PREVALENCE AND PREDICTORS OF FACING A LEGAL OBLIGATION TO DISCLOSE HIV SEROSTATUS TO SEXUAL PARTNERS AMONG A COHORT OF PEOPLE LIVING WITH HIV WHO INJECT DRUGS IN A CANADIAN SETTING: A CROSS-SECTIONAL ANALYSIS.

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ABSTRACT

Background: In October 2012, the Canadian Supreme Court ruled that people living with HIV must disclose their HIV status before sex that poses a "realistic possibility" of HIV transmission, clarifying that in circumstances where condomprotected penile-vaginal intercourse occurred with a low viral load (<1500 copies/mL), the realistic possibility of transmission would be negated. We estimated the proportion of people living with HIV who would face a legal obligation to disclose under these circumstances.

Methods: We used cross-sectional survey data from a cohort of people living with HIV who inject drugs. Participants interviewed since October 2012, self-reporting recent penile-vaginal intercourse were included. Participants self-reporting 100% condom use with a viral load consistently <1500 copies/mL were assumed to have no legal obligation to disclose. Logistic regression identified factors associated with facing a legal obligation to disclose.

Results: 176 participants were included (44% women): 94% had a low viral load, 60% self-reported 100% condom use. If condom use and low viral load were required to negate the realistic possibility of transmission, 44% would face a legal obligation to disclose. Factors associated with facing a legal obligation to disclose were female gender (AOR: 2.19, 95% CI: 1.13-4.24), having one recent sexual partner (vs. >1) (AOR: 2.68, 95% CI: 1.24-5.78), and self-reporting a stable relationship (AOR: 2.00, 95% CI: 1.03-3.91).

Interpretation: Almost half the participants would face a legal obligation to disclose to sexual partners under these circumstances (with an increased burden among women), adding further risk of criminalization within this marginalized and vulnerable community.

250 words (max 250 words)

INTRODUCTION

Since the late 1980s, existing criminal or HIV-specific laws have been used in many settings worldwide to prosecute people living with HIV alleged to have put others at risk of acquiring HIV (1). The majority of these criminal prosecutions against people living with HIV have occurred in North America (1). Canada has the second highest absolute number of convictions of people living with HIV globally (1, 2). At the time of writing, an estimated 184 Canadians had been charged for allegedly failing to disclose their HIV status to sexual partners (3).

Most people accused of HIV non-disclosure in Canada have faced charges of aggravated sexual assault, based on the legal interpretation that non-disclosure of HIV status represents fraud, vitiating consent to an otherwise consensual sexual encounter. This charge carries a maximum life imprisonment sentence and mandatory life-long registration as a sexual offender, even in the absence of HIV transmission.

A new precedent for the use of the criminal law against people living with HIV in Canada was set on October 5, 2012, when the Supreme Court of Canada released its ruling on two major cases (4, 5). Proactive serostatus disclosure by an

HIV-positive individual must now precede any sexual activity that poses a "realistic possibility" of HIV transmission. The Supreme Court clarified that in circumstances where a person living with HIV engaged in condom-protected penile-vaginal intercourse with a low plasma HIV RNA viral load (defined by the Supreme Court as <1500 copies/mL), there would be no realistic possibility of HIV transmission, thus no legal duty to disclose (4). Whether this legal test would hold true for sexual encounters besides penile-vaginal intercourse was not clarified by the Supreme Court.

Establishing the absence of a realistic possibility of HIV transmission may be possible for circumstances other than condom protected penile-vaginal sex with a low viral load, depending on the evidence presented during criminal trials. Indeed, the Supreme Court indicated that differing circumstances and treatment advances could lead to future adaptations of this legal position (4). Lower courts may find greater flexibility in their interpretation of the realistic possibility of HIV transmission. After the 2012 Supreme Court rulings, a teenage boy was acquitted of aggravated sexual assault in the Nova Scotia Youth Justice Court after allegedly failing to disclose his HIV status prior to an episode of penile-vaginal intercourse (6). Based on evidence presented during the trial, the presiding judge deemed that there was no realistic possibility of HIV transmission in the context of an undetectable viral load, regardless of whether or not a condom was used. However, in the absence of consistency in the

application of the Supreme Court's legal test by the lower courts, it is prudent to assume the strictest interpretation of this ruling.

There is no consensus regarding the effectiveness of legally enforced disclosure as an HIV prevention tool (7). Concerns remain that the criminalization of HIV non-disclosure fails to acknowledge the significant challenges of HIV disclosure, including secondary disclosure; isolation; rejection by partners, friends and family; violence; stigma and discrimination (8-10). The literature suggests that people living with HIV who inject drugs face unique barriers to safe disclosure in the criminalized environment in which they live, navigate sexual relationships, and seek care (8, 11, 12); including loss of income, drugs or housing and threats to personal safety in the form of emotional, physical and sexual violence (8, 11, 13).

Using cross-sectional data from a community-recruited cohort of people living with HIV who inject drugs, we estimated the proportion of participants who would face a legal obligation to disclose their HIV status before penilevaginal intercourse if both condom use and a low viral load were required to remove the realistic possibility of HIV transmission, and avoid criminal liability for HIV non-disclosure (4, 5).

METHODS

Data Sources

The AIDS Care Cohort to evaluate Exposure to Survival Services (ACCESS) is an ongoing observational prospective cohort study of people living with HIV who use illicit drugs in Vancouver. The study has been described previously (14). Briefly, individuals were eligible for study participation if they were HIV-positive, aged •18 years and had used illicit drugs other than cannabis in the 30 days before baseline interview. Recruitment of ACCESS participants began in 2005 and is ongoing. Snowball sampling methods are used, building on self-referral, word of mouth, and extensive street outreach, with recruitment materials displayed in clinics and storefront agencies. Recruitment efforts are focused in the Downtown Eastside area of Vancouver; the site of an explosive outbreak of HIV infection among people living with HIV who inject drugs and their sexual partners beginning in the mid-1990s (15). This area has high levels of illicit drug use, homelessness and poverty, and an active open drug market.

At recruitment, participants complete a baseline interviewer-administered questionnaire, which elicits information on lifetime and recent characteristics, behaviours and exposures, and a nurse-led questionnaire and interview, which includes blood tests for HIV clinical monitoring. At six-month intervals, participants are invited to complete follow-up interviews and nursing examinations. Within the cohort, loss to follow-up (defined as missing all interviews in the preceding 12 months) is 6 (interquartile range: 5, 7) per 100 person years.

HIV treatment records and clinical profiles held by the British Columbia Centre for Excellence in HIV/AIDS Drug Treatment Program are accessed for all ACCESS participants through a secure, confidential linkage. The British Columbia Centre for Excellence in HIV/AIDS provides medications and clinical monitoring tests, free of charge to all people living with HIV in British Columbia through the government's universal healthcare plan (16).

The ACCESS study's semi-annual follow-up and confidential linkage to comprehensive HIV clinical data through the Drug Treatment Program permits longitudinal evaluation of the interrelationships of behavioural, environmental and social-structural exposures on access and adherence to antiretroviral therapy and HIV disease progression among more than 950 people living with HIV who use illicit drugs (cohort size at the time of writing). ACCESS has been approved by the University of British Columbia/Providence Healthcare Research Ethics Board. All participants provide written informed consent to participate in the study and are compensated \$30 for each visit. The survey does not collect data on serostatus disclosure practices, thus this analysis does not present behaviours that could be interpreted as legal offences under Canadian non-disclosure case law.

Eligibility criteria

This cross-sectional analysis included ACCESS participants who had completed an interview since October 5 2012, in order to capture sexual risk behaviours and viral profile since the Supreme Court ruling. We restricted inclusion to participants with a history of injection drug use, who had at least one viral load and CD4 measurement within 180 days of their baseline visit, and for whom data on condom use were available. If a participant completed more than one interview during the study period, data were drawn from the later interview. We restricted inclusion to individuals who were sexually active, defined as self-reporting penile-vaginal intercourse with commercial or non-commercial sex partners in the six-month period before the interview. Penile-vaginal intercourse was the focus of this analysis, as this was the type of sexual activity on which the 2012 Supreme Court ruling was based. The Supreme Court has yet to rule on HIV non-disclosure in the context of anal or oral sex. The date of administrative censoring was November 30, 2013.

Measures

Primary outcome

We sought to identify participants who would face a legal obligation to disclose their HIV status to sexual partners if condom-protected penile-vaginal intercourse in the context of a low viral load (<1500 copies/mL) was required to negate the realistic possibility of HIV transmission, and thus avoid criminal liability for HIV non-disclosure. Participants who self-reported 100% condom use during all episodes of penile-vaginal intercourse, and who also achieved viral load measurements consistently <1500 copies/mL within six months before

the study interview were assumed to face no legal obligation to disclose their HIV status to sexual partners (**Figure 1**). We assumed that participants would face a legal obligation to disclose if they self-reported <100% condom use (regardless of viral load), or if they failed to achieve a viral load consistently <1500 copies/mL (regardless of condom use).

Explanatory variables

Explanatory variables were selected based on perceived importance following a comprehensive literature review, and availability within the dataset. We considered the following explanatory variables: age (per year increase); gender (female vs. male); ethnicity (Caucasian vs. non-Caucasian); recent injection drug use (yes vs. no); recent illicit drug use (excluding cannabis) (yes vs. no); homelessness, defined as living on the streets or with no fixed address (yes vs. no); employment in a regular/temporary job or self-employed (yes vs. no); sex work, defined as exchange of sex for money, drugs, clothing, or other property (yes vs. no); incarceration, defined as being in detention, prison or jail (yes vs. no); stable relationship, defined as being legally married/common law or having a regular partner (yes vs. no); and number of recent commercial and noncommercial sex partners (1 vs. >1). All non-fixed variables referred to behaviours or exposures in the six-month period before the interview except for relationship status, which referred to current status. We defined HIV treatment status by assessing the number of days participants had been dispensed antiretroviral therapy in the six months before interview (• 1 vs. 0 days). While a history of injection drug use was specified as an inclusion criterion for this analysis, we included recent injection drug use as a covariate to signify ongoing drug use.

Statistical Analysis

We calculated the proportion of participants who would face a legal obligation to disclose HIV serostatus to sexual partners under the aforementioned circumstances. Sociodemographic, behavioural, and clinical characteristics were compared between participants who would face a legal obligation to disclose versus those who would not, using Pearson's chi-squared test for categorical variables (Fisher's exact test for small cell counts), and the Wilcoxon rank-sum test for continuous variables. Logistic regression identified independent covariates of facing a legal obligation to disclose. Candidates for model inclusion were variables having p<0.2 in the bivariable analysis, or variables considered *a priori* to influence likelihood of facing a legal obligation to disclose following literature review.

Imputation methods were used to recode data for 10 participants for whom data related to number of recent sexual partners were missing. Specifically, the median number of sexual partners within the cohort was assigned to participants for whom data were not available. This method was used to preserve statistical power and avoid biases associated with excluding these participants from the model.

Model construction was based on the backwards selection approach and Akaike Information Criterion. The most parsimonious model was selected as the model with the lowest Akaike Information Criterion value. We computed the Variance Inflation Factor to quantify the degree of collinearity present in the regression analysis on the basis that a strong correlation between variables would increase the variance of the coefficients, rendering them unstable and complicating interpretation of the model output. The Variance Inflation Factor was <1.2 for all variables in the final model, suggesting that no collinearity was present. P-values were two-sided and considered statistically significant at p<0.05. All statistical analyses were conducted using the SAS software version 9.3 (SAS Institute Inc, Cary, NC).

RESULTS

After applying the inclusion criteria, 176 (56% male) of the total 834 ACCESS participants recruited between 2005 and 2013 were included in our analytic sample. We excluded 97 participants without at least one viral load and CD4 count test recorded within 180 days of their earliest interview; 47 participants without a history of injection drug use; 204 participants who had not completed an interview since October 5, 2012; 307 participants who reported no episodes of penile-vaginal intercourse within 6 months of the interview; and 3 participants for whom data on condom use were not available (Figure 2).

The characteristics of the analytic sample are presented in **Table 1**. Of the 176 participants included in this analysis, 10 (6%) failed to achieve a viral load consistently <1500 copies/mL, and 70 (40%) self-reported <100% condom use during penile-vaginal intercourse within the six month period before the study interview. Among the 166 participants who consistently achieved a viral load <1500 copies/mL, 67 reported <100% condom use. If both condom use and a viral load <1500 copies/mL were required to negate the realistic possibility of HIV transmission and avoid criminal liability for HIV non-disclosure, 77 (44%) participants would face a legal obligation to proactively disclose their HIV status to sexual partners (**Table 2**). However, if either consistent condom use <u>or</u> a viral load <1500 copies/mL was sufficient to negate the realistic possibility of HIV transmission, only 3 (2%) participants would face a legal obligation to disclose (0% of males, 4% of females).

When stratifying the results by gender, 35% of men vs. 55% of women would face a legal obligation to proactively disclose their HIV serostatus to sexual partners if both condom use and a viral load <1500 copies/mL were required to negate the realistic possibility of HIV transmission (p=0.011). Compared to men, significantly fewer women achieved a viral load <1500 copies/mL (90% vs. 98%, p=0.022) and significantly fewer women self-reported 100% condom use (52% vs. 67%, p = 0.048) in the six month period before the study interview.

In the multivariable logistic regression model, factors independently associated with facing a legal obligation to disclose were female gender (adjusted odds ratio [AOR]: 2.19, 95% CI: 1.13-4.24); having only one recent sexual partner (vs. >1 partners) (AOR: 2.68, 95% CI: 1.24-5.78); and self-reporting a stable relationship (AOR: 2.00, 95% CI: 1.03-3.91) (**Table 3**).

INTERPRETATION

Among sexually-active participants in a community-recruited cohort of people living with HIV who inject drugs, we observed that almost half the participants would face a legal obligation to proactively disclose HIV serostatus to sexual partners if both condom use and a low viral load were required to negate the realistic possibility of HIV transmission. In a multivariable model, facing a legal obligation to disclose under these circumstances was positively associated with female gender, self-reporting a stable relationship and having only one recent sexual partner.

Facing a legal obligation to disclose was driven primarily by inconsistent condom use rather than viral load in this analysis. It should be noted that ACCESS is an older, treatment-experienced cohort, in a province with an ongoing Treatment-as-Prevention initiative (17, 18), and universal access to healthcare free-of-charge; including all HIV treatment, care and medications. In other jurisdictions where Treatment as Prevention initiatives are not widespread, additional challenges to the uptake and adherence to antiretroviral therapy may

be encountered, which may compromise the ability to satisfy this legal test for HIV non-disclosure. Indeed, studies in other North American settings have observed that members of marginalized and vulnerable groups, including people who inject drugs (19-22), ethnic minorities (23), sex workers (24) and homeless individuals (25) experience barriers to accessing antiretroviral therapy and achieving sustained viral suppression.

We observed that women were significantly more likely to face a legal obligation to disclose if both condom use and a low viral load were required to negate the realistic possibility of HIV transmission, driven by both viral load and condom use. Previous Canadian studies have shown that women demonstrate poorer HIV-related clinical outcomes compared to men, mediated by suboptimal engagement and retention within HIV services, and lower adherence to antiretroviral therapy (19-22, 26, 27). Inconsistent condom use among women living with HIV is well-described in the literature, attributed to fertility desire and serocondordant partnerships, in addition to challenges negotiating condom use; including gendered power imbalances, fear of inadvertent status disclosure, and the threat of violence (28-31). Marginalized women living with HIV may experience additional social-structural barriers to insisting upon safer sex practices, particularly those who are economically disadvantaged and who engage in survival sex work (9, 32, 33), compromising their ability to avoid criminal liability for HIV non-disclosure through both achievement of a low viral load and condom use.

The observed gender difference in facing a legal obligation to disclose is a particular concern, as previous work has shown that women experience unique barriers to HIV disclosure (8); particularly those who face power inequality within dependent partnerships and risk violence or abandonment associated with disclosure (13, 34-36). A recent cross-sectional study among harder-to-reach people living with HIV in Vancouver found that women were significantly less likely to disclose to new sexual partners compared to heterosexual male counterparts (37).

Participants in a stable relationship were more likely to face a legal obligation to proactively disclose to sexual partners based on the legal test applied in this analysis. Unsurprisingly, this finding is driven by inconsistent condom use. This observation is supported by a previous analysis within ACCESS, which reported an independent association between condomless sex and partnered relationship status (32), and literature from other international settings (38) (39, 40). Previous work has shown that people living with HIV are more likely to disclose to regular versus casual sexual partners (41-43), thus it stands to reason that many ACCESS participants who are in a stable relationship will have disclosed to their partners and made a mutual decision to engage in condomless sex. Participants with only one recent sexual partner were also more likely to face a legal obligation to proactively disclose, which was similarly driven by inconsistent condom use. We expect that participants with more than one sexual partner are less likely to proactively disclose, and more likely to insist

on condom use. Previous work supports that people living with HIV with one versus multiple sexual partners are more likely to self-report disclosing to partners (44).

Notably, if *either* condom use *or* a low viral load during penile-vaginal sex were sufficient to negate the realistic possibility of HIV transmission, and avoid criminal liability for non-disclosure, 98% participants in our cohort would face no legal obligation to disclose to sexual partners. Public health and human rights advocates have argued that, at a minimum, either condom use or a suppressed viral load during vaginal or anal sex should be sufficient to remove the legal obligation to disclose (emphasizing that additional factors might also be relevant in determining HIV transmission risk on a case-by-case basis) (45). Further, they maintain that the legal obligation to disclose should be removed in cases where there is very low risk of transmission, such as in cases of oral sex (45, 46). The requirement of both condom use and a low viral load to negate the realistic possibility of sexual HIV transmission stands in conflict with evidence-based science, demonstrating the dramatic reduction in HIV transmission risk associated with either viral suppression with antiretroviral therapy (47-51) or condom use (52). A recent consensus statement by Canadian HIV experts forcefully argues that empirical evidence does not justify the current use of the criminal law against people living with HIV in Canada (53). This statement has since been endorsed by more than 75 scientists and clinicians across Canada (54).

It must be acknowledged that many ACCESS participants will disclose their HIV status to sexual partners, thus will not be at risk of criminal charges regardless of condom use or viral profile. Disclosure practices are not measured within the ACCESS survey, however a cross-sectional survey of treatment-experienced people living with HIV in Vancouver found that the majority (73%) of participants self-reported disclosing their HIV serostatus to all new sexual partners (37).

Readers should be aware of some limitations to our study. As data on HIV serostatus of sexual partners are not routinely collected within the ACCESS survey, we could not identify seroconcordant partnerships where legal concerns around HIV exposure and transmission may be reduced, rates of disclosure may be higher (43) and condom use may be lower (55). Condom use was self-reported, therefore subject to recall and social desirability reporting biases, resulting in potential underestimation of the proportion of participants who would face a legal obligation to disclose.

Findings from this study may not be generalizable to non-Canadian settings due to the specificity of Canadian HIV non-disclosure case law. On account of the ambitious provincial scale-up of Treatment-as-Prevention in British Columbia (17, 18), our findings may underestimate the number of people living with HIV who inject drugs who would face a legal obligation to disclose in other provinces, where they may experience additional barriers to treatment engagement.

To conclude, we observed that if both condom use and a low viral load are required to remove the realistic possibility of HIV transmission and avoid criminal liability for HIV non-disclosure, almost half of the participants may risk criminal prosecution should they not disclose their HIV serostatus to sexual partners. Our study reveals another dimension to how the criminal justice system can shape the health and lives of people living with HIV who inject drugs, reinforcing the critical need for public health initiatives to address barriers to HIV treatment and support safe HIV status disclosure within marginalized communities.

Among this highly marginalized and criminalized cohort, women were at increased risk of prosecution if they did not disclose their HIV status. Our findings contravene the belief that HIV criminalization is a means of protecting women; a rationale previously used to support the expansion of the use of criminal law against people living with HIV (56). While women are underrepresented among defendants in Canadian non-disclosure prosecutions to date (46), marginalized women feature prominently among those who have faced criminal charges (46); including women living with addiction, survivors of abuse, and Indigenous women (57, 58). Our findings suggest that current case law may disproportionately impact the most marginalized and vulnerable women living with HIV in Canada, and may accentuate gendered barriers to healthcare engagement (59), and autonomous sexual decision-making (60). Future work should evaluate the awareness and impact of HIV criminalization

among women living with HIV in Canada who are disproportionately affected by HIV or underserved by health services, and who encounter considerable barriers to safe disclosure.

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AUTHORS' CONTRIBUTIONS

SP, AK, RH, GO and MJM conceived the idea for this analysis. RH, JM, MJM, TK and EW contributed to design and acquisition of data. Data preparation and statistical analysis were conducted by SD and PN. Data interpretation was performed by SP, MJM, PN, SD and AK. SP drafted the initial manuscript, and all authors contributed to the final version. All authors have critically reviewed and approved the final manuscript, gave approval for publication and act as guarantors of the work.

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Table 1. Characteristics of 176 people living with HIV who inject drugs, stratified by satisfaction of the specified legal test for HIV non-disclosure.

Characteristic	All participants (n=176)	Satisfy legal test (n=99)	Do not satisfy (n=77)	p-value
Age (in years)	(11 170)	(11 00)		
Median (interquartile range)	45 (40 – 51)	46 (41 – 52)	44 (39 – 50)	0.070
Caucasian ethnicity	10 (10 01)	10 (11 02)	11 (66 66)	0.070
Yes	93 (53)	49 (49)	44 (57)	0.313
No	83 (47)	50 (51)	33 (43)	0.010
Female gender	00 ()	00 (0.)	33 (13)	
Yes	77 (44)	35 (35)	42 (55)	0.011
No	99 (56)	64 (65)	35 (45)	
Homeless*	11 (11)	()	33 (13)	
Yes	21 (12)	9 (9)	12 (16)	0.242
No	155 (88)	90 (91)	65 (84)	-
Employed*		,	, ,	
Yes	44 (25)	25 (25)	19 (25)	0.930
No	132 (75)	74 (75)	58 (75)	
Incarcerated*	,	, ,	,	
Yes	10 (6)	4 (4)	6 (8)	0.337
No	166 (94)	95 (96)	71 (92)	
Illicit drug use* [†]		, ,		
Yes	162 (92)	93 (94)	69 (90)	0.401
No	14 (8)	6 (6)	8 (10)	
Injection drug use*				
Yes	117 (66)	66 (67)	51 (66)	0.952
No	59 (34)	33 (33)	26 (34)	
≥1 day antiretroviral therapy dispensation*				
Yes	168 (95)	98 (99)	70 (91)	0.022
No	8 (5)	1 (1)	7 (9)	
Engaged in sex work*				
Yes	29 (16)	19 (19)	10 (13)	0.271
No	147 (84)	80 (81)	67 (87)	
Currently in a stable relationship				
Yes	74 (42)	31 (31)	43 (56)	0.001
No	102 (58)	68 (69)	34 (44)	
Number of sexual partners* The state of t				
1	124 (70)	61 (62)	63 (82)	0.004
>1	52 (30)	38 (38)	14 (18)	

^{*}in the 6 months before interview; † excluding cannabis use; ¶ median imputation was used to recode missing data for 10 participants.

	of condom use stratified by plasma H	
≥1500 c/mL) amor	ng 176 male and female people living	with HIV who inject drugs.
All participants (n	n=176)	
	Viral load <1500 c/mL, n (%)	Viral load ≥1500 c/mL, n (%)
Condom use		
100%	99 (56)	7 (4)
<100%	67 (38)	3 (2)
Male participants	Viral load <1500 c/mL, n (%)	Viral load ≥1500 c/mL, n (%)
Condom use		
100%	64 (65)	2 (2)
<100%	33 (33)	0 (0)
Female participar	nts (n=77)	
	Viral load <1500 c/mL, n (%)	Viral load ≥1500 c/mL, n (%)
Condom use		
100%	35 (45)	5 (7)
<100%	34 (44)	3 (4)

Table 3. Bivariable and multivariable logistic regression analyses of factors associated with facing a legal obligation to disclose HIV serostatus to sexual partners among 176 people living with HIV who inject drugs.

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Characteristic		Bivariable			Multivariable	
	OR ²	95% CI ¹	p-value	AOR ³	95% CI ¹	p-value
Age						
Per year increase	0.96	0.93 - 1.00	0.070			
Gender						
Female vs. male	2.19	1.19 – 4.04	0.011	2.19	1.13 – 4.24	0.020
Homeless						
Yes vs. no	1.85	0.74 - 4.64	0.242	2.50	0.93 - 6.76	0.070
Incarcerated*						
Yes vs. no	2.01	0.55 - 7.38	0.337			
Engaged in sex work*						
Yes vs. no	0.63	0.27 - 1.44	0.271			
Currently in a stable relationship						
Yes vs. no	2.77	1.49 - 5.15	0.001	2.00	1.03 - 3.91	0.042
Number of sexual partners*						
1 vs. >1	2.80	1.38 - 5.68	0.004	2.68	1.24 – 5.78	0.012

median imputation was used to recode missing data for 10 participants; 195% Confidence Interval; 2Odds Ratio; Adjusted Odds Ratio; *within the 6 months before interview..

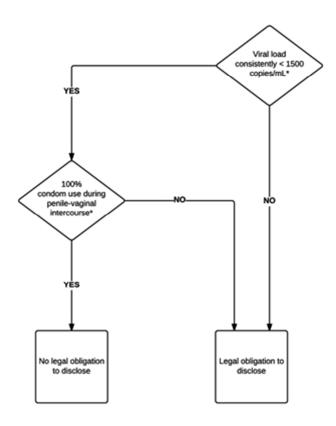


Figure 1: Criteria used to determine whether participants would face a legal obligation to disclose in this analysis.

*In the six-month period before study interview 120x146mm (72 x 72 DPI)

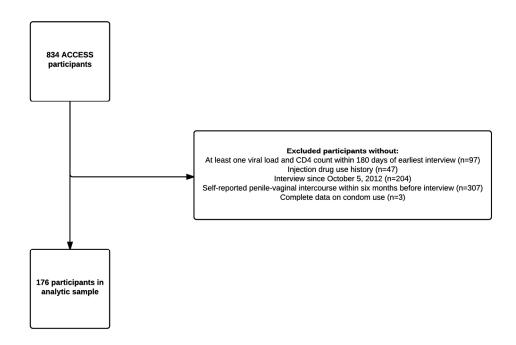


Figure 2: Exclusion criteria applied to reach final analytic sample.

STROBE Statement—Checklist of items that should be included in reports of cross-sectional studies

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract
		(b) Provide in the abstract an informative and balanced summary of what was done
		and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment,
6		exposure, follow-up, and data collection
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of
1		participants
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect
		modifiers. Give diagnostic criteria, if applicable
Data sources/	8*	For each variable of interest, give sources of data and details of methods of
measurement		assessment (measurement). Describe comparability of assessment methods if there is
		more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable,
		describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding
		(b) Describe any methods used to examine subgroups and interactions
		(c) Explain how missing data were addressed
		(d) If applicable, describe analytical methods taking account of sampling strategy
		(e) Describe any sensitivity analyses
Results		9/
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially
		eligible, examined for eligibility, confirmed eligible, included in the study,
		completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and
		information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
Outcome data	15*	Report numbers of outcome events or summary measures
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and
		their precision (eg, 95% confidence interval). Make clear which confounders were
		adjusted for and why they were included
		(b) Report category boundaries when continuous variables were categorized
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a
		meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and
-		- · · · · · · · · · · · · · · · · · · ·

Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or
		imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations,
		multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if
		applicable, for the original study on which the present article is based

^{*}Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.