

Determinants of HAART discontinuation among injection drug users

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Abstract

The objective of this study was to identify psychosocial determinants of, and self-reported reasons for, HAART discontinuation among HIV-positive injection drug users (IDUs). We examined correlates between sociodemographic characteristics, drug use and risk behaviors, outcome expectations, adherence self-efficacy, social support and HAART discontinuation among 160 HIV-positive participants in the Vancouver Injection Drug Users' Study (VIDUS). Logistic regression was used to identify the factors independently associated with discontinuation of HAART. Seventy-one (44%) study participants discontinued HAART during the study period. Factors independently associated with discontinuation of HAART included recent incarceration (OR = 4.84, $p = 0.022$), negative outcome expectations (OR = 1.41, $p = 0.001$), adherence efficacy expectations (OR = 0.70, $p = 0.003$) and self-regulatory efficacy (OR = 0.86, $p = 0.050$). The most frequently cited reasons provided for discontinuing HAART were being in jail (44%) and medication side effects (41%). The results of this study suggest that psychological constructs derived from self-efficacy theory are highly germane to the understanding of HAART discontinuation behavior and interventions that may change it. Incarceration may result in interruptions in HAART among IDUs, and programmatic changes may be needed to promote optimal retention on HAART among incarcerated HIV-infected IDUs.

Introduction

The medical management of HIV/AIDS changed dramatically with the advent of highly active antiretroviral therapy (HAART), producing substantial reductions in both AIDS-related morbidity and mortality (Hammer et al., 1997; Hogg et al., 1999; Porter et al., 2003). While HAART has greatly improved clinical outcomes among persons living with HIV/AIDS, the optimism generated by this new approach has been tempered by concerns about inequitable access to HAART and low levels of adherence to these complex regimens (Altice & Friedland, 1998; Wood et al., 2003a).

Among those known to have low rates of access and adherence to HAART, and consequently poor HIV/AIDS-related health outcomes, are injection drug users (Porter et al., 2003; Wood et al., 2003b). HIV-positive injection drug users (IDUs) have been found

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to have lower uptake of antiretroviral therapy compared to other HIV-positive persons in Canada, the United States and Europe (Ferrando et al., 1996; Muma et al., 1995; Singh et al., 1996; Strathdee et al., 1998; Wall et al., 1995), and consequently higher rates of AIDS-related morbidity and mortality (Porter et al., 2003; Wood et al., 2003b).

Also of concern are findings indicating that as much as 50% of IDUs who initiate HAART discontinue therapy against medical advice (Demas, 1998; Palepu, 2001). Available evidence suggests that rates of HAART discontinuation may be higher among IDUs than in the general population (Demas et al., 1998; Murri et al., 2003; Palepu et al., 2001). These rates of discontinuation indicate potentially adverse outcomes for individual and public health due to the heightened risk for loss of virologic control and subsequent viral rebound (Harrigan et al., 1999), and the development of drug resistance and the transmission of resistant virus to others (Bangsberg et al., 2000; Deeks, 2001). While there has been a rapidly growing body of literature addressing issues associated with adherence to HAART, these studies have relied primarily on clinic-based samples or those who complete follow-up surveys, and therefore instances of outright discontinuation of HAART are generally not considered or characterized. As a result, little is known about the events or characteristics that may predict discontinuation of HAART among population-based samples of IDUs. Further, although psychosocial variables that are amenable to intervention, such as self-efficacy and social support (Chesney et al., 2000; Gifford et al., 2000; Gordillo et al., 1999; Kalichman et al., 2001; Singh et al., 1999; Tuldra et al., 2000) have been examined in the adherence literature, these variables have not been studied in the context of discontinuation of HAART, in particular among IDUs. Consequently, potential psychosocial interventions for retaining IDUs in care have received little attention. Therefore, the present study was undertaken to identify psychosocial characteristics associated with discontinuation of HAART among IDUs, as well as self-reported reasons for discontinuation, in a setting that delivers HAART and AIDS care free of charge.

Methods

The Vancouver Injection Drug Users' Study (VIDUS)

Beginning in May 1996, persons who had injected illicit drugs at least once in the previous month and resided in the Greater Vancouver region were recruited into VIDUS, a prospective cohort study of injection drug users that has been described in detail previously (Strathdee et al., 1997; Wood et al., 2001). Over 1,500 subjects have been recruited through self-referral and street outreach efforts. Eligible subjects were those who had injected illicit drugs at least once in the previous month, resided in the Greater Vancouver area and provided written informed consent. All participants were informed of the nature of the study and asked to sign a consent form that permitted linkages with external medical records. At baseline and semi-annually, participants provided blood samples and completed an interviewer-administered questionnaire. The questionnaire is designed to elicit demographic data and information about drug use, HIV risk behaviors and drug treatment. Participants were reimbursed \$20 for each study visit, at which time referrals were provided for universal medical care, HIV/AIDS care and available drug and alcohol treatment. The VIDUS study has ethical approval from the University of British Columbia/Providence Health-care Office of Research Services. The present analysis was restricted to the follow-up period occurring from 1 December 2001 to 30 November 2002.

The HIV/AIDS Drug Treatment Program

The British Columbia Centre for Excellence in HIV/AIDS supports the province-wide HIV/AIDS Drug Treatment Program (DTP) that distributes antiretroviral agents at no cost to eligible HIV-infected individuals, and <1% of eligible HIV-infected individuals obtain antiretrovirals from outside the program (Strathdee et al., 1998). At the time of patient enrollment physicians must complete a drug request enrollment form which acts as a legal prescription and the DTP maintains information on the HIV-positive applicant, the follow-up physician, past HIV-specific drug history, viral load, CD4 cell counts and current medication requests. All HAART medications are stored within a centralized pharmacy and the DTP maintains records of all medications that are dispensed.

HAART discontinuation among HIV-infected IDUs in the VIDUS study

These analyses were restricted to HIV-infected VIDUS participants who had taken or were currently receiving HAART. Sociodemographic characteristics derived from the VIDUS questionnaire and considered in the present analyses included: gender, age, recent incarceration (overnight or longer), sex work involvement and unstable housing. Unstable housing was defined as living in a single-room occupancy hotel, transitional living arrangements or being homeless. Drug use and related behavioral variables considered in the analyses included: frequent heroin injection, frequent cocaine injection, frequent crack use and bingeing. All questions use the previous six months as a reference period (e.g., 'In the past six months, when you were using, which of the following drugs did you inject?'). As in our previous work (Wood et al., 2002), persons who reported injecting cocaine or heroin once or more per day were defined as frequent cocaine and frequent heroin users, respectively. Individuals smoking crack once or more daily were considered to be frequent crack users. The follow-up procedures also document if participants were currently on methadone maintenance therapy.

Self-reported initiation, use and discontinuation of HAART were confirmed through a confidential record linkage with the DTP. Individuals were considered to have discontinued HAART if: (1) they had been prescribed HAART and picked up at least one prescription; and (2) they reported that they were no longer taking HAART and DTP pharmacy dispensation records confirmed that they had not picked up any components of their HAART regimen for one month. Individuals who reported being taken off HAART by their physicians were not defined as having discontinued in this analysis. Participants were also asked to indicate reasons for discontinuing HAART from a list of possible responses, including: being out of area, fed-up, sick with side effects, methadone interaction, was in jail, and other reasons.

Adherence Self-efficacy Measure (ASEM)

We developed an eight-item adherence self-efficacy measure (ASEM) for use in the present study. The items and response scales that were finalized after extensive piloting are presented in Table I. As is common in the measurement of self-efficacy, items were tailored to reflect the specific behaviors and skills under study (Bandura, 1997), and included six items assessing adherence efficacy expectations and two items assessing self-regulatory efficacy. Composite efficacy expectation and self-regulatory efficacy scores were calculated by adding sub-scale scores and dividing the sum by the total number of sub-scale items. Also included in Table I is an additional item that was developed to assess outcome

Table I. Descriptive statistics for Adherence Self-efficacy Measure and outcome expectation items.

Dimensions and item	Mean	SD
Efficacy expectations		
Remember how many HIV pills you have to take	87.61	22.81
Remember to pick up prescription refills	83.39	26.31
Obtain the food you are supposed to take with your HIV medications	82.86	25.25
Arrange daily activities in order to take your HIV medications as directed	82.29	24.59
Remember to take your HIV medications at right time	72.91	27.81
Manage side effects that come with taking your HIV medications	70.55	30.23
Self-regulatory efficacy		
Ability to take medications when dopesick (i.e., in withdrawal)	61.27	38.89
Ability to take medications when using drugs	69.04	33.09
Outcome expectation		
Taking HIV medications will make me feel sicker	57.04	37.61

For efficacy expectation and self-regulatory efficacy items participants were asked to indicate their level of confidence in their ability to perform the specified behaviors. For the outcome expectation item, participants were asked to indicate the extent to which they believed taking HIV medications would make them sicker. Responses were given using an 11-point scale ranging from 0 to 100 (i.e., 0, 10, 20... 100), with 0 anchored as 'Can't/ Couldn't do it at all' and 100 anchored as 'Certain can/Could do it' for efficacy expectation and self-regulatory items, and with 0 anchored as 'Certain it will happen' and 100 anchored as 'Certain it won't happen' for the outcome expectation item.

expectations associated with HAART. The internal consistency reliability of the ASEM was assessed using the study sample and found to be high ($\alpha = 0.82$).

Self-reported social support was measured using the social support survey contained within the Medical Outcome Studies (MOS) questionnaire (Sherbourne & Stewart, 1991). The MOS Social Support Survey is a brief survey developed for patients with chronic illnesses, and includes 19 items that focus on perceived availability of functional support. The MOS Social Support Survey has undergone substantial psychometric validation and was found to have high internal-consistency reliability, convergent and discriminate validity (Sherbourne, 1991).

In this cross-sectional analysis, survey instruments and measures of HAART use were applied during the same period (1 December 2001 to 30 November 2002). Descriptive and univariate statistics were used to determine rates of discontinuation and factors associated with discontinuation. All composite self-efficacy scores were transformed to a 0–11 scale format so that a one-point change in odds ratios reflected a one-point change on the respective scales. Categorical and explanatory variables were analyzed using Pearson χ^2 , normally distributed continuous variables were analyzed using *t*-tests for independent samples, and skewed continuous variables were analyzed using Mann-Whitney U tests. The logistic regression model of factors associated with HAART discontinuation was fit by adjusting for all variables that were statistically significant ($p < 0.05$) in univariate analyses. All reported *p* values are two-sided.

Results

In total, 160 participants were eligible for the present analyses and returned for follow-up during the study period. Of these participants, 91 (57%) were men and 69 (43%) were women. The mean age was 39 years (SD = 7.04), with ages ranging from 26 to 56 years. In total, 71 (44%) participants discontinued HAART, and 89 (56%) remained on HAART.

The descriptive statistics for the efficacy expectation, self-regulatory and outcome expectation items are shown in Table I. As indicated, efficacy expectations pertaining to one's ability to manage side effects were lowest among participants (mean = 70.55, SD = 30.23), and expectations pertaining to one's ability to remember how many pills to take were highest (mean = 87.61, SD = 22.81). The mean score for self-regulatory efficacy concerning 'dope sickness' was 61.27 (SD = 38.89), while the mean score for self-regulatory efficacy pertaining to drug use was 69.04 (SD = 33.09). The mean outcome expectation score for the sample was 57.04 (SD = 37.61).

The univariate analysis of association between HAART discontinuation and socio-demographic and drug use characteristics is shown in Table II. As indicated, younger age (OR = 0.94 [95% CI: 0.9–1.0]; $p = 0.019$), recent incarceration (OR = 4.50, [95% CI: 1.5–14.3]; $p = 0.003$) and frequent heroin use (OR = 3.70, [95% CI: 1.5–9.0]; $p = 0.003$) were associated with discontinuation of HAART.

The univariate analysis of association between HAART discontinuation and social support, adherence efficacy expectations, self-regulatory efficacy and outcome expectations is shown in Table III. As indicated, higher efficacy expectations (OR = 0.59, [95% CI: 0.4–0.7]; $p < 0.001$) and self-regulatory efficacy (OR = 0.82, [95% CI: 0.7–0.9]; $p < 0.001$) were negatively associated with discontinuation of HAART, while higher negative outcome expectations were positively associated with discontinuation of HAART (OR = 1.35, [95% CI: 1.2–1.5]; $p < 0.001$).

The logistic regression analysis of factors associated with discontinuation of HAART is shown in Table IV. Variables found to be negatively associated with discontinuation of HAART included efficacy expectations (OR = 0.70, [95% CI: 0.5–0.9]; $p = 0.003$) and self-regulatory efficacy (OR = 0.86, [95% CI: 0.7–0.9]; $p = 0.050$). Variables found to be positively associated with discontinuation of HAART included negative outcome expectations (OR = 1.41, [95% CI: 1.2–1.6]; $p < 0.001$) and recent incarceration (OR = 4.84, [95% CI: 1.2–18.7]; $p = 0.022$).

The analysis of self-reported reasons for discontinuing HAART indicated that the most commonly cited reason for discontinuing HAART was being in jail, with 44% of participants citing this reason. The second most commonly cited reason was problems with side effects (41%). Reasons for discontinuing HAART that were cited by smaller proportions of participants included: being fed-up with HAART (7%); interactions with methadone (3%); and being 'out of the area' (1%).

Discussion

We found that 44% of HIV-positive IDUs had discontinued HAART during the study period. The high rate of discontinuation of HAART reported here is consistent with previous studies (Demas et al., 1998; Palepu et al., 2001) that have found that up to 50% of IDUs surveyed had discontinued HAART. Factors independently and positively associated with discontinuation of HAART included recent incarceration and negative outcome expectations, while higher efficacy expectations and self-regulatory efficacy were negatively associated with HAART discontinuation. The most frequently cited reasons for discontinuation of HAART included incarceration and medication side effects.

While those IDUs who were recently incarcerated were highly likely to discontinue HAART, it should be noted that this study reveals only an association between incarceration in the past six months and HAART discontinuation, and therefore it is difficult to determine whether HAART has been discontinued prior to, during or following

Table II. Univariate analyses of study participants' sociodemographic and drug use characteristics stratified by those that did and did not discontinue HAART.

Characteristic	HAART discontinuation				
	No (<i>n</i> = 89) <i>n</i> (%)	Yes (<i>n</i> = 71) <i>n</i> (%)	Unadjusted OR	(95% CI)	<i>p</i>
Mean age (range)	40 (26–56)	37 (24–55)	0.94	(0.9–1.0)	0.019
Gender					
Female	39 (43.8)	30 (42.2)	0.93	(0.5–1.6)	0.842
Male	50 (56.2)	41 (57.8)			
Unstable housing					
Yes	36 (40.5)	40 (56.3)	1.90	(1.0–3.6)	0.068
No	53 (59.5)	31 (43.7)			
Recent incarceration*					
Yes	5 (5.6)	15 (21.2)	4.50	(1.5–4.3)	0.003
No	84 (94.4)	56 (78.8)			
Sex work*					
Yes	80 (89.9)	59 (83.1)	1.81	(0.7–4.5)	0.206
No	9 (10.1)	12 (16.9)			
Methadone use*					
Yes	48 (53.9)	30 (42.2)	0.62	(0.3–1.2)	0.142
No	41 (46.1)	41 (57.8)			
Cocaine injection frequency*					
≥ 1 per day	15 (16.9)	18 (25.4)	1.67	(0.8–3.7)	0.187
< 1 per day	74 (83.1)	53 (74.6)			
Heroin injection frequency*					
≥ 1 per day	8 (9.0)	19 (26.7)	3.70	(1.5–9.0)	0.003
< 1 per day	81 (91.0)	52 (73.3)			
Crack use frequency*					
≥ 1 per day	27 (30.3)	22 (31.0)	1.03	(0.5–2.0)	0.930
< 1 per day	62 (69.6)	49 (69.0)			
Bingeing*					
Yes	14 (15.7)	15 (21.1)	1.43	(0.6–3.2)	0.379
No	75 (84.3)	56 (78.9)			

* refers to the last six months at time of interview.

incarceration. However, this finding is consistent with previous studies demonstrating high rates of HAART discontinuation among those recently or currently incarcerated (Altice et al., 2001; Palepu, 2001), and was further indicated by participants' self-reports, as 43% of participants cited being in jail as a reason for discontinuing HAART.

Canadian law requires that prisons provide inmates with essential health care (Jürgens, 1996), and evidence of effective delivery of HAART in prisons has been demonstrated previously (White et al., 2001). However, it has been argued that the structural characteristics of prisons and the associated routines make maintaining a HAART regimen in prison challenging (de Bruyn, 1998). The dispensing intervals and dietary requirements associated with some HAART may not be easily accommodated within prisons, and prisoners may also be likely to miss medications if they go to court, are transferred or released. A second explanation for this finding relates to HIV/AIDS-related discrimination.

Table III. Univariate analyses of study participants' self-efficacy, self-regulation, outcome expectation, and social support scores stratified by those that did and did not discontinue HAART.

Characteristic	HAART discontinuation				<i>p</i>
	No (<i>n</i> =89) Mean (SD)	Yes (<i>n</i> =71) Mean (SD)	Unadjusted OR	(95% CI)	
Efficacy expectations	87.6 (19.2)	70.5 (19.6)	0.59	(0.4–0.7)	<0.001
Self-regulatory efficacy	68.4 (34.2)	46.6 (31.4)	0.82	(0.7–0.9)	<0.001
Outcome expectation	26.1 (34.8)	65.3 (32.9)	1.35	(1.2–1.5)	<0.001
Social support	56.8 (34.7)	65.8 (34.7)	1.01	(1.0–1.2)	0.090

Many prisoners may avoid taking HAART in prison in an effort to conceal their HIV status. It is well known that disclosure of HIV-positive status in prison settings can result in significant negative consequences (e.g., intimidation, violence) for prisoners (de Bruyn, 1998), and HIV-positive prisoners have been known to voluntarily enter protective custody to ensure their safety (Jürgens, 1996). Efforts should be made to ensure that HIV-positive prisoners are given additional support designed to prevent premature discontinuation of HAART. In particular, efforts should be made to ensure that HIV-positive prisoners receive medications in a manner that preserves privacy and accommodates dietary requirements and changes in prison routines.

The present findings also bear implications for interventions to prevent discontinuation and promote adherence, as several psychological variables studied were found to be associated with the discontinuation of HAART, including negative outcome expectations concerning HAART. The specific outcome expectation explored pertained to the belief that taking HAART will make one sicker. While concerns regarding negative outcomes of HAART may seem odd in light of the observed efficacy of HAART and the fatal consequences associated with untreated HIV disease, the side effects associated with HAART are numerous, and in some instances rather severe (Heath et al., 2001). Outcome expectations result from observed conditional relations between specific events and the outcomes given actions produce (Bandura, 1986), and while the side effects associated with HAART are often experienced early in treatment, the clinical benefits are rarely experienced in the short term, which may prompt premature discontinuation of therapy. This interpretation is supported by our finding that a substantial proportion of participants identified side effects as a reason for discontinuing HAART, as well as previous studies demonstrating associations between side effects and adherence to HAART (Gifford et al., 2000; Johnston-Roberts, 2000; Moatti et al., 2000).

Consistent with previous studies of adherence involving self-efficacy variables (Gifford et al., 2000; Kalichman et al., 2001; Tuldra et al., 2000), efficacy expectations in this study were found to be negatively associated with discontinuation of HAART. Self-assessments of

Table IV. Logistic regression analysis of factors associated with discontinuation of HAART.

	AOR	(95% CI)	<i>P</i>
Age	0.99	(0.9–1.1)	0.811
Frequent heroin injection	1.99	(0.6–6.3)	0.243
Self-regulatory efficacy	0.86	(0.7–0.9)	0.050
Efficacy expectations	0.70	(0.5–0.9)	0.003
Outcome expectation	1.41	(1.2–1.6)	<0.001
Recent incarceration	4.84	(1.2–18.7)	0.022

personal efficacy determine choice (O'Leary, 1985) and therefore decisions to continue taking HAART, refill prescriptions, manage side effects and obtain required food are likely mediated by efficacy expectations. Further, efficacy expectations determine effort, persistence and coping exerted in the face of challenges (Bandura, 2001), and therefore efficacy expectations likely affect individual persistence in managing medication side effects and other challenges, including incarceration, conflicting daily routines, concerns regarding privacy and discrimination. Self-regulatory efficacy was also negatively associated with discontinuation of HAART. The specific dimensions of self-regulatory efficacy examined were beliefs concerning one's ability to take HAART as prescribed when using drugs or when experiencing withdrawal from drugs (e.g., when 'dopesick'). In the present study, decisions concerning discontinuation of HAART may have been influenced by judgments concerning the potential impact of drug use on maintaining a HAART regimen, as well as individual ability to manage these impacts.

Interventions based on self-efficacy may help to prevent discontinuation of HAART. As well, the psychosocial measures employed in this study, if administered prior to the initiation of treatment, could be used to identify patients at risk of discontinuing HAART. With respect to negative outcome expectations concerning HAART, psycho-educational methods focused on providing accurate information about HIV disease progression, drug resistance and the clinical effects of HAART should be employed to alter existing beliefs about conditional relationships between HAART and health (Sorensen et al., 1998; Williams, 1999). These approaches could also be supported through use of cognitive restructuring techniques designed to identify and modify negative cognitions concerning HAART and the related side effects (Farber & McDaniel, 1999).

Our study has several limitations. First, the cross-sectional nature of this study does not allow for an investigation of causal relationships between the variables studied and the outcome of interest. Likewise, because the adherence and psychosocial measures were applied during the same period, the direction of the observed associations cannot be inferred. Therefore, the associations noted in the present study should be further examined in longitudinal analyses. Second, although HAART discontinuation was evaluated through a linkage with the provincial pharmacies, the study relied primarily on self-report and subjects were reimbursed for their participation, and therefore the results could be susceptible to socially desirable reporting. Third, as discussed previously, the present study reveals only an association between incarceration and HAART discontinuation. Whether HAART has been discontinued prior to, during or following incarceration is unclear. However, given that jail was cited as the most common reason for discontinuing HAART, it is likely that HAART is being discontinued while participants are in jail, not after they are released. Fourth, it should also be noted that due to the size of the sample there was a wide range around some estimates. Nevertheless, despite the sample size, there was sufficient statistical power to demonstrate large differences across several factors.

In summary, we found high rates of HAART discontinuation among HIV-positive IDUs. Factors independently associated with HAART discontinuation included recent incarceration, negative outcome expectations, efficacy expectations and self-regulatory efficacy. Given the findings from elsewhere in North America that 25% of all HIV-infected citizens pass through a correctional facility in a given year (Hammett et al., 2002), research and programmatic changes are urgently needed within prisons to better understand and promote the optimal uptake of HAART among incarcerated HIV-positive IDUs. As well, our study suggests that psychological constructs based on self-efficacy theory are germane

to the understanding of HAART discontinuation and interventions that may promote engagement in HIV care for this population.

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