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Impact of Interim Methadone Maintenance on HIV Risk Behaviors

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ABSTRACT *The extent to which interim methadone (IM) without counseling reduces HIV risk behavior has not been reported. The AIDS Risk Assessment scale was administered at baseline and 4-month follow-up to 319 adult heroin-dependent participants randomly assigned to IM or waiting list. On an intent-to-treat basis, there was a significantly greater reduction in drug injection and unprotected sex while high from baseline to follow-up, favoring the IM condition. Remedying the shortage of methadone capacity through the expansion of IM would be a worthwhile approach to reducing the spread of HIV infection.*

KEYWORDS *HIV, Interim maintenance, Injection, Sex risks*

INTRODUCTION

Interim methadone (IM) treatment (methadone with only emergency counseling), compared to waiting list (WL), has been shown in a randomized clinical trial (RCT) to increase methadone treatment entry and reduce heroin and cocaine use and criminal behavior at 4 months post-enrollment.[1] There are limited data from RCTs of standard methadone treatment which incorporated an HIV risk measure[2,3] and even less from trials of methadone alone.

The present study examined the extent to which IM would impact HIV drug and sexual risk behavior. We hypothesized that the IM condition, on an intent-to-treat basis, would have significantly greater reduction in HIV drug and sexual risk behaviors over time than would a WL condition. The former was hypothesized because of an expected decrease in heroin and syringe use and the latter was hypothesized because of decreased disinhibition and trading sex for drugs.

METHODS

The parent project, described elsewhere,[1] was a two-group RCT in which opioid-dependent adults enrolling into a methadone treatment program (MTP) WL in Baltimore, Maryland were assigned to IM or WL as usual on a 3:2 basis. IM was provided according to the US Federal Regulations[1] and consisted of daily administration of methadone with only emergency counseling for up to 120 days. Participants were assessed at baseline and at transfer into a comprehensive MTP or

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at 120 days after admission to IM (for participants who did not enter comprehensive treatment).

Participants

There were 319 heroin-dependent adults randomly assigned to IM (n=199) or to WL without automatic admission after 120 days (n=120). The study was approved by the Friends Research Institute's Institutional Review Board.

Measures. Participants were administered the Texas Christian University AIDS Risk Assessment (ARA) at baseline and follow-up. The average participant remained in IM 102.6 days.

AIDS Risk Assessment

The ARA is a brief questionnaire whose index scores and items assess HIV infection and HIV sex risk over the 30-day period prior to the interview.[4] Its scales consist of the sum of the number of times the respondent reported doing each behavior in the past 30 days and have internal consistency alphas above 0.70.[5] Select items from the scales are shown in Table 1. This instrument has shown changes in risk levels over time during methadone treatment[6–8] and an HIV risk reduction intervention[9] and relates psychological functioning to HIV risk taking.[9,10]

Scores on the injection risk scale ranged from 0 to 840 (M=28.45, SD=3.24) and the sex risk scale scores ranged from 0 to 99 (M=7.29, SD=0.58). After scores were calculated, each item regarding the past 30 days was transformed to binary form: *no* (0=zero times) or *yes* (1=one or more times) because many participants had a response of "0" for a given item.

Statistical Methods. A generalized linear mixed model approach was used to analyze the risk scale scores, while a generalized estimated equations (GEE) approach was used to conduct the analyses of the items. The between-subjects factor was treatment condition (IM vs. WL control) and the repeated factor was time point (baseline vs. follow-up) to evaluate possible differential change from baseline to treatment entry. For the GEE analyses, the mean represents the model-derived estimate of the proportion of respondents who did *not* engage in the behavior. In both analyses, the correlation matrix for the repeated factor, time, was specified as unstructured.

Follow-up data were available from 294 (92%) of the 319 participants enrolled in the study. The analyses of the scale scores and of the unprotected sex and drug injection items were conducted on an intent-to-treat basis, while the analysis of each of the remaining sex risk items was conducted on the 155 respondents who reported at baseline that they had unprotected sex in the past 30 days, and the analysis of each of the remaining injection risk items was conducted on the 118 respondents who indicated at baseline that they had injected drugs in the past 30 days.

RESULTS

Participant Demographic and Background Characteristics

Participants were 93.1% African American, 40.8% female, and their mean age was 41.4 (SD=5.9). The majority of the participants (60.2%) were non-injection heroin users, although a significant minority (39.8%) injected heroin. Only 5.6% reported being HIV-positive. There were 79.6% of participants who reported having been detoxified or in another drug treatment prior to study entry. There were no

TABLE 1 ARA scales and items (past 30 days)

	Treatment condition main effect		Time main effect		Treatment condition × time	
Outcome variable	Test statistic	*p* value	Test statistic	*p* value	Test statistic	*p* value
Total sample ($N=319$)						
Injection risk scale score	$F(1, 318.9)=7.24$	<0.008	$F(1, 321.1)=48.52$	<0.001	$F(1, 321.1)=1.46$	0.227
Injected drugs	$\chi^2(1)=5.20$	<0.030	$\chi^2(1)=44.68$	<0.001	$\chi^2(1)=5.13$	<0.030
Sex risk scale score	$F(1, 320.1)=4.44$	<0.040	$F(1, 316.7)=6.42$	<0.020	$F(1, 316.7)=3.77$	0.053
Injection sample ($N=118$)						
Used unsterilized	$\chi^2(1)=3.80$	0.051	$\chi^2(1)=4.56$	<0.040	$\chi^2(1)=1.45$	0.229
Used same cooker, cotton, or rinse water someone else used	$\chi^2(1)=6.68$	<0.020	$\chi^2(1)=7.59$	<0.007	$\chi^2(1)=2.96$	0.085
Injected with people who were also injecting	$\chi^2(1)=7.08$	<0.009	$\chi^2(1)=36.92$	<0.001	$\chi^2(1)=2.36$	0.125
Unprotected sex sample ($N=155$)						
Unprotected sex with spouse or primary partner	$\chi^2(1)=1.32$	0.250	$\chi^2(1)=43.65$	<0.001	$\chi^2(1)=0.33$	0.568
Unprotected sex with someone who shoots drugs with needles	$\chi^2(1)=0.45$	0.501	$\chi^2(1)=0.17$	0.677	$\chi^2(1)=0.74$	0.388
Unprotected sex with someone who sometimes smokes crack/cocaine	$\chi^2(1)=3.25$	0.071	$\chi^2(1)=10.08$	<0.003	$\chi^2(1)=0.21$	0.646
Unprotected sex while high	$\chi^2(1)=0.18$	0.672	$\chi^2(1)=72.58$	<0.001	$\chi^2(1)=7.740$	<0.006
Had unprotected vaginal sex	$\chi^2(1)=0.43$	0.511	$\chi^2(1)=27.23$	<0.001	$\chi^2(1)=1.82$	0.177

significant differences between the two treatment conditions on any of the demographic and background variables.[1]

Injection Risk

Entire Sample Analysis As shown in Table 1, on an intent-to-treat basis, for the ARA Injection Risk Scale, the treatment condition and time main effects were significant, $p<0.008$ and $p<0.001$, respectively, with the IM condition showing less needle risk than the control condition (*M*s=19.7 vs. 37.2) and greater needle risk at baseline than at follow-up (*M*s=42.3 vs. 14.6).

In terms of the drug injection item, the treatment condition and time main effects were significant, $p<0.030$ and $p<0.001$, respectively, with the IM condition less likely to inject drugs than the control condition (*M*s=0.25 vs. 0.36) and a greater likelihood of injecting at baseline than at follow-up (*M*s=0.38 vs. 0.24, respectively). The treatment condition×time interaction was significant, $p<0.030$, with the means for the IM condition at baseline of 0.34 dropping at 4 months to 0.18, while the control condition decreased more modestly from 0.42 to 0.32, respectively.

Injectors-Only Subsample Analyses Among participants who reported injecting drugs in the 30 days prior to either interview, there was a greater likelihood of injecting at baseline with unsterilized needles compared to follow-up, $p<0.04$ (*M*s= 0.11 and 0.26, respectively). The IM condition compared to the control condition showed a lower likelihood of using the same cooker, cotton, or rinse water, $p<0.020$ (*M*s=0.11 vs. 0.26, respectively), and of injecting drugs with others, $p<0.009$ (*M*s= 0.32 vs. 0.53, respectively). There was also a higher likelihood at baseline than at follow-up of using the same cooker, cotton, or rinse water [$p<0.007$, *M*s=0.26 vs. 0.11, respectively] and of injecting drugs with other people [$p<0.001$, *M*s=0.63 vs. 0.24, respectively].

Unprotected Sex Risk

Entire Sample Analysis On an intent-to-treat basis, for the ARA Sex Risk Scale, the treatment condition×time interaction effect was not significant, $p=0.053$. However, the treatment condition (IM had a higher mean score than the control; *M*s=8.5 vs. 6.1, respectively) and time effects (*M*s=8.4 vs. 6.1, respectively) were both significant, both *p*s<0.04.

Unprotected Sex Subsample Analyses There was a greater likelihood of having unprotected sex with someone who smokes crack/cocaine at baseline than at follow-up [*M*s=0.14 vs. 0.04, respectively; $p<0.003$]. Of particular interest was the fact that there was a significant treatment condition×time interaction for the item concerning unprotected sex while high, $p<0.006$. Both the IM and the control conditions decreased their unprotected sex while high from baseline to follow-up (both *p*s<0.001); however, the likelihood for the IM condition decreased by two thirds from 0.91 at baseline to 0.31 at follow-up, while the likelihood for the control condition decreased by one half from 0.81 at baseline to 0.46 at follow-up.

There was a markedly higher likelihood of engaging in unprotected sex while high at baseline than at follow-up [*M*s=0.87 vs. 0.39, respectively; $p<0.001$].

Finally, there was a greater likelihood of engaging in unprotected vaginal sex at baseline than at follow-up [*M*s=0.94 vs. 0.64, respectively; $p<0.001$].

DISCUSSION

This study is one of the few RCTs of methadone treatment that included a specific measure of HIV risk related to drug use and sexual behaviors.[2,3] The present study found a significantly greater reduction in drug injection from baseline to follow-up for the IM condition compared to the WL condition. Despite this finding, the condition×time interaction for the overall ARA drug use behavior score was nonsignificant, perhaps because 60.2% of the study sample was non-injectors and the injectors reported low levels of risky injection practices at baseline.

While there were no significant differences between conditions over time in sharing of unclean needles, the IM compared to the WL group reported significantly lower likelihood of sharing cookers, cottons, and rinse water and of injecting with other people present. It is noteworthy that the baseline levels of sharing of needles, cookers, cottons, and rinse water were quite low, consistent with other studies in Baltimore among injection drug users.[11]

The condition×time interaction on ARA Sexual Risk Scale scores was non-significant. This is not entirely surprising given that participants received no specific sexual risk reduction intervention aside from the availability of free condoms at the treatment program. It is also important to note that, in contrast to other studies, we found some changes in sexual risk behaviors, some of which could be attributed to the differences seen between the two treatment conditions at baseline but not at follow-up.

Remedying the shortage of methadone treatment capacity through expansion of IM would be an important public health intervention to reduce the spread of HIV infection through drug injection.[12] Gender-specific sexual risk reduction interventions, based on recent research,[13,14] should be delivered in drug abuse treatment programs.

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REFERENCES

1. Schwartz RP, Highfield DA, Jaffe JH, et al. A randomized controlled trial of interim methadone maintenance. *Arch Gen Psychiatry*. 2006; 63(1): 102–109.
2. Gowing LR, Farrell M, Bornemann R, Sullivan LE, Ali RL. Brief report: methadone treatment of injecting opioid users for prevention of HIV infection. *J Gen Intern Med*. 2006; 21(2): 193–195.
3. Lott DC, Strain EC, Brooner RK, Bigelow GE, Johnson RE. HIV risk behaviors during pharmacologic treatment for opioid dependence: a comparison of levomethadyl acetate [corrected] buprenorphine, and methadone. *J Subst Abuse Treat*. 2006; 31(2): 187–194.
4. Simpson DD, Knight K, Ray S. Psychosocial correlates of AIDS-risk drug use and sexual behaviors. *AIDS Educ Prev*. 1993; 5(2): 121–130.

5. Simpson DD, Copher JI, Vogtsberger KN, Watson DD. Needle-risk changes and reliability of measures. In: Third Annual Meeting of the National AIDS Demonstration Research (NADR) Project, Washington, DC; 1991.
6. Ball JC, Lange WR, Myers CP, Friedman SR. Reducing the risk of AIDS through methadone maintenance treatment. *J Health Soc Behav*. 1988; 29(3): 214–226.
7. Camacho LM, Bartholomew NG, Joe GW, Cloud MA, Simpson DD. Gender, cocaine and during-treatment HIV risk reduction among injection opioid users in methadone maintenance. *Drug Alcohol Depend*. 1996; 41(1): 1–7.
8. Metzger DS, Woody GE, McLellan AT, et al. Human immunodeficiency virus seroconversion among intravenous drug users in- and out-of-treatment: an 18-month prospective follow-up. *J Acquir Immune Defic Syndr*. 1993; 6(9): 1049–1056.
9. Boatler JF, Knight K, Simpson DD. Assessment of an AIDS intervention program during drug abuse treatment. *J Subst Abuse Treat*. 1994; 11(4): 367–372.
10. Camacho LM, Brown BS, Simpson DD. Psychological dysfunction and HIV/AIDS risk behavior. *J Acquir Immune Defic Syndr Hum Retrovirol*. 1996; 11(2): 198–202.
11. Galai N, Safaeian M, Vlahov D, Bolotin A, Celentano DD. Longitudinal patterns of drug injection behavior in the ALIVE Study cohort, 1988–2000: description and determinants. *Am J Epidemiol*. 2003; 158(7): 695–704.
12. Highfield DA, Schwartz RP, Jaffe JH, O'Grady KE. Intravenous and intranasal heroin-dependent treatment-seekers: characteristics and treatment outcome. *Addiction*. 2007; 102(11): 1816–1823.
13. Calsyn DA, Hatch-Maillette M, Tross S, et al. Motivational and skills training HIV/sexually transmitted infection sexual risk reduction groups for men. *J Subst Abuse Treat*. 2009; 37(2): 138–150.
14. Tross S, Campbell AN, Cohen LR, et al. Effectiveness of HIV/STD sexual risk reduction groups for women in substance abuse treatment programs: results of NIDA Clinical Trials Network Trial. *J Acquir Immune Defic Syndr*. 2008; 48(5): 581–589.