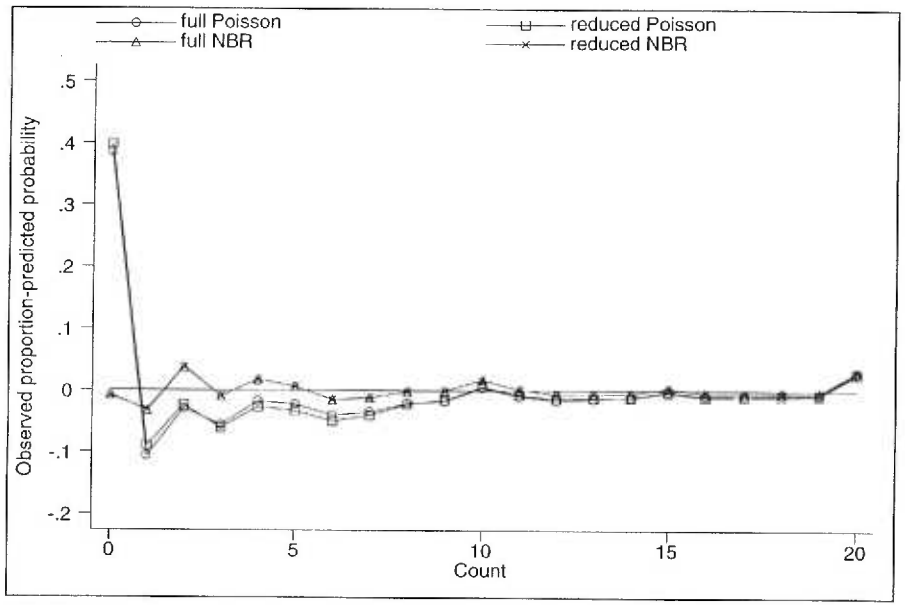
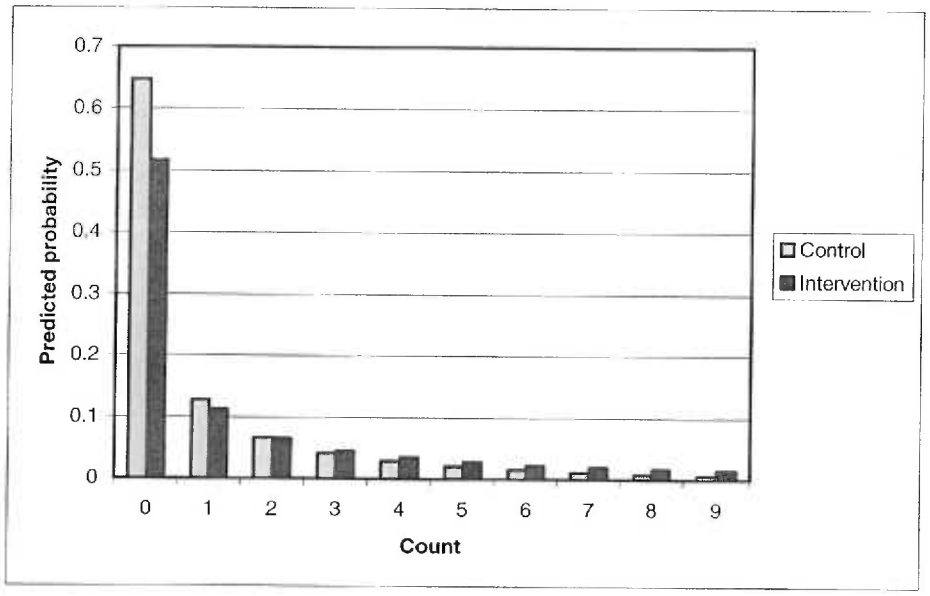


Figure 11. Predicted counts of episodes of needle sharing at follow-up from the reduced negative binomial regression model for the control and intervention groups with other variables held at their mean values.



Diagnostics for Reduced Negative Binomial Regression Model

Deviance residuals were calculated for the reduced negative binomial regression model (Cameron & Trivedi, 1998). The deviance residuals have mean = –0.48, variance = 0.56, and range = -1.59, 2.14. The deviance residuals were plotted against observed counts of needle sharing at follow-up (Figures 12 and 13), predicted mean counts of sharing at follow-up (Figures 14 and 15), and counts of sharing at baseline (Figure 16).

Figure 12. Plot of deviance residuals and observed counts of sharing at follow-up from reduced negative binomial regression model.

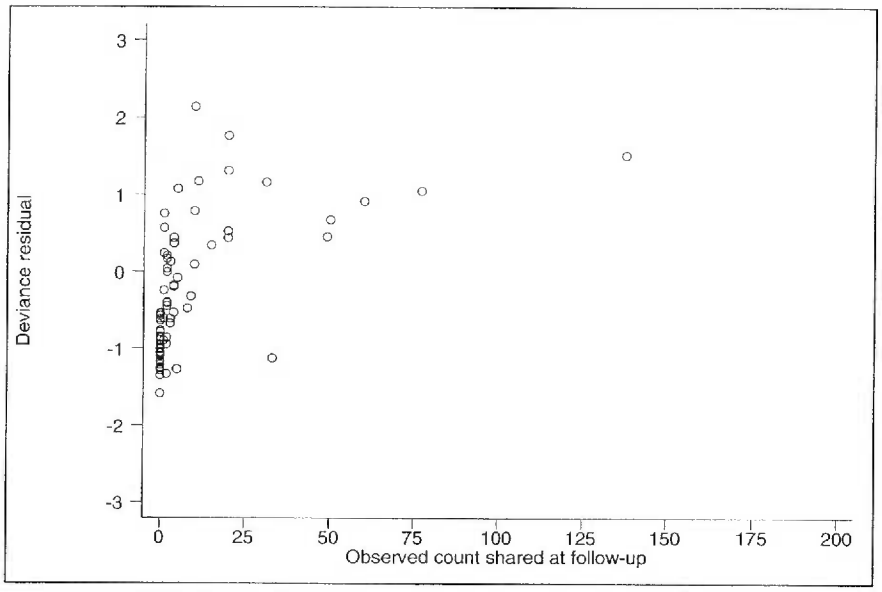


Figure 13. Plot of deviance residuals and observed values from reduced negative binomial regression model for observed values less than 25.

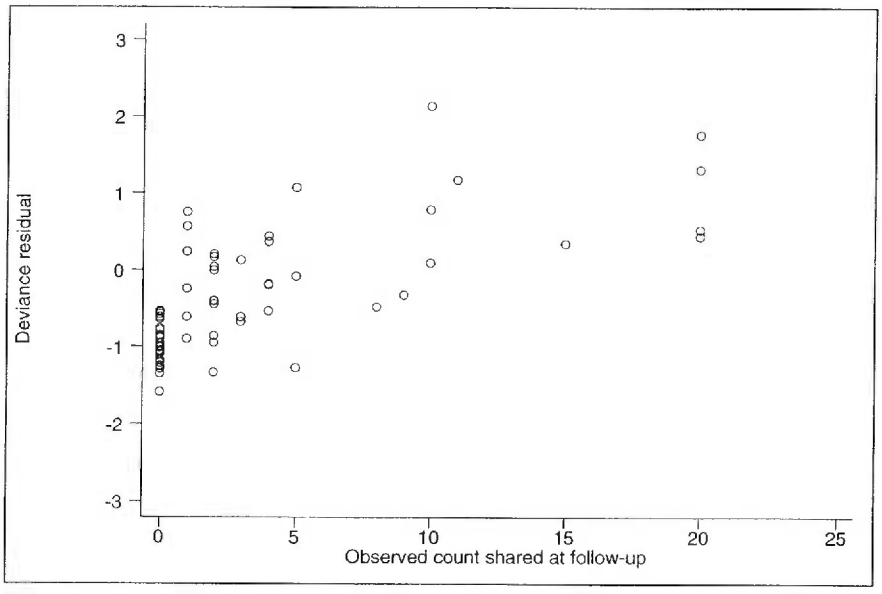


Figure 14. Plot of deviance residuals and predicted mean counts from reduced negative binomial regression model.

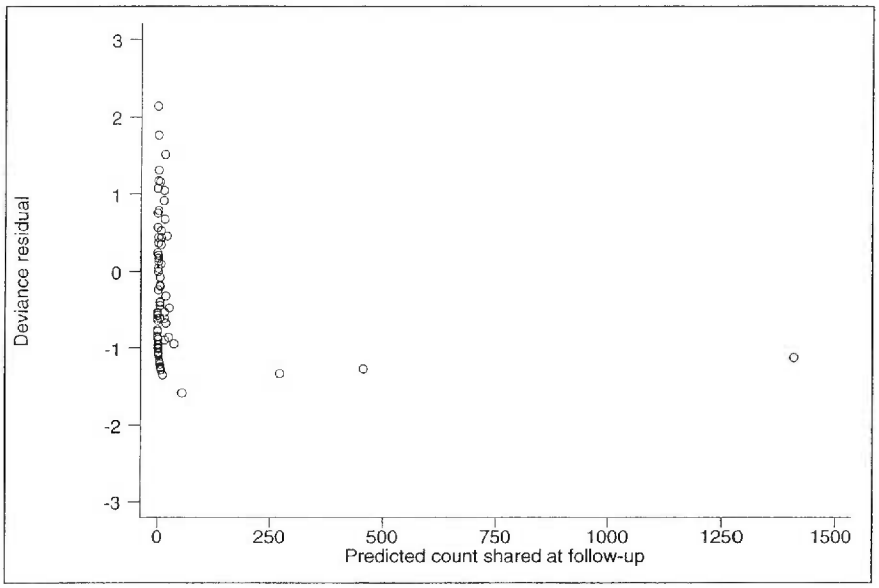


Figure 15. Plot of deviance residuals and predicted mean counts from reduced negative binomial regression model for predicted values less than 100.

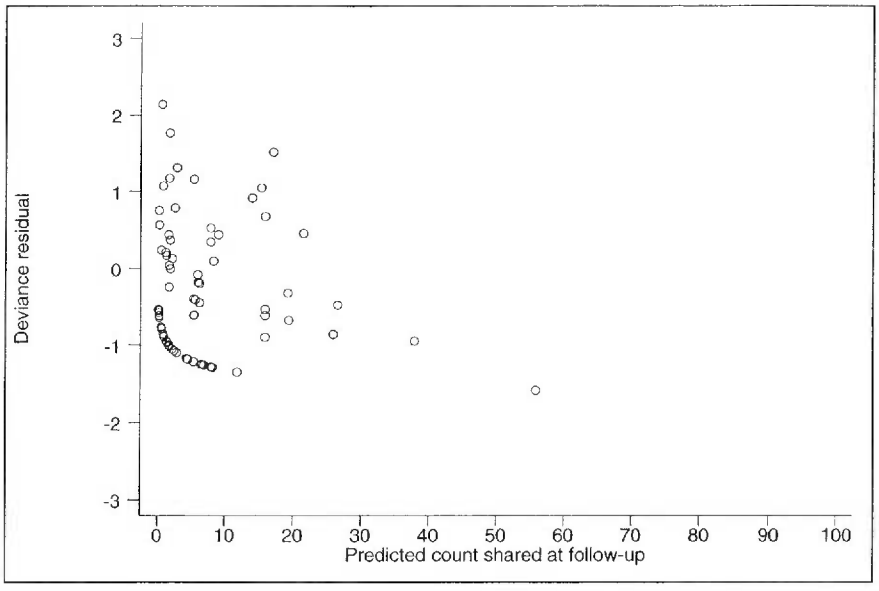
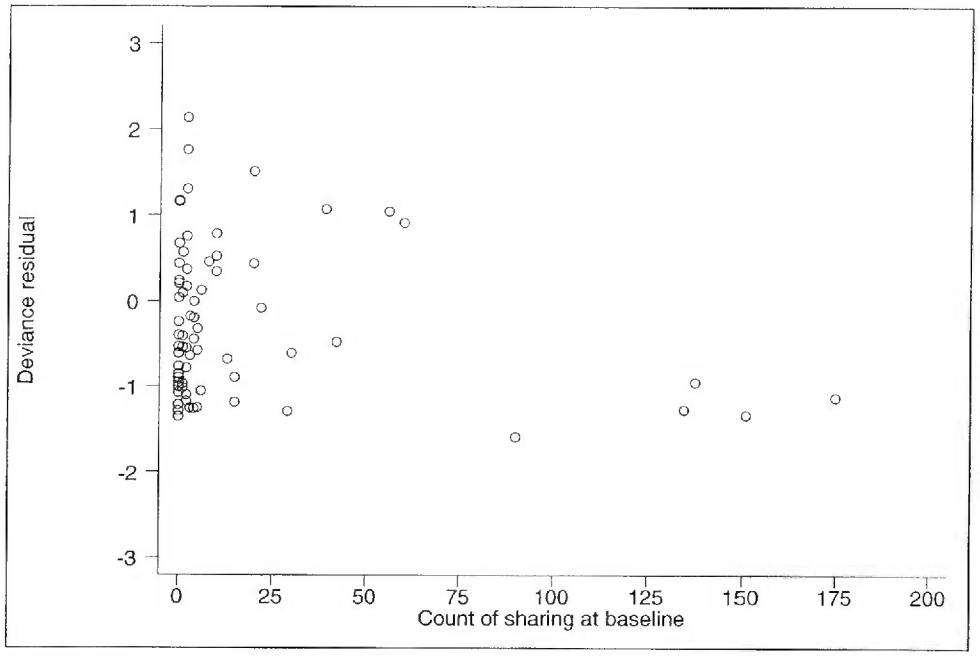


Figure 16. Plot of deviance residuals and counts of needle sharing at baseline from reduced negative binomial regression model.



Figures 12 and 13 show that the deviance residuals increase with increasing values of the dependent variable. This type of relationship is expected for negative binomial regression models (Cameron & Trivedi, 1998). Figures 14 and 15 show that the deviance residuals are more negative for higher predicted mean counts, indicating that the model does not fit well for higher predicted mean counts. A similar conclusion is drawn from Figure 16. Deviance residuals are more negative for subjects with higher counts of needle sharing at baseline, indicating that the model may not fit well for these subjects. An examination of the deviance residuals for subjects with different values of the other covariates in the reduced negative binomial regression model did not reveal any systematic relationships (data not presented).

Figures 17 and 18 present scatterplots of predicted mean counts by observed count of sharing at follow-up for the reduced negative binomial regression model with symbols representing counts of sharing at baseline. These figures show that high predicted counts are associated with high counts of sharing at follow-up.

To explore the effect of these outliers on the reduced negative binomial regression model, number of episodes of sharing at baseline and follow-up were Winsored (truncated) at 77. The Winsoring of outliers resulted in only minor changes in the regression coefficients (data not presented).

Figure 17. Scatterplot of predicted mean counts by observed count of sharing at follow-up for the reduced negative binomial regression model with symbols representing counts of sharing at baseline.

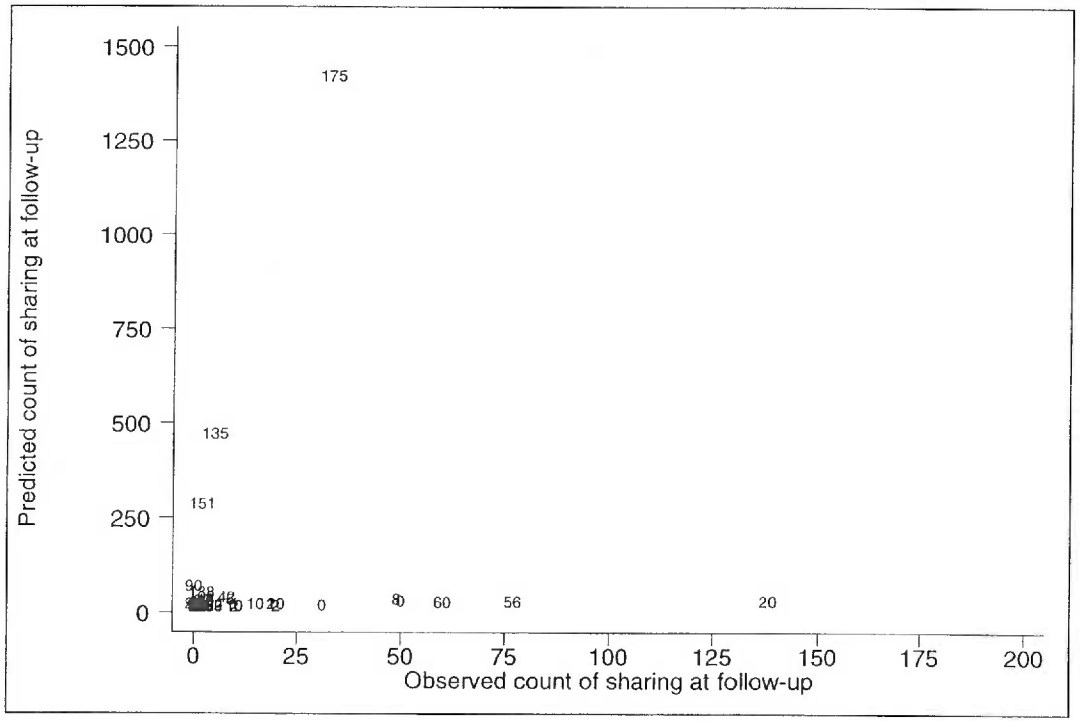
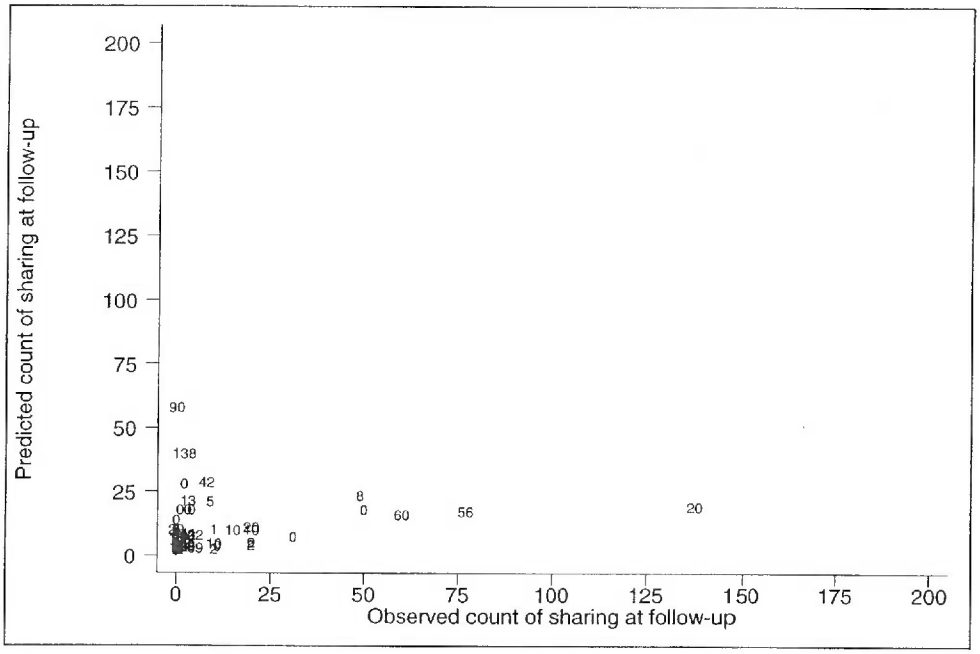


Figure 18. Scatterplot of predicted mean counts by observed counts of sharing at follow-up for the reduced negative binomial regression model with symbols representing counts of sharing at baseline limited to subjects with 50 or fewer predicted and observed counts of needle sharing at follow-up.



Logistic Regression Analysis of Any Needle Sharing at Follow-up

Needle sharing at follow-up was categorized as any versus no needle sharing in the last 30 days. A higher proportion of subjects in the intervention group reported needle sharing at follow-up (47%) than subjects in the control group (35%), but this difference was not significant ($\chi^2_{(1)} = 1.83$, p=.18). Table 13 presents the associations between baseline variables and reported needle sharing at follow-up. In these univariable tests, having had sex at baseline, having had sex with and IDU at baseline, and sharing needles at baseline were associated with sharing needles at follow-up.

Table 13. Associations between baseline characteristics and needle sharing at follow-up.

		Needle sharing at follow-up					
		No		Yes			
Baseline variable		N	(%)	N	(%)	chi-sq	p-value
Group	Control	34	(65.4)	18	(34.6)	1.83	0.18
	Intervention	35	(53.0)	31	(47.0)		
Gender	Male	43	(58.1)	31	(41.9)	0.01	0.92
	Female	26	(59.1)	18	(40.9)		
White	No	21	(55.3)	17	(44.7)	0.24	0.63
	Yes	48	(60.0)	32	(40.0)		
Age	18-24	4	(40.0)	6	(60.0)	1.97*	0.16
	25-34	23	(59.0)	16	(41.0)		
	35-44	28	(56.0)	22	(44.0)		
	44+	14	(73.7)	5	(26.3)		
Completed high sch./GED	No	19	(57.6)	14	(42.4)	0.83	0.66
	Yes	50	(58.8)	35	(41.2)		
Employed	No	58	(61.7)	36	(38.3)	1.98	0.16
	Yes	11	(45.8)	13	(54.2)		
Crack use	No	31	(59.6)	21	(40.4)	0.05	0.82
	Yes	38	(57.6)	28	(42.4)		
Sex last 30 days	No	33	(76.7)	10	(23.3)	9.3	0.002
	Yes	36	(48.0)	39	(52.0)		
Number of partners	0-1	59	(60.2)	39	(39.8)	0.71	0.40
	2+	10	(50.0)	10	(50.0)		
Sex with IDU	No	45	(72.6)	17	(27.4)	10.71	0.001
	Yes	24	(42.9)	32	(57.1)		
Used shared needle	No	51	(75.0)	17	(25.0)	18.05	0.00002
	Yes	18	(36.0)	32	(64.0)		

*Test of linear-by-linear association.

Each baseline variable was modeled individually against needle sharing at follow-up while controlling for needle sharing at baseline (see Table 14). Baseline variables significantly associated with needle sharing at follow-up after controlling for sharing at baseline include group assignment, having had sex in the last 30 days at baseline, and having had sex with an IDU at baseline. Other baseline variables associated with needle

sharing at follow-up at $p < 0.25$ include age as an ordinal variable and employment status.

Table 14. Odds ratios, 95% confidence intervals, and significance values of each of the baseline variables controlling for needle sharing at baseline in separate logistic regression models of sharing at follow-up.

Baseline variable	OR	95% CI		p-value
Group	2.08	0.99	4.39	0.054
Gender	0.85	0.40	1.80	0.68
White	0.96	0.45	2.03	0.90
Age	0.76	0.49	1.18	0.22
Completed high sch./GED	1.12	0.51	2.48	0.77
Employed	1.92	0.81	4.56	0.14
Crack use	0.78	0.38	1.62	0.51
Sex last 30 days	2.47	1.08	5.64	0.03
Multiple partners	0.68	0.27	1.73	0.42
Sex with IDU	2.66	1.27	5.56	0.01

In the logistic regression analysis a full model was constructed containing all predictor variables associated with needle sharing at follow-up at $p < 0.25$ after controlling for needle sharing at baseline (see Table 15). Multivariable backward stepwise logistic regression ($p_{Enter} = 0.10$, $p_{Remove} = 0.20$) was conducted with the full logistic regression model. Terms in the final reduced model included group, employment status at baseline, sex with an IDU at baseline, and injecting with a shared needle at baseline. The parameter estimates and associated statistical tests and significance values are presented in Table 16. Examination of second-order interaction terms among the variables in the reduced logistic regression model revealed no significant interactions.

Table 15. Parameter estimates, significance levels, and odds ratios with 95% confidence intervals for full logistic regression model of needle sharing at follow-up.

Baseline variable	Coef.	Std. Err.	z	p	OR	LB	UB
Group	0.91	0.47	3.83	0.05	2.49	1.00	6.23
Age	-0.20	0.27	0.55	0.46	0.82	0.48	1.39
Employed	1.10	0.56	3.81	0.05	2.99	1.00	8.99
Sex last 30 days	0.25	0.68	0.14	0.71	1.29	0.34	4.89
Sex with IDU	1.06	0.63	2.88	0.09	2.90	0.85	9.89
Needle sharing	1.90	0.48	15.96	<.001	6.71	2.64	17.06
Constant	-1.94	1.17	2.75	0.10	0.14		

Table 16. Parameter estimates, significance levels, and odds ratios with 95% confidence intervals for reduced logistic regression model of needle sharing at follow-up.

Baseline variable	Coef.	Std. Err.	z	p	OR	LB	UB
Group	0.94	0.47	4.10	0.04	2.56	1.03	6.38
Employed	1.11	0.56	3.97	0.05	3.04	1.02	9.05
Sex with IDU	1.26	0.44	8.00	0.005	3.51	1.47	8.37
Needle sharing	1.94	0.47	16.81	<.001	6.94	2.75	17.52
Constant	-2.62	0.56	22.27	<.001	0.07		

Controlling for the other variables in the model, subjects in the intervention group who injected at follow-up were over two and a-half times as likely to have injected with a shared needle at follow-up than control subjects who injected drugs at follow-up (OR = 2.56, 95% CI = 1.03, 6.38). Needle sharing was more likely to be reported among subjects who were employed at baseline, had sex with an IDU at baseline, and had used a shared needle at baseline.

Diagnostics for Reduced Logistic Regression Model

In logistic regression analysis, numerical problems can occur when zero counts arise in stratified contingency tables of cell counts of the outcome variable, when a collection of covariates completely separates the outcome groups, and when collinearity

occurs among the independent variables. These types of numerical problems are generally detected through extraordinarily large estimated standard errors (Hosmer & Lemeshow, 2001). The estimated standard errors in the final model are not excessively large. Examination of all possible combinations of the covariates in the reduced model shows no numerical problems (i.e., all of the cells of the table of outcome counts stratified by the covariates have counts greater than zero).

The correlations between the independent variables were examined for evidence of possible collinearity. There was a high correlation between sex with an IDU in the last 30 days and any sex in the last 30 days ($r = 0.71$), indicating that inclusion of both these variables in a logistic regression model could lead to collinearity. However, any sex in the last 30 days was not included in final negative binomial regression and logistic regression models. All other independent variable pairs had correlation coefficients of less than 0.35.

DISCUSSION

The primary aim of this study was to determine whether intervention subjects who received counseling and testing had lower levels of HIV-related needle risk behavior at follow-up than control subjects. This discussion first summarizes the findings of this study, including: baseline equivalence and attrition, cessation of injection drug use, changes in risk behavior over time within groups, the appropriateness of Poisson and negative binomial distributions for modeling HIV-related risk behavior, and differences between the intervention and control groups in the multivariable negative binomial regression model of number of episodes of needle sharing at follow-up and in the multivariate logistic regression model of any needle sharing at follow-up. Next, the discussion will provide an interpretation of the findings, including an evaluation of alternate explanations. Finally the discussion will address possible limitations of this study in regards to validity of the data, appropriateness of analytic strategies, and overall study design.

Baseline Equivalence and Attrition

Selection bias has been evident in previous NIDA Cooperative Agreement studies (CSR, Incorporated, 2001). The randomization procedures in this study appear to have been successful in minimizing baseline differences between the two groups. Of the eleven demographic and baseline risk variables examined, the groups differed only in education level, with more intervention than control subjects having obtained a high

school education. The overall follow-up rate of 68% is similar to the follow-up rate at other NIDA Cooperative Agreement sites (mean = 66%, range = 45-78%; CSR, Inc., 2001). No differences were found between subjects with and without follow-up data, indicating that subjects who completed the follow-up assessment were representative of subjects who completed the baseline assessment for the variables measured. Among subjects who completed the follow-up assessment, no differences were found between the two groups.

Cessation of Injection Drug Use at Follow-up

The main analyses of needle sharing at follow-up are limited to subjects who reported injection drug use at follow-up. Injection drug use at follow-up in the two groups was examined to determine whether including subjects who ceased injection drug use might lead to different results. Among subjects who completed the follow-up assessment 20% of intervention subjects and 25% of control subjects did not inject drugs at follow-up. Group assignment was not associated with cessation of injection drug use at follow-up in either univariable or multivariable models.

Injection drug using behaviors at baseline and follow-up were examined to describe the changes within groups over time and to identify any differences between the groups on the outcome measures at baseline. Among subjects who injected at follow-up, within-group comparisons of frequency of injection drug use from baseline to follow-up show similar rates and reductions in the two groups. Needle sharing among subjects who injected at follow-up show different results. The percent of control subjects who shared

needles decreased from 48.1% at baseline to 35.8% at follow-up, whereas the percent of intervention subjects who shared needles increased from 35.8% at baseline to 46.3% at follow-up. Among control subjects the mean number of injections with a shared needle decreased from 14.8 to 4.9 while in the intervention group the mean number of injections with a shared needle increased from 5.8 to 6.2. The decrease in needle sharing among control subjects but not among intervention subjects is similar to the reductions seen among subjects receiving the Standard Intervention in previous NIDA Cooperative Agreement studies.

Poisson and Negative Binomial Regression Models

Despite the appropriateness of Poisson-family distributions for modeling HIV-related risk behaviors, such models have rarely been employed in HIV prevention research. Poisson and negative binomial regression have the advantage of being able to model highly skewed distributions common in measures of HIV-related risk behavior without data reduction or transformation. The poor fit of the Poisson distribution is not surprising due to the assumption of the model of equidispersion—that the conditional variance is equal to the conditional mean. HIV risk behavior among IDUs is a complex outcome with multiple determinants (Des Jarlais et al., 1994). Without being able to accurately and measure all of the determinants of risk behavior, unobserved heterogeneity will exist, leading to overdispersion in the model. The negative binomial regression model allows for overdispersion, and more closely models the observed counts of needle sharing than the Poisson regression model.

While the deviance residuals for the reduced negative binomial regression model were of reasonable magnitude, there is evidence that the model fit less well for subjects with high counts of needle sharing at baseline. The consistency of the findings from the negative binomial regression and logistic regression models provides evidence that the negative binomial distribution can be successfully used to model episodes of HIV-related needle risk behavior. Zero-inflated and zero-truncated Poisson and negative binomial regression models (Cameron & Trivedi, 2001) may also be appropriate for modeling HIV-related needle risk behavior.

Needle Sharing at Follow-up

Analyses of number of injections with a shared needle at follow-up among subjects who used injection drugs at follow-up show significantly more risk in the intervention group than in the control group. In the negative binomial regression model of number of episodes of needle sharing among subjects who injected at follow-up, subjects in the intervention group had more episodes of needle sharing than subjects in the control group (IRR = 2.94, 95% CI = 1.18, 7.35) while controlling for baseline employment status, number of sex partners, sex with an IDU, and episodes of needle sharing. In the logistic regression analysis of having injected with a needle used by someone else at follow-up among subjects who used injection drugs at follow-up, subjects in the intervention group were more likely to have injected with a shared needle than subjects in the control group (OR = 2.56, 95% CI = 1.03, 6.38) while controlling for baseline employment status, sex with an IDU, and any needle sharing. The variables in

the logistic regression model are a subset of the corresponding variables in the negative binomial regression model.

Interpretation of Findings

These results, in and of themselves, suggest that HIV counseling and testing leads to increases in HIV-related drug use behaviors. However, these results need to be examined in the context of other studies of the effects on HIV counseling and testing on needle sharing. The finding that the proportion of intervention subjects who shared needles increased from baseline to follow-up is inconsistent with the findings of other NIDA Cooperative Agreement studies. These studies consistently show that subjects receiving the NIDA Standard Intervention of HIV counseling and testing are less likely to share needles at follow-up than at baseline. Data from the Final Analytic Report of the NIDA Cooperative Agreement (see Figure 2) show decreases in the number of episodes of needle sharing among subjects receiving the Standard Intervention. This pattern is also evident among subjects who received the Standard Intervention at the Portland Cooperative Agreement site prior to the initiation of the current study (i.e., November, 1994). Of 168 Standard Intervention subjects who reported injection drug use at both baseline and follow-up, 53.0% had shared needles at baseline while only 31.5% shared needles at follow-up, and the mean number of injections in the last 30 days dropped from 11.4 at baseline to 4.9 at follow-up (unpublished data). The observed increase in needle sharing from baseline to follow-up among intervention subjects in this study is incongruous with these other findings. Consequently, concluding that HIV counseling

and testing leads to increases in needle sharing is unwarranted. However, it is reasonable to conclude that this study does not support the contention that HIV counseling and testing leads to decreases in needle sharing among out-of-treatment injection drug users.

There are several possible alternate explanations for the observed associations that also must be considered in randomized trials, including bias in group assignment, differential attrition, measurement bias, and differences in non-intervention procedures for the two groups. As previously discussed, there does not appear to be any evidence of differential attrition or lack of equivalence at baseline among subjects included in the analyses. Measurement bias can occur when the social desirability of certain responses differ between intervention and control subjects or by assessors interacting or interpreting responses differently when interviewing intervention or control subjects. While double-blinding of subjects and assessors is desirable to limit potential measurement bias, it is often impossible to achieve double-blinding in behavioral research studies. Researchers are ethically required to inform participants of study procedures, and it is difficult to make subjects unaware of whether they are receiving an intervention. In this study efforts were made to keep assessors blind to group assignment, but it is likely that they did become aware of group assignment in some instances. For example, the subject may have divulged whether he or she received HIV counseling and testing during the follow-up assessment, or the assessor may have recognized a subject from an intervention session visit. However, measurement bias in the form of greater social desirability or expectations among assessment staff would be expected to lead to lower reported levels

of risk behavior at follow-up in the intervention group than the control group. It is difficult to imagine how measurement bias could lead to lower reported needle sharing among control subjects than among intervention subjects.

One of the primary assets of a randomized controlled trial design is the ability to limit procedural differences between the groups to exposure to the intervention. In this study, however, the experiences of subjects in the two groups did differ outside of whether they received the intervention. While the follow-up assessment was identical for both groups, the baseline assessments were not. At baseline, the standard NIDA Cooperative Agreement Risk Behavior Assessment Instrument was used to interview intervention subjects and a shorter assessment instrument was used to interview control subjects. While the difference in the baseline assessment could affect the groups differently, one would expect that the longer baseline assessment would lead to greater reductions in risk behavior among intervention subjects than control subjects. The difference in the baseline assessment for the two groups would not have resulted in higher levels of reported risk behavior subjects in the intervention group than subjects in the control group.

The most reasonable explanation for the greater level of risk behavior among intervention subjects at follow-up compared to control subjects at follow-up and intervention subjects at baseline is that these finding are anomalous. These observed changes in needle sharing among subjects in the intervention group are incongruous with the findings of previous NIDA Cooperative Agreement studies, and there does not appear

to be any other plausible explanation. If there is no true association between receiving HIV counseling and testing and needle risk behavior at six months, odds ratios and incident rate ratios that differ as or more dramatically from unity than what was observed in this study would be expected to occur in one in 22 studies of similar sample size based on the observed standard errors. If this study were replicated, it is reasonable to hypothesize that the intervention group would show similar reductions in needle sharing as the control group.

While it is not reasonable to conclude from this study that HIV counseling and testing leads to increased needle sharing in this population, it is reasonable to conclude that this study does not provide any evidence that HIV counseling and testing leads to reductions in needle sharing in this population. Assuming that the reductions in risk behavior observed in previous studies were due exclusively to the effects of HIV counseling and testing, data from subjects who received HIV counseling and testing at the Portland site of the NIDA Cooperative Agreement prior to initiation of the present study, presented earlier in the discussion, can be used to estimate expected odds and incident rate ratios for the present study. Assuming that there is no change in risk behavior among subjects who do not receive HIV counseling and testing, the estimated odds ratio for any needle sharing at follow-up would be 0.41 for intervention subjects versus control subjects, and the incident rate ratio for episodes of needle sharing at follow-up would be 0.43 for intervention subjects versus control subjects. In contrast, the odds ratio and incident ratio for intervention versus control subjects observed in this study were 2.56 and

2.94, respectively. If the reductions in risk behavior observed among subjects who received HIV counseling and testing at the Portland site prior to initiation of the present study were due exclusively to and accurately reflect the effects of HIV counseling and testing, in studies with sample sizes similar to the present study and based on the observed standard errors, odds ratios and incident rate ratios of equal or greater magnitude than what was observed in this study would be expected to occur in approximately one in 25,000 studies and one in 54,000 studies, respectively. While the likelihoods of the observed results are clearly at odds with the supposition that changes in risk behavior following HIV counseling and testing are due exclusively to the effects of HIV counseling and testing, the likelihoods would be less inconsistent if HIV counseling and testing has a more moderate effect on risk behavior.

The reductions in needle sharing observed among subjects in the control group and among subjects receiving the Standard Intervention in other NIDA Cooperative Agreement studies could have resulted from regression to the mean or the effects of the baseline assessment. Regression to the mean may occur when selection of subjects is biased towards individuals who are currently engaging in higher than usual levels of risk behavior. IDUs have been found to cycle between living in a drug-using street culture and living in working-class neighborhoods (Mason, Lusk, & Gintzler,1992). Efforts to recruit out-of-treatment IDUs often focus on disenfranchised individuals who are accessible through street outreach. Furthermore, the modest monetary compensation this and other studies offer may lead to self-selection bias for individuals in need of money.

Such a bias in recruitment is often not unintended, as HIV interventions are often targeted at the highest risk populations in an effort to serve those in greatest need. Consequently, IDUs recruited into this and other HIV intervention studies may tend to be 'near bottom.' A reasonable hypothesis is that when the living situations of IDUs have deteriorated, IDUs may have a greater propensity to engage in risk behavior and increased probability of being enrolled in a HIV prevention study. Such individuals may have 'nowhere to go but up,' i.e., their behavior would be expected to regress toward the mean over time.

The effect of baseline assessments could also account for the observed reductions in needle sharing from baseline to follow-up observed in other NIDA Cooperative Agreement studies. Answering questions about HIV-related risk behavior may lead subjects to actively consider behavior which may be largely habitual and unconsidered, forcing subjects to come face-to-face with the scope of risky behavior in which they engage. Examination of one's behavior is an essential component of many interventions, including the Transtheoretical Model of Behavior Change, Health Beliefs Model, and Motivational Interviewing. Other researchers have concluded that reductions in risk behaviors among subjects receiving counseling and testing may be the result of the baseline interview. As noted by Gibson et al. (1999), "anecdotally, our interviewers observed that the interview appeared to establish a bond with many drug users, some of whom were for the first time recognizing how their behavior put them at risk of injection with HIV (p.10)." In a review of psychosocial interventions to reduce HIV risk behavior among IDUs, Gibson et al. (1998) describe a conference presentation by Ray et al. (1991)

specifically examining the impact of behavioral assessments on the risk behavior of in-treatment and out-of-treatment IDUs. Subjects randomized into a baseline and follow-up assessment group showed lower levels of injection risk at follow-up than subjects randomized into a follow-up assessment only group.

Study Limitations

As with all studies that rely on self-report of HIV-related risk behavior, the validity of self-reports may be affected by underreporting of socially undesirable behaviors and reliability may be affected by poor memory recall. While the assessment instrument used in this study has been demonstrated to be fairly valid and reliable, it is likely that measurement error did occur, and that the reported levels of risk behavior differ somewhat from the true levels of risk behavior among these subjects. Measurement error would not be expected to differ for the control and intervention groups, and thus would not be a threat to the internal validity of this study. Measurement error in this study would not be expected to differ from measurement error in other studies of the NIDA Cooperative Agreement, and thus would not affect comparability of the findings to the findings of these other studies.

The finding of this study could lack validity if there were errors in the analytic methods employed, such as inappropriate inclusion criteria for the analyses, inappropriate use of analytic models, inappropriate coding of variables, and inappropriate specification of regression parameters. The main outcome analyses were limited to subjects who reported injection drug use at baseline and follow-up. While no difference was found

between the two groups in cessation of drug use, it is possible the inclusion of these subjects in the main outcome analyses could result in different findings. To test this hypothesis, the backward stepwise logistic and negative binomial regression models were repeated with data from all subjects who completed the follow-up assessment. The resulting reduced models contained the same variables and similar parameter estimates as in the reduced models described above. The exclusion of subjects who did not inject at follow-up did not bias the findings of this study.

In this study, the two main analytic strategies, negative binomial regression and logistic regression, produced very similar models and lead to similar conclusions about the effectiveness of HIV counseling and testing in reducing needle sharing. While negative binomial regression models have rarely been used in HIV prevention research, logistic regression models are commonly used. These analytic strategies also employed different coding strategies for the independent variables and many of the dependent variables. It is unlikely that inappropriate use of an analytic model, errors in the coding of variables, or misspecification of regression parameters would have resulted in consistent findings between the two analytic strategies.

There are several limitations in the overall design of this study. The primary limitation is that subjects in this study were not actively seeking HIV counseling and testing. Consequently, the external validity of this study may not extent to out-of-treatment IDUs who are actively seeking HIV counseling and testing. In other words, while it does not appear that HIV counseling and testing leads to reductions in risk

behavior among the subjects in this study, it is possible that HIV counseling and testing may lead to reductions in risk behavior among individuals seeking HIV counseling and testing.

The recruitment method for this study differed from other NIDA Cooperative Agreement studies, where subjects were recruited through street outreach. During outreach, staff would engage prospective subjects in discussions about the threat of HIV. As it was not possible to easily randomize individuals to receive or not receive outreach, this component of the NIDA Cooperative Agreement protocol was avoided in this study. It is possible that the reductions in risk behavior seen in subjects who received the Standard Intervention in other NIDA Cooperative Agreement studies resulted from the intervention effect of street outreach.

This study is also significantly limited by the size of the sample. A larger sample size may have revealed equivalence between the groups at follow-up or possibly greater reductions in risk behavior among intervention subjects than control subjects. Unfortunately, funding ended at the Portland site ended before a larger number of subjects could be enrolled.

SUMMARY AND CONCLUSIONS

HIV counseling and testing plays an essential role in identifying individuals infected with HIV, allowing early initiation of treatment regimens, and understanding the epidemiology of the disease. However, the contention that HIV counseling and testing leads to reductions in HIV-related risk behavior among seronegative IDUs is dubious. Subjects who received HIV counseling and testing in this study did not have lower levels of HIV-related needle risk behavior at follow-up than subjects who did not receive HIV counseling and testing. The findings of this study do not support the hypothesis that HIV counseling and testing leads to reductions in needle sharing among out-of-treatment IDUs.

The reductions in risk behavior among control subjects in this study are similar to the reductions in risk behavior among subjects receiving the Standard Intervention in other NIDA Cooperative Agreement studies, indicating that the reductions in risk behavior in these and other studies is due at least in part to effects other than the intervention, such as regression to the mean, or the effects of the baseline assessment.

This study demonstrates the importance of control groups in the evaluation of HIV prevention interventions. Conducting additional randomized controlled trials of HIV counseling and testing would provide for a better understanding of its effectiveness and would allow for the application of limited public health resources based on sound scientific evidence.

REFERENCES

Bandura, A. (1977). Self-efficacy: Toward a unifying theory of behavioral change. Psychological Review, 84: 191-215.

Becker, M. H. (1974). The health belief model and personal health behavior. Health Education Monograph, 2: 324-508.

Blumberg, S. J. (2000). Guarding against threatening HIV prevention messages: An information-processing model. Health Education and Behavior, 27: 780-795.

Booth, R. E., & Wiebel, W. W. (1992). The effectiveness of reducing needle-related risks for HIV through indigenous outreach to injection drug users. American Journal of Addiction, (1): 277–88.

Brisson, M., Boily, M. C., Mâsse, B. R., Adrien, A., & Léaune, V. (1999). Highlights of the sexual activity of the heterosexual population in the province of Quebec. Sexually Transmitted Infections, 75(5): 296-9.

Camacho, L. M., Williams, M. L., Vogtsberger, K. N., & Simpson, D. D. (1995). Cognitive readiness of drug injectors to reduce AIDS risks. American Journal of Addictions, 4(1): 49-55.

Cameron, A. C. & Trivedi, P. K. (1998). Regression Analysis of Count Data. New York, NY: Cambridge University Press.

Cameron, A. C. & Trivedi, P. K. (2001). Essentials of count data regression. Badi H. Baltagi ed., A Companion to Theoretical Econometrics. Oxford, UK: Blackwell.

Caslyn, D. A., Saxon, A. J., Freeman G., Jr., & Whittaker, S. (1992). Ineffectiveness of AIDS education and HIV antibody testing in reducing high-risk behaviors among injection drug users. American Journal of Public Health, (82): 573-75.

Centers for Disease Control and Prevention (CDC). (1985). Results of human T-lymphotropic virus type III test kits reported from blood collection centers-United States, April 22-May 19, 1985. Morbidity and Mortality Weekly Report, 34: 375-376.

Centers for Disease Control and Prevention (CDC). (1987). Public Health Service guidelines for counseling and anti-body testing to prevent HIV infection and AIDS. Morbidity and Mortality Weekly Report, 36: 509-515.

Centers for Disease Control and Prevention (CDC). (2001). Revised Guidelines for HIV Counseling, Testing, and Referral. Morbidity and Mortality Weekly Report, 50(RR19): 1-58.

Centers for Disease Control and Prevention (CDC). (2002). Reports of Cases of AIDS and HIV infection (not AIDS). Morbidity and Mortality Weekly Report, 14(Addendum): 1-8.

Colon, H. M., Robles, R. R., Freeman, D., & Matos, T. (1993). Effects of a HIV risk reduction education program among injection drug users in Puerto Rico. Puerto Rico Health Sciences Journal, 12: 27–33.

Compton, W. M. (2000). Cocaine use and HIV risk in out of treatment drug abusers. Drug & Alcohol Dependence, 58(3): 2115-118.

Coyle, S. L. (1993). The NIDA HIV Counseling and Education Intervention Model. Washington, DC: US Government Printing Office.

Coyle, S. L., Boruch, R. F., & Turner, C. F. (1991). Evaluating AIDS Prevention Programs. Washington, DC: National Academy Press.

Coyle, S. L., Needle, R. H., & Normand, J. (1998). Outreach-based HIV prevention for injecting drug users: a review of published outcome data. Public Health Reports, 113(Supplement 1): 19-30.

CSR, Incorporated & Logicon/ROW Sciences. (2001). Final Analytic Report: NIDA Cooperative Agreement Program. Washington, DC.

Deren, S., Davis, W. R., Beardsley, M., Tortu, S., & Clatts, M. (1995). Outcome of a risk reduction intervention with high risk populations: the Harlem AIDS Project. AIDS Education and Prevention, 7(5): 379-90.

Des Jarlais, D. C., Choopanya, K., Vanichseni, S., Plangsringarm, K., Sonchai, W., Carballo, M., Friedmann, P., & Friedman, S. R. (1994). Determinants of AIDS risk reduction among injecting drug users in New York City, USA and Bangkok, Thailand. International Conference on AIDS 8(2): D468.

Fox, R, Odaka, N. J., Brookmeyer, R., & Polk, B. F. (1987). Effect of antibody test disclosure on subsequent sexual activity in homosexual men. AIDS, 1(4), 241-46.

Friedman, S. R., Neaigus, A., Des Jarlais, D. C., Sotheran, J. L., Woods, J., Sufian, M., Stepherson, B., & Sterk, C. (1992). Social intervention against AIDS among injection drug users. British Journal of Addictions, (87): 393-404.

Gardner, W., Mulvey, E. P., & Shaw, E. C. (1995). Regression analyses of counts and rates: Poisson, overdispersed Poisson, and negative binomial models. Psychological Bulletin, 118(3): 392-404.

Gianstefano, M., Serpelloni, G., et al. (1994). An Audiovisual presentation for AIDS risk reduction in IV drug users. International Conference on AIDS 6(3): 273.

Gibson, D. R., Lovelle-Drache, J., Young, M., Hudes, E. S., & Sorensen, J. L. (1999). Effectiveness of brief counseling in reducing HIV risk behavior in injection drug users: final results of a randomized trials of counseling with and without testing. AIDS and Behavior, 3(1): 3-12.

Gibson, D. R., McCusker, J., & Chesney, M. (1998). Effectiveness of psychological interventions in preventing HIV risk behaviour in injection drug users. AIDS, 12: 919-29.

Guo, J., Chung, I. J., Hill, K. G., Hawkins, J. D., Catalano, R. F., & Abbott, R. D. (2002). Developmental relationships between adolescent substance use and risky sexual behavior in young adulthood. Journal of Adolescent Health, 31(4): 354–62.

He H., Stark M., Fleming D., Gould J., Russell-Alexander Y., Weir, B. (1996). Facilitation Into Drug Treatment or Self-Help Among Out-of-Treatment IDUs in Portland: You Can Lead a Horse to Water, But.... Journal of Drug Issues, 26(3): 649-61.

Higgens D. L., Galavotti C., O'Reilly, K. R., Schnell, D. J., Moore, M., Rugg, D. L., & Johnson, R. (1991). Evidence for the effects of HIV antibody counseling and testing on risk behaviors. Journal of the American Medical Association, 266(17): 2419-29.

Hosmer, D. W. & Lemeshow, S. (2000). Applied logistic regression. New York, NY: John Wiley & Sons, Inc.

Hutchinson, M. K., Jemmott, J. B., III, Jemmott, L. S., Braverman, P. Fong, G. T. (2003). The role of mother-daughter sexual risk communication in reducing sexual risk behaviors among urban adolescent females: A prospective study. Journal of Adolescent Health, 33(2): 98-107.

Ickovics, J.R., Morrill, J.D., Beren, S. E., Walsh, U., & Rodin, J. (1994). Limited effects of HIV counseling and testing for women: a prospective study of behavioral and psychological consequences. Journal of the American Medical Association, 272(6): 443-8.

Long, J. S. (1998). Regression models for categorical and limited dependent variables. Thousand Oaks, CA: Sage Publications.

Long, J. S. & Freese, J. (2001). Regression models for categorical dependent variables using Stata. College Station, TX: Stata Press.

Longshoure, D. (1992). AIDS education for drug users: Existing research and new directions. Journal of Drug Issues, 22(1):1-16.

Mason, D. T., Lusk, M. W., Gintzler, M. (1992). Beyond ideology in drug policy: The primary prevention model. Journal of Drug Issues, 22(4): 959-976.

Myers, H. F., Javanbakht, M., Martinez, M., Obediah, S. (2003). Psychosocial predictors of risky sexual behaviors in African American men: Implications for prevention. AIDS Education & Prevention, 15(Supplement 1): 66-79.

Neaigus, A., Sufian, M., Friedman, S. R., Goldsmith, D. S., Stephenson, B., Mota, P., Pascal, J., & Des Jarlais, D. C. (1990). Effects of outreach intervention on risk reduction among intravenous drug users. AIDS Education and Prevention, 2: 253-71.

Needle, R., Fisher, D. G., Weatherby, N., Chitwood, D., Brown, B., Cesari, H., Booth, R., Williams, M. L., Watters, J., Andersen, M., & Braunstein, M. (1995). Reliability of self-reported HIV risk behaviors of drug users. Psychology of Addictive Behaviors, 9(4): 242-250.

Oregon Department of Human Services. (2002). Oregon HIV/AIDS Epidemiologic Profile 2002. http://www.dhs.state.or.us/publichealth/hiv/epiprofile.cfm.

Ray, S., Jones, A., Bouie, J., Shorty, V., Ratcliff, S., & Wise, G. (1991). Pretest and drug treatment effects of AFA outcome measures among IVDUs. In Community-Based AIDS Prevention: Proceedings of the Second Annual National AIDS Demonstration Research National Meeting. Washington DC: US Government Printing Office.

Rhodes, F., Humfleet, G. (1993). Using goal-oriented counseling and peer support to reduce HIV/AIDS risk among drug users not in treatment. Drugs & Society, 7(3-4):185-204.

Rosser, B. R. S., & Ross, M. W. (1991). Psychological resistance and HIV counseling. Journal of Gay & Lesbian Psychotherapy, 1: 93-107.

Schroder, K. E. E., Carey, M. P., & Vanable, P. A. (2003). Methodological challenges in research on sexual risk behavior: item content, scaling, and data analytical options. Annals of Behavioral Medicine, 26(2): 76-103.

Shannon, C. E. and Weaver, W. (1949). The Mathematical Theory of Communication. Chicago, IL: University of Illinois Press.

Simpson, D. D, Camacho, L. M., Vogtsberger, K. N., Williams, M. L., Stephens, R. C., Jones, A., & Watson, D. (1994). Reducing AIDS risks through community outreach interventions for drug injectors. Psychology of Addictive Behaviors, 8(2): 86-101.

SPSS Statistical Software. (2001). Version 11 for Windows. SPSS Inc. Chicago, IL.

StataCorp. (2001). Intercooled Stata 7.0 for Windows. Stata Corporation. College Station, TX.

Stephens, R. C., Simpson, D. D., Coyle, S. L., McCoy, C. B., & the National AIDS Research Consortium. (1993). Comparative effectiveness of NADR interventions. In Brown, B. S. and Beschner, G. M., editors. Handbook on Risk of AIDS. Westport, CT: Greenwood Press.

Watters, J.K., & Biernacki, P. (1989). Targeted sampling: options for the study of hidden populations. Social Problems, 36: 416-30.

Weatherby, N. L., Needle, R., Cesari, H., et al. (1994). Validity of self-reported drug use among injection drug users and crack cocaine users recruited through street outreach. Evaluation & Program Planning, 17(4): 347-55.

Weddington, W. W., & Brown, B. S. (1989). Counseling regarding human immunodeficiency virus-antibody testing: An interactional method of knowledge and risk assessment. Journal of Substance Abuse Treatment, 6(2): 77-82.

Weinhardt, L. S., Carey, M. P., Johnson, B. T., & Bickham, N. L. (1999). Effects of HIV counseling and testing on sexual risk behavior: a meta-analytic review of published research, 1985-1997. American Journal of Public Health, 89(9): 1397-1405.

Wenger N. S., Linn, L. S., Epstein, M., & Shapiro, M. F. (1991). Reduction of high-risk sexual behaviors among heterosexuals undergoing HIV antibody testing: a randomized clinical trial. American Journal of Public Health, 91: 1580-85.