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## The Association between Poor Antiretroviral Adherence and Unsafe Sex: Differences by Gender and Sexual Orientation and Implications for Scale-Up of Treatment as Prevention

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### Abstract

Non-adherence to safer sex and non-adherence to ART can each have adverse health consequences for HIV-infected individuals and their sex partners, but little is known about the association of these behaviors with each other. This “dual risk” has potential negative public health consequences since non-adherence can lead to the development of resistant virus that can then be transmitted to sex partners.

Among participants in the Multi-site Adherence Collaboration in HIV (MACH14) we examined, at study baseline, the association between the frequency of unprotected sex (assessed by self-report) and ART adherence (assessed by Medication Event Monitoring System, Aardex) among

the sexually active participants in the five studies (N=459) that collected sexual risk behavior. The bivariate association between sexual risk behaviors and ART adherence was assessed by Pearson correlations; subsequently ANOVAs were used to evaluate the role of demographic characteristics, depression and substance use in explaining the “dual risk” outcome (sexual risk and non-adherence).

Among participants who had been sexually active, more unprotected anal/vaginal sex was weakly associated with poorer ART adherence ( $r = -.12$ ,  $p=0.01$  for the overall sample). Further analysis showed this association was driven by the heterosexual men in the sample ( $r = -.29$ ,  $p<0.001$ ), and was significant only for this group, and not for gay/bisexual men or for women (heterosexual and homosexual). Neither substance use nor depression accounted for the association between sexual risk and ART adherence.

HIV-infected heterosexual men who are having difficulty adhering to ART are also more likely to engage in risky sexual behaviors and therefore may benefit from counseling about these risk behaviors. We must identify procedures to screen for these risk behaviors and develop interventions, appropriately tailored to specific populations and identified risk factors, that can be integrated into routine clinical care for people living with HIV. This will become increasingly important in the context of wider access to treatment globally, including new recommendations for ART initiation earlier in a patients’ disease course (e.g., “Test and Treat” paradigms).

## Keywords

ART adherence; sexual risk behavior; test-and-treat; depression; substance use

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## INTRODUCTION

Effective antiretroviral therapy (ART) has significantly reduced morbidity and mortality among people living with HIV so that for many people with adequate access to HIV treatment and care, HIV is now a chronic rather than fatal disease (1–3). However, individuals living with HIV now face two significant ongoing behavioral challenges, namely the need to maintain high levels of adherence to ART and to engage in safer sex practices to protect both personal and the public health (4,5).

Studies have documented the strong relationship between high adherence to antiretroviral therapy (ART) and better virologic, immunologic, and clinical outcomes (6,7). The clinical goal of ART is complete viral suppression to undetectable levels. Poor adherence can lead to inadequate viral suppression, which is a serious problem for the individual because it can lead to clinical and immunological decline and development of drug resistant virus (8–10). There is also a public health concern associated with poor ART adherence, namely the potential for transmission of drug-resistant viral strains to others during unprotected sex (11,12).

During the past decade there has been a growing emphasis on “prevention for positives” with the goal of limiting further HIV transmission, as well as protecting the health of the infected individual (4). “Test and treat” paradigms are being promoted by many in public health to help curtail the HIV epidemic (13,14). Strong evidence for the efficacy of ART as

an HIV prevention strategy was demonstrated in HPTN 052 which showed 96% reduction in HIV transmission to HIV-negative partners upon early initiation of ART by HIV-positive partners (15), proving what had earlier been seen in observational studies of HIV serodiscordant couples, specifically that viral load and HIV transmission are highly associated (16). Thus, to achieve substantial protection, individuals must either have complete viral suppression, always practice safer sex, or preferably both. Unfortunately, it is estimated that only 19–28% of HIV-infected individuals in the United States achieve full viral suppression (17, 18). Furthermore, poor adherence to ART increases HIV infectiousness due to increased viral shedding in the genital compartment (19). In the absence of viral suppression there is a greater reliance on safer sex behaviors to prevent HIV transmission.

Several studies among people living with HIV have examined either their sexual risk behavior or their ART adherence and have sought to describe determinants of the pertinent behavioral outcomes. Few studies however have looked at the intersection between poor adherence and risky sexual behavior - that is, the risk factors for HIV transmission in individuals on therapy. The studies that did examine these behaviors together found that poorer adherence was associated with having greater numbers of sexual partners and higher rates of unprotected sex, among populations of women and men who have sex with men (20–22) and among homeless people living with HIV (23). Another study also found a positive relationship between adherence and sexual risk in a diverse sample that included heterosexual men as well as women and men who have sex with men, but was unable to identify specific factors associated with both behavioral outcomes (24). These studies have been limited by the use of self-reported adherence to ART that may share response biases and measurement variance with self-reported sexual behaviors.

Thus, we examined the association between medication adherence and sexual risk behaviors in a very large and diverse sample (by race, ethnicity, sexual orientation), without relying on self-reported adherence, which tends to overestimate adherence when compared with electronic monitoring tools (25, 26). Among participants in the Multi-site Adherence Collaboration in HIV among 14 institutes (MACH14), we examined the association between the frequency of unprotected sex (assessed by self-report) and ART adherence assessed by electronic drug monitoring (EDM) among the sexually active participants in the five studies that collected sexual risk behavior. In addition, we examined whether other individual characteristics (i.e., demographic characteristics, depression and substance use) influenced the relationship between adherence and sexual risk behavior, since each of these have often been shown to be independently associated with non-adherence (27, 28) and HIV transmission risk behaviors (29–31). Finally, we also conducted stratified descriptive analyses by gender and sexual orientation to assess these associations within sexual risk groups.

## **METHODS**

### **MACH14 Study**

The MACH14 (Multi-site Adherence Collaboration among 14 institutes in HIV) cohort was a National Institute of Mental Health-funded project that pooled individual patient data from

16 studies of electronically monitored ART adherence conducted at 14 research sites in the United States between 1997 and 2009 (32, 33). Each study included in MACH14 collected adherence data using Medication Event Monitoring System, Aardex (MEMS). The MACH14 sample included data from 2,860 individuals. Demographic, psychosocial, and biological data collected in separate studies were combined by creating new variables incorporating consistent data across studies. The current report is based on a subsample of 459 sexually active participants pooled from the five MACH14 studies that collected data on the frequency of unprotected vaginal or anal intercourse. Five of the MACH 14 sites contributed data for this report. Study participants within each of these US cities (Kansas City, Miami, New York, San Francisco, and Seattle) were recruited from a wide array of venues including general medical clinics and hospitals, HIV-care clinics (free-standing and hospital based), private medical practices, community-based AIDS-service organizations and other community service programs (e.g., free-lunch programs), and homeless shelters.

## Measures

Sexual risk was defined as the number of episodes of unprotected vaginal or anal intercourse within a given time frame, and was measured by self-report. Since the time period assessed differed from study to study, all values were adjusted to reflect number of occasions per one month assessed. Adherence was the proportion of prescribed pills that were taken in one month, based on MEMS data. These devices are pill bottles with a microchip in the cap that records the date and time when the bottle is opened. Demographic data included study site, gender, self-reported sexual orientation, income, education, age, and race/ethnicity. Substance use was assessed as the proportion of recent days (the time frame ranged from 2 months to 1 year) on which the substance was used and four substances were included: alcohol, marijuana, cocaine, and heroin. A standardized depression score was calculated for each participant by converting data from the Beck Depression Index (BDI) I or II (34), or the Center for Epidemiologic Studies Depression Scale (*CES-D*) (35) based on published norms.

## Data analysis

Generalized Additive Models were used to test for non-linear associations between adherence and sexual risk behavior, and no significant non-linear terms were found. Demographic variables, frequency of unprotected sex, and adherence were compared across the four sexual identity groups (heterosexual men, gay/bisexual men, heterosexual women, and lesbian/bisexual women) by chi-square tests and analysis of variance (ANOVA). We used Pearson correlations to test for an association between sexual risk and adherence, for the full sample and separately by sexual identity group. Subsequent regression models were fitted in each sexual identity group to determine how sexual risk and adherence were associated after controlling for all demographic variables. In cases where a statistically significant association between sexual risk and adherence was found, additional regression analyses were conducted to test whether adding either depression or substance use to the model would reduce the degree of the association, thereby partially explaining the relationship between sexual risk and adherence. In these regressions, the initial model included only adherence as a predictor of sexual risk behavior. Then in a second set of

models, either depression or four substance use variables were added to the model, and the magnitude of the reduction in the regression coefficient for adherence was evaluated.

## RESULTS

Table 1 includes a description of the sample of the 459 participants who were included in these analyses. Gay and bisexual men made up the largest sexual orientation group. Annual income was low, with 62% reporting \$10,000 or less in income. A majority of the sample had graduated high school, and 19% reported a college degree. Participants were, on average, in their early 40s. Slightly over half of the participants were African American.

The four sexual orientation groups differed on several demographic variables. Gay/bisexual men were the most likely to have a post-high school education. Heterosexual men were the most likely to have participants over the median age of 41. The majority of all groups were African American, with the exception of the gay/bisexual men, who had a higher proportion of white participants.

Table 2 shows descriptive statistics for the frequency of unprotected vaginal or anal sex and for ART adherence for the full sample and the four sexual orientation subgroups. Participants typically had 1–2 unprotected sex occasions per month and adherence was, on average, 75%. The four groups did not significantly differ on either of these variables.

The association between sexual risk and adherence is shown in Table 3. In bivariate correlations, better adherence was significantly associated with fewer occasions of unprotected sex for the total sample. However, this association was quite modest ( $r = -.120$ ) and clearly driven by the association found among heterosexual men ( $r = -.287$ ). The association was not significant among any other sexual orientation group. In the total sample, the modest association between sexual risk and adherence became non-significant after adjusting for demographic variables. However, the association remained significant among the heterosexual men after adjusting for demographics.

Additional regression analyses (results not shown) were conducted for the full sample and the heterosexual male subsample to determine whether the association between sexual risk and adherence could be partially explained by either 1) depression or 2) substance use. In each case, the change in the regression coefficient for adherence was nearly zero (the largest reduction was only 4%). In addition, depression and substance use were generally not correlated with adherence or sexual risk (results not shown). The one exception was that more marijuana use was associated with more sexual risk behavior, but the size of this association was modest ( $r = .126$ ,  $p = .009$ ). Therefore there was no evidence that either depression or substance use explains the association found between sexual risk behavior and adherence in the full sample or in the heterosexual male sub-sample.

## DISCUSSION

We found an association between sexual risk behavior and adherence to ART among HIV-positive heterosexual men in a diverse sample from a multi-site cohort of people on ART. This is not the first study to find this association, although findings have been inconsistent

(21). However, this is the first study of its kind to examine the association among a diverse sample that included heterosexual and homosexual men and women within the same analysis and having measured adherence to ART with a strong objective measure (i.e., MEMS). It is noteworthy that the association between the two behavioral outcomes of interest was significant among heterosexual men and not women (heterosexual or homosexual) or gay/bisexual men. We can only speculate on the reasons for this finding. It is possible that heterosexual men are the least likely to receive HIV prevention messages in the context of their HIV care. Some researchers have identified factors such as substance use, poverty, unemployment, lack of educational opportunities, and marginalization from the health care system to be barriers to care for vulnerable subpopulations of HIV-infected heterosexual men (36). Others have hypothesized that sociocultural constructions of masculinity are associated with risk-taking behaviors, a denial of health information, services, or self-care, and a general lack of interest in one's own health (37). The one significant demographic difference between our two largest sub-samples (gay men and heterosexual men) was that the gay men were more likely to have a higher education and to be White; thus healthcare disparities may have contributed to the association between medication adherence and sexual risk behavior within the heterosexual male sample. We did not have any measure of masculinity in this study.

It is also important to consider the context of heterosexual sexual relationships as compared to homosexual sexual relationships. It is known that anal sex carries significantly more risk for HIV transmission than vaginal sex (38) which can in turn influence decisions about consistency of condom use in these different contexts, particularly within married relationships where condom use may be less likely than with outside partners. Nevertheless, there are individual and public health concerns when HIV-infected people who are not optimally adherent to ART engage in unprotected sex, regardless of the gender and relationship or HIV-status of the partner.

Interestingly, Friedman et al (23) also found very little overall association between sexual risk and non-adherence among a large sample of homeless men and women, but did find that an association between substance use and non-adherence was largely driven by the heterosexual male subgroup in their sample, compared to women and gay/bisexual men; among gay/bisexual men in the same study there was an association between substance use and sexual risk. In our study, neither substance use nor depression was associated with the dual risk of being non-adherent and engaging in sexual transmission risk behaviors. In another large cohort study with a similarly diverse sample, using self-reported adherence and sexual risk as outcomes, the investigators were also unable to identify specific factors associated with this dual-risk (24). Similarly, Kalichman and colleagues found that substance use did not moderate the association between nonadherence and sexual risks among HIV-positive men in Atlanta, GA (22), but did find that alcohol use moderated the association between medication adherence and HIV transmission risk behaviors among a sample of men, women, and transgendered individuals in the same city (39).

It is important that we more fully understand the factors associated with the "dual risk" of having unprotected sex in the context of non-adherence, since there are important public health concerns about the potential for the development and subsequent transmission of



medication-resistant virus to newly infected partners in this context. HIV-infected heterosexual men may be particularly vulnerable to having both poor adherence and also engaging in sexual transmission risk behaviors and therefore may benefit from tailored counseling about these behaviors. The field has several evidence-based behavioral interventions that have been successful in producing sexual risk reduction of HIV-positive people (40, 41) or improving adherence to ART among HIV-positive people who are on ART (42), but has not focused efforts on addressing both of these behaviors at the same time. Such interventions may be particularly needed for HIV-positive heterosexual men. Couple-based approaches should also be considered (43).

There are a few study limitations that should be noted. First, this study is based on a widely diverse sample, recruited in multiple US cities through diverse venues within each city and thus not representative of any specific patient population. Second, the study needed to rely on self-reported sexual risk behavior and we did not have biological markers for sexual risk. Also, given the differences in sexual risk assessments across the studies, we were not able to exam levels of unprotected sex that were specific to either relationship status, marital status, or HIV status of partners. Finally, this study also was not able to examine other potential factors that could be associated with our outcomes of interest, namely beliefs about the association between being on ART and having an undetectable viral load with level of infectiousness; nor did we have data on actual viral load for participants across all of the studies. In spite of these limitations, this study is able to report findings that are relevant to our understanding of the important but complex relationship between medication adherence and adherence to safer-sex practices among HIV-positive adults.

Use of ART as an effective means to reduce HIV infectiousness is an important advance in the field of HIV prevention. However, if we are to move forward with widespread scale-up of “Test and Treat” approaches to curtail the HIV epidemic, we must pay attention to the behavioral factors necessary for success. While it is true that a suppressed HIV viral load is associated with a reduction in risk of HIV transmission from an infected to an uninfected partner, medical and public health recommendations remain in place for HIV-infected individuals to use barrier protection with their sex partners, whether on or off of treatment. And since lapses in adherence to ART can lead to an elevated viral load as well as the development of resistant virus, increasing the risk of transmission of HIV (possibly resistant) to an HIV-negative sex partner, interventions are needed to address both sexual risk and non-adherence behaviors among people living with HIV, including the ongoing encouragement and facilitation of optimal medication adherence and adherence to safer sex practices. We must also identify procedures to screen for these risk outcomes, and develop interventions to address them, appropriately tailored to specific populations, that can be integrated into routine clinical care for people living with HIV. This will become increasingly important in the context of expanded treatment roll-out globally, including newly emerging recommendations for ART initiation earlier in a patients’ disease course.

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Table 1

Sample description (N=459)	Total Sample (N=459)				Hetero-sexual Men (N=131)		Gay/Bisexual Men (N=156)		Hetero-sexual Women (N=75)		Lesbian/Bisexual Women (N=23)		$\chi^2$ p
	N <sup>a</sup> (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)		
Study Site													
Site 2	16 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)		<.001
Site 5	24 (5%)	6 (5%)	7 (4%)	7 (4%)	7 (4%)	9 (12%)	1 (4%)	1 (4%)	1 (4%)	1 (4%)	1 (4%)		
Site 9	166 (36%)	54 (41%)	37 (24%)	37 (24%)	37 (24%)	54 (72%)	19 (83%)	19 (83%)	19 (83%)	19 (83%)	19 (83%)		
Site 12	160 (35%)	62 (47%)	44 (28%)	44 (28%)	44 (28%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)		
Site 13	93 (20%)	9 (7%)	68 (44%)	68 (44%)	68 (44%)	12 (16%)	3 (13%)	3 (13%)	3 (13%)	3 (13%)	3 (13%)		.245
Income													
<\$10,000	281 (62%)	80 (63%)	83 (53%)	83 (53%)	83 (53%)	51 (68%)	17 (74%)	17 (74%)	17 (74%)	17 (74%)	17 (74%)		
\$10–20,000	114 (25%)	31 (24%)	42 (27%)	42 (27%)	42 (27%)	18 (24%)	4 (17%)	4 (17%)	4 (17%)	4 (17%)	4 (17%)		
\$20–30,000	28 (6%)	7 (5%)	14 (9%)	14 (9%)	14 (9%)	3 (4%)	2 (9%)	2 (9%)	2 (9%)	2 (9%)	2 (9%)		
\$30–40,000	14 (3%)	7 (5%)	7 (4%)	7 (4%)	7 (4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)		
>\$40,000	16 (4%)	3 (2%)	10 (6%)	10 (6%)	10 (6%)	3 (4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)		
Education													
<HS graduate	111 (24%)	31 (24%)	17 (11%)	17 (11%)	17 (11%)	24 (32%)	12 (52%)	12 (52%)	12 (52%)	12 (52%)	12 (52%)		<.001
HS graduate	260 (57%)	76 (58%)	93 (60%)	93 (60%)	93 (60%)	45 (60%)	11 (48%)	11 (48%)	11 (48%)	11 (48%)	11 (48%)		
College degree	88 (19%)	24 (18%)	46 (29%)	46 (29%)	46 (29%)	6 (8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)		.007
Age													
<41 years	243 (53%)	57 (44%)	93 (60%)	93 (60%)	93 (60%)	41 (55%)	17 (74%)	17 (74%)	17 (74%)	17 (74%)	17 (74%)		
41 years +	213 (47%)	74 (56%)	61 (40%)	61 (40%)	61 (40%)	34 (45%)	6 (26%)	6 (26%)	6 (26%)	6 (26%)	6 (26%)		
Race/Ethnicity													
African American	240 (52%)	72 (55%)	44 (28%)	44 (28%)	44 (28%)	52 (69%)	17 (74%)	17 (74%)	17 (74%)	17 (74%)	17 (74%)		<.001
White, not Latino	121 (26%)	27 (21%)	71 (46%)	71 (46%)	71 (46%)	11 (15%)	4 (17%)	4 (17%)	4 (17%)	4 (17%)	4 (17%)		
Latino	98 (21%)	32 (24%)	41 (26%)	41 (26%)	41 (26%)	12 (16%)	2 (9%)	2 (9%)	2 (9%)	2 (9%)	2 (9%)		

<sup>a</sup>Ns do not always sum to 459 due to missing data.

Table 2

Risk and adherence by sexual orientation group

	Total Sample (N = 459)	Heterosexual Men (N = 131)	Gay/Bisexual Men (N = 156)	Heterosexual Women (N = 75)	Lesbian/Bisexual Women (N = 23)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Sexual Risk <sup>a</sup>	1.16 (4.46)	1.50 (4.61)	0.77 (3.63)	2.20 (6.42)	1.97 (6.87)
Adherence <sup>b</sup>	0.75 (0.28)	0.76 (0.28)	0.75 (0.29)	0.74 (0.25)	0.71 (0.28)

<sup>a</sup>Frequency of unprotected vaginal and/or anal sex per 1 month.<sup>b</sup>Proportion of prescribed pills taken.

Table 3

Association between adherence and sexual risk.

	Correlations		Regressions <sup>a</sup>			
	N	r	p	b	se	p
Total Sample	459	-.120	.010	-0.005	0.003	.157
Heterosexual Men	131	-.287	<.001	-0.016	0.005	.004
Gay/Bisexual Men	156	-.097	.227	0.009	0.011	.380
Heterosexual Women	75	-.053	.654	-0.002	0.005	.629
Lesbian/Bisexual Women	23	.189	.387	0.017	0.012	.172

<sup>a</sup> GLM, adjusting for demographic variables shown in Table 1. Analyses for female groups are presented for completeness, but limited due to low Ns.