Published in final edited form as:
Sex Transm Infect. 2014 August ; 90(5): 418–422. doi:10.1136/sextrans-2013-051408.

SUBOPTIMAL PLASMA HIV-1 RNA SUPPRESSION AND ADHERENCE AMONG SEX WORKERS WHO USE ILLICIT DRUGS IN A CANADIAN SETTING: AN OBSERVATIONAL COHORT STUDY

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Abstract

Objective—Studies have demonstrated the central function of plasma HIV-1 RNA viral load (pVL) levels on determining the risk of HIV disease progression and transmission. However, there is limited empirical research on virologic outcomes among sex workers who use illicit drugs (SW-DU).

Methods—Data were derived from the AIDS Care Cohort to evaluate Exposure to Survival Services, a cohort of HIV-positive illicit drug users. Using generalised estimating equations, we studied the longitudinal relationship between sex work and pVL suppression. We also tested whether adherence to antiretroviral therapy (ART) mediated the relationship between sex work and pVL suppression.

Results—Between May 1996 and May 2012, 587 ART-exposed participants (2224 person-years of observation) were included in the study, among whom 127 (21.6%) reported sex work. In a time-updated multivariate model adjusted for various demographic, socioeconomic and clinical confounders (eg, gender, incarceration, CD4 cell count), SW-DU had an independently reduced

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Contributors The specific contributions of each author are as follows: LT, M-JM and EW were responsible for the study design; AS conducted the statistical analyses; LT prepared the first draft of the manuscript; M-JM, KS, AS, RSH, SG, JM, TK and EW provided critical comments on the first draft of the manuscript and approved the final version to be submitted.

Ethics Approval University of British Columbia/Providence Healthcare Research Ethics Board.

Competing Interests For the remaining authors, no conflicts of interest were declared.

odds of pVL suppression compared to non-SW-DU (adjusted OR (AOR)=0.66; 95% CI 0.45 to 0.96). However, adding ART adherence to the multivariate model eliminated this association (p>0.05), suggesting adherence mediated the relationship between sex work and pVL suppression.

Conclusions—Evidence-based interventions to improve adherence to ART among SW-DU are urgently needed to help produce the maximum HIV treatment and prevention benefit of ART among this highly vulnerable population.

INTRODUCTION

Advancements in the clinical management of HIV infection through the use of antiretroviral therapy (ART) have resulted in dramatic declines in HIV-related morbidity and mortality among people living with HIV.[1] Optimal adherence to ART is strongly associated with reducing plasma HIV-1 RNA viral load (pVL), slowing HIV disease progression and prolonging survival.[2] Additionally, recent studies have demonstrated the central role played by pVL on HIV transmission dynamics.[3] In light of these findings, the HIV treatment as prevention approach (TasP) has been endorsed by a number of major international public health bodies, including the Joint United Nations Programme on HIV/AIDS and the World Health Organization (WHO), with various models to seek, test, treat and retain individuals in treatment being implemented worldwide.[4]

However, among people who use illicit drugs (DU), the successful clinical management of HIV infection is complicated by individual, social and structural factors that often impede optimal outcomes from ART.[5] For instance, although evidence has linked ongoing illicit drug use to greater risk of suboptimal ART adherence,[6] recent studies have also highlighted the array of social, structural and environmental barriers that DU often contend with as a function of drug addiction. These include high rates of homelessness[7] and incarceration,[8] often resulting in suboptimal adherence and clinical outcomes.

Sex workers who use illicit drugs (SW-DU) face particularly high risks of HIV infection,[9] with increasing research over the last decade in North America and the UK suggesting that SWDU face among the highest rates of new HIV infections among DU.[10] Furthermore, a recent meta-analysis of 50 low-income and middle-income countries revealed an overall prevalence of HIV of 11.8% and a pooled OR for HIV of 13.5 among female sex workers (SW) compared to the general population of women of reproductive age.[11] However, there is a near-complete dearth of information regarding plasma HIV-1 RNA outcomes among SW in high-income settings, particularly SW-DU, with free HIV/AIDS treatment and care. To address this, we sought to investigate the effect of sex work on virologic outcomes among DU in a setting of universal HIV/AIDS care.

METHODS

Study design

Data were collected from the AIDS Care Cohort to Evaluate Access to Survival Services (ACCESS), a prospective cohort study of HIV-positive DU in Vancouver, Canada. The specific methods employed have been described in detail elsewhere.[12] In brief, beginning in 1996, participants were recruited through self-referral and street-based outreach from

Vancouver's Downtown Eastside neighbourhood, a postindustrial area with a large open drug market and high levels of illicit drug use, poverty and HIV infection. Individuals were eligible to participate in ACCESS if they were aged 18 years or older, were HIV-seropositive, have used illicit drugs other than cannabis in the month prior to enrolment, and provided written informed consent. Participants were compensated $C20 at each study visit.

At baseline and semiannually, participants complete an interviewer-administered questionnaire soliciting demographic data, information on drug use patterns, as well as other characteristics and exposures. At each of these visits, individuals also undergo an examination by a study nurse and provide blood samples for serologic analyses. Information gathered at each interview is augmented by comprehensive information on HIV care and treatment outcomes from the local centralised HIV/AIDS registry. Specifically, through a confidential linkage, a complete clinical profile of all CD4 T-cell counts, HIV-1 RNA pVL observations and exposure to specific antiretroviral agents for each participant are obtained. In British Columbia, all provision of ART is centralised through a province-wide ART dispensation programme, where ART and related care are provided free of charge. The ACCESS study has been approved by the University of British Columbia/Providence Healthcare Research Ethics Board.

Study participants

We included all individuals who had received at least 1 day of ART at the time of the baseline interview. Individuals who were ART-naïve at baseline but who initiated treatment during follow-up were included from the next follow-up interview forward. As well, to be included in these analyses, at least one observation of CD4 cell count and pVL had to be completed within±180 days of the day they entered the study.

Variable selection

The primary outcome of interest was non-detectable pVL in the previous 6 months, defined as having achieved a HIV-1 RNA load <500 copies/mL plasma (yes vs no). In the event that more than one pVL observation was collected within a 6-month follow-up, we used the median of all the observations, which was then categorised into either having achieved a HIV-1 RNA load <500 copies/mL plasma or not. The primary explanatory variable of interest was reporting sex work, defined as the exchange of sex for money, gifts, food, shelter, clothes, drugs, or favours, at any time in the 6-month period prior to the follow-up interview (yes vs no). This variable was measured longitudinally at each follow-up and it was included in the analysis as a time-updated measure. To estimate the relationship between sex work and pVL, we considered secondary explanatory variables that may potentially confound this relationship. These included a range of demographic and socioeconomic variables, such as age (dichotomised at the median); gender (female vs male); homelessness (yes vs no); illicit drug use (any illicit injection drug use vs any illicit non-injection drug use only vs none); binge drug use of illicit drugs by either injection or non-injection (yes vs no); current enrolment in methadone maintenance therapy (MMT) (yes vs no); and incarceration (yes vs no). We included aboriginal ancestry (yes vs no) as a potential variable of interest given that past research has shown links between aboriginal ethnicity and various HIV-related outcomes, including pVL suppression and virologic

failure.[13] Homelessness was defined as living on the street or having no fixed address in the last 6 months. Illicit drug use was considered using a three-level variable where abstinence constituted the reference category and was compared to the influence of any injection drug use (ie, heroin, cocaine, or crystal methamphetamine injecting) and illicit non-injection drug use only during the previous 6 months. The illicit injection drug use category could also include polysubstance users who also used illicit drugs by non-injection routes. All time-varying variables are time-updated and refer to the 6-month period prior to the follow-up interview unless otherwise indicated. Additionally, we included the following clinical variables: year of ART initiation (per year increase); the presence of a protease inhibitor in the first ART regimen (yes vs no); pVL at ART initiation (copies/mL, log10 transformed); CD4 cell count in the last 6 months (per 100 cells/mL); and HIV physician experience (per 100 patients). ART adherence was also included and defined as the quotient of the number of days that ART was dispensed divided by the total number of days an individual was eligible for ART (determined by the number of days in any period after the first dispensation of ART); this proportion was dichotomised as ≥95% vs <95%. For instance, if an individual was dispensed 90 days of medications and was eligible for treatment for the entire 180-day period prior to the interview, adherence was 50%. This validated measure using pharmacy refill data has been used extensively in previous research and has been shown to reliably predict pVL suppression[14] and survival.[1]

Statistical analyses

As a first step, we examined the baseline characteristics of our sample, stratified by whether participants achieved pVL suppression in the 6 months prior to the baseline interview. Categorical variables were analysed using Pearson's $\chi 2$ test and continuous variables were analysed using the Wilcoxon Rank-Sum test. Next, we used generalised estimating equations (GEE) to estimate unadjusted OR for the effect of sex work and all other secondary explanatory variables on pVL suppression. We used GEE for the analysis of correlated data since the factors potentially associated with pVL suppression during follow-up were time-dependent measures. We only included individuals with complete data at each given time point.

To estimate the independent effect of sex work on pVL suppression, we constructed a multivariate GEE model using a variable selection process described previously by Maldonado and Greenland.[15] In this process, we employed a conservative p value cutoff ≤0.20 to determine which variables were possibly associated with pVL suppression in GEE analyses described above. Then we fit a full model including these explanatory variables, noting the value of the coefficient associated with sex work. In a stepwise manner, we removed the secondary explanatory variable corresponding to the smallest relative change in the effect of sex work on pVL suppression from further consideration. We continued this iterative process until the maximum change of the value of the coefficient for sex work from the full model exceeded 5%. Remaining variables were considered confounders in multivariate analyses. We have previously used this approach to estimate the independent relationship of a primary explanatory variable on an outcome of interest[8]

As a final step, we conducted a mediation analysis to determine whether adherence to ART mediated the relationship between sex work and pVL suppression. Two methods were used: the Baron and Kenny approach,[16] which involved running two GEE models, one with and one without the adherence variable, to determine whether the sex work variable maintained its significance after the adherence variable was added, and the Sobel test statistic.[17] These statistical tests for mediation have been used previously in other studies.[18,19]

RESULTS

Between May 1996 and May 2012, 622 HIV-seropositive DU met the inclusion criteria for this analysis. Due to missing observations in the variables of interest, 35 (5.6%) participants were excluded from the analysis to provide a total of 587 participants in the final analytic sample with a median of 32 months (IQR: 18–60) of prospective follow-up. Among the participants, 169 (28.8%) initiated ART during the study period. The sample comprised 186 (31.7%) females. Over the study period, the participants contributed 2224 person-years of follow-up. Table 1 shows the baseline characteristics of the study sample stratified by pVL suppression.

Among participants, 91 (15.5%) participants reported sex work at baseline; of these, 17 (18.7%) were male. In total, 127 (21.6%) participants reported sex work at least once sometime during the study period. At baseline, pVL suppression was observed in 275 (46.9%) participants and, in total, 492 (83.8%) participants achieved at least one period of pVL suppression sometime during the study.

The crude longitudinal estimates of the odds of pVL suppression are presented in table 2. SW had significantly lower odds of achieving pVL suppression in unadjusted analysis compared to non-SW (OR=0.50, 95% 95% CI 0.38 to 0.65, $p<0.001$). Factors associated with significantly higher odds of pVL suppression included older age and enrolment in MMT (both $p<0.001$). Additionally, participants who were women, reported homelessness, injection drug use, binge drug use and incarceration, had lower odds of pVL suppression (all $p\leq0.010$). Among clinical factors, year of ART initiation, ART adherence, CD4 cell count and HIV physician experience were positively associated with higher odds of pVL suppression, whereas pVL at ART initiation was inversely associated with the outcome (all $p\leq0.001$).

As presented in table 3, in the first multivariate model that adjusted for age, gender, homelessness, illicit drug use, enrolment in MMT, pVL at ART initiation and CD4 cell count, SW had independently lower odds of pVL suppression (adjusted OR (AOR)=0.66; 95% CI 0.45 to 0.96). In the second model, when ART adherence was included as an additional variable, the effect of sex work on pVL suppression was no longer significant (AOR=0.72; 95% CI 0.49 to 1.04), supporting the role of adherence as a mediating variable in the relationship between sex work and pVL suppression. A second test of mediation confirmed the role of ART adherence as a mediating variable (Sobel test statistic=−2.12, $p=0.034$).

DISCUSSION

In the present study, we observed that a large proportion of our participants achieved pVL suppression, with over 80% of participants experiencing at least one period of pVL suppression. After controlling for a range of relevant individual, social and structural factors, SW-DU remained at significantly reduced odds of achieving pVL suppression compared to non-SW-DU. However, this relationship did not persist when ART adherence was included as a mediating variable. To our knowledge, this study is the first to demonstrate the dramatically reduced rates of pVL suppression among SW-DU, and the role of ART adherence on virologic response in a setting where there are no financial barriers to HIV treatment and care.

Our study has several limitations that should be noted. First, because of the observational nature of the ACCESS study, the potential effect of residual confounding must be considered when interpreting the effect of adherence and sex work on pVL suppression. Second, our sample was not randomly recruited and, therefore, may not be representative of all local DU. Third, the study included some data derived from self-report and, thus, may be subject to reporting biases, including socially desirable reporting and recall bias. However, our outcome of interest and ART adherence measures were observed from comprehensive administrative records and we do not believe individuals differentially reported engagement in sex work based on pVL or adherence.

Local and international research in settings with free ART access have identified an array of individual, social and structural barriers to poor adherence and retention among SW, including stigma and discrimination in healthcare settings, lack of support, criminalisation of sex work and HIV, and geographic mobility.[20,21] These factors can impede daily medication regimes and access to conventional ART clinics due to avoidance of police, violent predators or partners, and working late night hours and away from health services.[21] At the same time, data suggest that where programmes can address these gaps in retention, SW can have the same clinical and biological outcomes as other key affected populations.[22] Ongoing drug use and poverty may also indirectly prevent SW from achieving optimal ART adherence.[20,21] Given these past findings, our results have important implications for efforts to promote improved HIV treatment outcomes and reduce morbidities for SW-DU, as well as population-level benefits of increasing universal coverage of HIV treatment to SW.

As demonstrated in the present study, poor adherence to ART predictably leads to inferior pVL suppression. Consequently, increases in HIV-related morbidity and mortality are likely to occur among SW-DU, in the absence of optimal adherence. In order to improve virologic outcomes among SW living with HIV, evidence-based interventions aimed at improving the health and social conditions of SW are urgently needed. Since much sex work among street-involved populations in this setting involves exchanging sex directly for illicit drugs, and given the high rates of untreated addiction among this population, efforts to expand harm reduction and addiction treatment are also urgently needed.

In December 2012, new UN guidelines were released on HIV prevention, treatment and care among SW.[23] These guidelines specifically address ART coverage and scale up, and follow

standard WHO guidelines for ART for all HIV-positive individuals, with special consideration of potential HIV comorbidities (eg, STIs, addiction). Importantly, these guidelines call on governments, public health and community to address structural barriers to improve access and retention in HIV prevention and ART for SW, including removal of criminal and punitive approaches targeting SW, voluntary and non-coercive access to testing and treatment and addressing stigma by health providers and community. In many settings globally, obstacles to optimal HIV treatment and care remain despite a large body of research demonstrating the problematic use of criminalising approaches to sex work, drug use and HIV.[5,11] For example, studies have shown that the reliance on law enforcement efforts (eg, police crackdowns) in Canada can deter SW-DU from accessing health services,[24] and thus may subsequently impact their access to, and continued engagement in, ART. Given the substantial burden of HIV among SW and DU in our setting[9] as well as others,[11,25] efforts to implement these guidelines and develop strategies to reduce social and structural barriers to ART adherence and patient retention in care for SW-DU in higher-income settings are urgently needed.

Prior studies have documented the value of a multidisciplinary approach to adherence support for SW and DU, including close follow-up with a peer health advocate and outreach team as well as collective support from peer educators, physicians and other healthcare workers.[22,26] Peer and sex work-led models, such as the San Francisco Occupational Health and Safety clinic,[27] and the Songachi model in India,[28] have been shown to reduce stigma and barriers to healthcare and increase trust with service providers that could promote increased retention in HIV care. Indeed, a recent study in Vancouver demonstrated a positive impact on adherence and pVL outcomes from implementing a peer-driven intervention model among SW.[26] Other strategies that warrant consideration include mobile and text messaging ART adherence programmes that may be adaptable to SW, given increasing use of mobile technologies and high levels of mobility among this population.[29]

To conclude, we analysed the effect of sex work on pVL suppression using data from a long-running prospective cohort of HIV-positive DU with free access to ART. Our results demonstrate that SW-DU have a reduced odds of pVL suppression compared to their non-SW-DU counterparts, and that this relationship was mediated by ART adherence. Our findings highlight the overall need for strategies to improve HIV care among SW-DU, including peer and sex work-led initiatives to support retention and adherence. Future research should seek to explore factors other than ART adherence that may potentially mediate the relationship between sex work and pVL suppression. Additionally, further research that explores why SW-DU may have lower rates of adherence to ART in comparison to other DU will be helpful to inform intervention strategies. Given past research demonstrating the need to improve access to harm reduction and addiction treatment among this population, efforts to expand evidence-based addiction treatment must also be prioritised. Similarly, given past research highlighting how laws criminalising sex work contribute to barriers to individuals' safety and access to care, strategies to improve SW safety that can help facilitate improved HIV care must also be prioritised.

Acknowledgments

The authors thank the study participants for their contributions to the research, as well as current and past researchers and staff. We would specifically like to thank Deborah Graham, Tricia Collingham, Carmen Rock, Brandon Marshall, Caitlin Johnston, Steve Kain, Benita Yip and Jennifer Matthews for their research and administrative assistance.

This work was supported in part by a Tier 1 Canada Research Chair in Inner-City Medicine awarded to EW. The study is supported by the US National Institutes of Health (R01-DA021525). JM is supported by the British Columbia Ministry of Health; through an Avant-Garde Award (No. 1DP1DA026182-01) from the National Institute of Drug Abuse (NIDA), at the US National Institutes of Health (NIH); and through a KT Award from the Canadian Institutes of Health Research (CIHR). He has also received financial support from the International AIDS Society, United Nations AIDS Program, World Health Organization, National Institutes of Health Research-Office of AIDS Research, National Institute of Allergy & Infectious Diseases, The United States President's Emergency Plan for AIDS Relief (PEPfAR), Bill & Melinda Gates Foundation, French National Agency for Research on AIDS & Viral Hepatitis (ANRS), the Public Health Agency of Canada, the University of British Columbia, Simon Fraser University, Providence Health Care and Vancouver Coastal Health Authority. He has received grants from Abbott, Biolytical, Boehringer-Ingelheim, Bristol-Myers Squibb, Gilead Sciences, Janssen, Merck and ViiV Healthcare. M-JM is supported by the Michael Smith Foundation for Health Research and the Canadian Institutes of Health Research.

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Key messages

- Among a cohort of HIV-positive people who use illicit drugs (DU), sex work was negatively associated with plasma HIV-1 RNA viral load (pVL) suppression.
- Adherence to antiretroviral therapy (ART) mediated the relationship between sex work and pVL suppression.
- Evidence-based interventions to improve adherence to ART among sex workers who use illicit drugs (SW-DU) are urgently needed.
- There is a need for strategies to improve HIV care among SW-DU, including peer and sex work-led initiatives to support retention and adherence.

Table 1

Baseline characteristics of ART-exposed DU in Vancouver, Canada, stratified by pVL suppression in the last 6 months (n=587)

Characteristic	Total (%) (n=587)	Viral load suppression		p Value
		Yes (%) (n=275)	No (%) (n=312)	
Sex work*	91 (15.5)	30 (10.9)	61 (19.6)	0.004
≥43 years old	268 (45.7)	170 (61.8)	98 (31.4)	<0.001
Female gender	186 (31.7)	65 (23.6)	121 (38.8)	<0.001
Aboriginal ancestry	214 (36.5)	90 (32.7)	124 (39.7)	0.078
Homelessness*	143 (24.4)	53 (19.3)	90 (28.9)	0.007
Illicit drug use*				
Any injection drug use	443 (75.5)	184 (66.9)	259 (83.0)	<0.001
Any illicit drug use	109 (18.6)	79 (28.7)	30 (9.6)	<0.001
Binge drug use*	320 (54.5)	141 (51.3)	179 (57.4)	0.139
Current enrolment in MMT	211 (36.0)	106 (38.6)	105 (33.7)	0.218
Incarceration*	76 (13.0)	26 (9.5)	50 (16.0)	0.018
Year of ART initiation (per year) (med, IQR)	2000 (1997–2006)	2002 (1997–2007)	1998 (1996-2006)	<0.001
≥95% ART adherence	325 (55.4)	207 (75.3)	118 (37.8)	<0.001
PI in first regimen	240 (40.9)	112 (40.7)	128 (41.0)	0.942
pVL at ART initiation (per loglO) (med, IQR)	2.56 (1.65–4.30)	1.65 (1.54–1.69)	4.11 (2.98–4.87)	<0.001
CD4 cell count (per 100 cells)* (med, IQR)	3.20 (1.93–4.50)	3.77 (2.53–4.90)	2.64 (1.47–4.00)	<0.001
HIV physician experience (per 100 patients) (med, IQR)	0.44 (0.11–1.26)	0.58 (0.17–1.53)	0.30 (0.09–0.94)	<0.001

*Refers to the 6-month period prior to the interview.

ART, antiretroviral therapy; DU, people who use illicit drugs; MMT, methadone maintenance therapy; PI, protease inhibitor; pVL, plasma viral load.

Table 2

Bivariate GEE analysis off actors associated with pVL suppression in the last 6 months among ART-exposed DU in Vancouver, Canada (n=587)

Characteristic	Crude OR (95% CI)	p Value
Sex work*		
(yes vs no)	0.50 (0.38 to 0.65)	<0.001
Median age		
(≥median vs <median)	3.63 (2.75 to 4.80)	<0.001
Gender		
(female vs male)	0.53 (0.41 to 0.69)	<0.001
Aboriginal ancestry		
(yes vs no)	0.85 (0.66 to 1.10)	0.229
Homelessness*		
(yes vs no)	0.54 (0.45 to 0.66)	<0.001
Illicit drug use*		
Any injection drug use	0.45 (0.33 to 0.61)	<0.001
Any illicit drug use	1.07 (0.75 to 1.54)	0.703
None	1.00 (reference)	
Binge drug use*		
(yes vs no)	0.87 (0.76 to 0.98)	0.027
Current enrolment in MMT		
(yes vs no)	2.14(1.61 to 2.83)	<0.001
Incarceration*		
(yes vs no)	0.59 (0.48 to 0.71)	<0.001
Year of ART initiation		
(per year increase)	1.08 (1.05 to 1.11)	<0.001
ART adherence		
(≥95% vs <95%)	8.84 (7.22 to 10.83)	<0.001
PI in first regimen		
(yes vs no)	1.11 (0.86 to 1.44)	0.424
pVL at ART initiation		
(per Iog 10 increase)	0.44 (0.40 to 0.48)	<0.001
CD4 cell count*		
(per 100 cells)	1.48 (1.36 to 1.62)	<0.001
HIV physician experience		
(per 1000 patients)	1.28 (1.11 to 1.47)	<0.001

*Refers to the 6-month period prior to the interview.

ART, antiretroviral therapy; DU, people who use illicit drugs; GEE, generalised estimating equations; MMT: methadone maintenance therapy; PI: protease inhibitor; pVL, plasma viral load.

Table 3

Adjusted ORs highlighting the effect of sex work on pVL suppression in GEE models (n=587)

Model	Adjusted OR (95% CI)	p Value
Model 1.Effect of sex work, without adherence (mediator) variable included*	0.66 (0.45 to 0.%)	0.031
Model 2.Effect of sex work, including adherence (mediator) variable*	0.72 (0.49 to 1.04)	0.080

*Adjusted for age, gender, homelessness, injection drug use, enrolment in methadone maintenance therapy, pVL at ART initiation, and CD4 cell count.

ART, antiretroviral therapy; GEE, generalised estimating equation; pVL, plasma viral load.