

# Determinants of HIV Seroconversion Among Men Who Have Sex With Men Living in a Low HIV Incidence Population in the Era of Highly Active Antiretroviral Therapies

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**Objective:** To estimate human immunodeficiency virus (HIV) incidence and associated risk factors among men who have sex with men (MSM) participating in the Omega Cohort Study in Montreal, 1996–2003.

**Methods:** Longitudinal study of 1587 MSM seronegative at baseline with  $\geq 1$  six-month follow-up visit. Multivariate Cox regression with time-dependent variables was used for data analysis.

**Results:** HIV incidence was 0.62 per 100 person-years (95% confidence interval: 0.41–0.84). In multivariate analyses compared with subjects not reporting any anal sex with serodiscordant or casual partners, those reporting anal sex with such partners (all *P* values <0.05), whether consistently protected [hazard ratio (HR) = 3.4], or unprotected exclusively receptive (HR = 12.0), exclusively insertive (HR = 4.7), or both receptive and insertive (HR = 8.3), were at increased risk of seroconversion. Sexual behaviors with seroconcordant regular partners were not associated with seroconversion.

**Conclusion:** These results observed in a cohort of MSM with low HIV incidence provide new insights regarding the debate about harm-reduction strategies to prevent sexual HIV transmission.

HUMAN IMMUNODEFICIENCY VIRUS (HIV) incidence among men who have sex with men (MSM) has been found to be lower in Montreal, Canada, than in many other major cities of the developed world.<sup>1,2</sup> However, the increased use of highly active antiretroviral therapies since the mid-1990s has been associated with an increase in sexually transmitted infections (STI), particularly outbreaks of syphilis in many MSM communities. Consequently, it has been hypothesized that this new era of therapies

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against HIV could have led to more risky behaviors, potentially leading in turn to increases in HIV incidence.<sup>3</sup> Although the scientific community has been interested in understanding these behaviors, some MSM have adopted various strategies to prevent HIV infection, for example, “serosorting,” i.e., engaging in unprotected anal sex only with partners of the same HIV status as one’s own.<sup>4</sup> Presented as a harm-reduction approach, this strategy is sometimes promoted to prevent HIV transmission, but it remains controversial.<sup>3–5</sup> In this context of highly active antiretroviral therapies and changing patterns of sexual behaviors, we wished to estimate HIV incidence from 1996 to 2003 and to identify socio-demographic and behavioral risk factors associated with HIV seroconversion among MSM in Montreal.

## Methods

### Background

The Omega Cohort Study was a prospective longitudinal study carried out from October 1996 to July 2003 to assess HIV incidence and its determinants among MSM in the Montreal metropolitan area; the methods have been described in detail elsewhere.<sup>1,6</sup> Briefly, men were eligible if they self-identified as MSM, were aged  $\geq 16$  years, and were HIV-negative or did not know their HIV status. They were recruited on an ongoing basis through bilingual promotion in the general and gay communities. After signing an informed consent and receiving counseling, volunteers were tested for HIV, syphilis, and hepatitis B, had their first structured interview, and completed a self-administered questionnaire. Participants found HIV-positive at baseline were excluded from further study and referred to appropriate services. Participants were in-

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vited to a follow-up visit every 6 months consisting of a structured interview, a self-administered questionnaire, and HIV testing and counseling as well as syphilis testing. The study was approved by the ethics committees of the Centre hospitalier *affilié* universitaire de Québec, Laval University, and the Université du Québec à Montréal.

#### *Study Instruments and Variables*

Validated self-administered questionnaires and structured interviews provided sociodemographic, psychosocial, and behavioral information about the participants during the 6-month period before the interview. Baseline questionnaires also collected data on risk behaviors during the participant's lifetime. Sociodemographic data were collected on birth date, ethnic group, language (maternal and commonly used), religion, number of children, siblings, birth place, moving history, education, income, region of residence (Montreal or elsewhere), marital status, and work status. Risk behaviors assessed included number of partners; frequency of oral sex (both insertive and receptive) and of condom use; frequency of anal sex (both insertive and receptive) and of condom use; frequency of drug/alcohol use before anal sex; frequency of condom breakage or slippage, of lubricant use, and of anal bleeding during anal sex; frequency of drug injection, including needle sharing (and with someone known to be HIV-positive); STI history. Questions on sexual behaviors were asked separately for regular partners with unknown, known negative, and known positive HIV serostatus, for casual partners and for partners in the context of prostitution (defined as money, drugs, or goods received or given in exchange of sex). Frequencies were measured on different point scales, depending on the type of variable.

The dependent variable was HIV seroconversion before loss to follow-up or study end (July 2003). All time-stable and time-dependent sociodemographic variables as well as time-dependent behavioral variables previously described were considered as independent variables in the analyses. Oral sex was analyzed as risky oral sex, defined as unprotected receptive oral sex with a regular partner known to be HIV-positive, a casual partner, or a partner in the context of prostitution, as suggested in a published analysis of the HIV transmission probability through receptive oral sex.<sup>7</sup>

Inspired by the concept of negotiated safe sex proposed by Kippax,<sup>8,9</sup> we assessed risky behaviors separately for 2 broad types of partners as follows: (a) those who had the behavior only with regular partners known to be HIV negative (henceforth referred to as "HIV seroconcordant regular partners") and (b) those who had had the behavior with any other type of partner, including regular partners of positive or unknown HIV status, casual partners, and partners within the context of prostitution (henceforth referred to as "HIV serodiscordant/casual partners"). Note that participants were included in the cohort study only if HIV negative at baseline.

#### *HIV and Syphilis Testing*

Enzyme immunoassays for the detection of HIV antibodies (AxSYM HIV-1/HIV-2, Abbott Diagnostic, Mississauga, Ontario) and rapid plasma reagin (RPR Card test, NCS Diagnostics Inc., Mississauga, Ontario) for syphilis testing were performed at the Department of Microbiology, Centre Hospitalier de l'Université de Montréal, Hôpital Saint-Luc. Sera positive by HIV enzyme immunoassays were retested in duplicate and, if 2 of 3 tests were reactive, Western blot was performed at the Laboratoire de Santé Publique du Québec for confirmation. Samples positive by RPR were tested by microhemagglutination assay for *Treponema pallidum* (MHA-TP) at the Laboratoire de Santé Publique du Québec for confirmation of the presence of active syphilis.

#### *Statistical Analyses*

HIV incidence with a 95% confidence interval was estimated using as the denominator the sum of person-years (py) contributed by MSM remaining seronegative between their baseline interview and their last follow-up visit and by seroconverters from their baseline interview up to the midpoint between their last HIV-negative test and first HIV-positive test.<sup>10</sup>

Univariate Cox proportional hazard models of survival time before HIV seroconversion were applied on time-dependent behavioral and sociodemographic variables. These analyses allowed a preliminary selection of the variables most probably associated with seroconversion. For the final multivariate model, anal sex-related behaviors were classified into 5 categories. This was carried out separately for serodiscordant/casual partners and for seroconcordant regular partners. For each of these types of partners, the reference category included participants who reported no anal sex with or no partner of the corresponding type within the previous 6 months, and the other 4 categories represented the 4 other possible scenarios: anal sex always protected, unprotected anal sex both insertive and receptive, insertive exclusively, and receptive exclusively. Covariates were selected for multivariate modeling if their statistical significance was less than 0.25 using the likelihood ratio test.<sup>11</sup> The final model was obtained through a combination of different modeling strategies, for each of which automatic stepwise and manual backward methods were applied for variable selection. The variation between the full and the reduced models in the remaining coefficients was then assessed. A 20% change in the remaining hazard ratio estimate was used to identify potential confounders. All variables excluded from the initial models were added back into the final ones to confirm the absence of confounding effect.<sup>11</sup> Confounding was also assessed for a potential cohort effect by considering a variable corresponding to the length of time from the beginning of recruitment in the cohort (October 1996) to the participant's baseline interview. The proportional hazard assumption was tested by adding interaction with time to each of the retained variables in the final multivariate model.<sup>11</sup>

## **Results**

#### *Descriptive Analysis*

##### *Baseline Characteristics*

From October 19, 1996, to December 23, 2002, we carried out 1890 baseline interviews. Of these potential participants, 44 tested HIV positive at their first visit and were excluded from the cohort, leaving 1846 participants. The mean and median age at study entry in our MSM cohort were 32.0 (standard deviation = 9.9) and 30 years (interquartile range: 24–38), respectively. About 75% of the participants reported being single and 20% were unemployed. Despite the fact that the education level was high (67% had more than a high-school degree), about half of the participants had an annual income of less than CAN\$ 20,000.

Table 1 displays reported lifetime HIV-related behaviors. About one-third of the participants reported ever having a known HIV-positive partner and more than half had had sex with a woman. The vast majority of the subjects had been tested for HIV. A history of previous STI was frequent.

Table 2 presents behaviors reported during the period between enrolment and the first 6-monthly follow-up visit. About 40% of the subjects had more than 2 regular partners during this period, whereas one-third reported more than 5 casual partners. Any unprotected anal sex during the previous 6 months was reported by close to 40% of the participants. This practice was more frequent with HIV-negative regular partners than with other types of partners.

TABLE 1. Lifetime Behaviors Reported at Baseline Among Initially HIV-Seronegative Men Who Have Sex With Men Participating in the Omega Cohort Study in Montreal, 1996–2003

Lifetime Behaviors	% (n = 1846)*
Injected substances	10.4
Shared $\geq 1$ needle	5.7
Used alcohol before sex	83.8
Used drugs before sex	51.6
Had $\geq 1$ known HIV-positive sexual partner	31.5
Had sex with $\geq 1$ woman	55.7
Performed prostitution	21.8
Consumed prostitution	21.8
Had an HIV test	80.5
Started his sexual life before HIV epidemic	50.6
Ever had a STI	40.1

\*Numbers entered in the analyses do not always equal total number of participants because of missing values.  
HIV indicates human immunodeficiency virus.

#### Follow-Up, HIV Incidence, and Frequency of STI

Over almost 7 years of follow-up from October 1996 to July 2003, 1587 subjects with at least one follow-up visit (mean: 6 follow-up visits) contributed 5121 py. In the first 2 years of recruitment, 978 MSM had been recruited. Thereafter, the number of participants interviewed during every 6-month wave of observation fluctuated from 990 to 1126. The mean attrition per 6-month period, weighted for the number of eligible participants at each visit, was 9.8%, which is close to the level expected before the study began (10%).

During follow-up, 32 MSM seroconverted for HIV, for an overall incidence of 0.62 per 100 py (95% confidence interval: 0.41–0.84). Subjects were asked at each follow-up visit whether they had been diagnosed with any of 6 named STIs in the previous 6 months. The overall rate of positive responses was as follows:

TABLE 2. Behaviors in the Previous 6 Months Reported at the First Follow-Up Visit Among Initially HIV-Seronegative Men Who Have Sex With Men Participating in the Omega Cohort Study in Montreal, 1996–2003

Behaviors in the Previous 6 Months	% (n = 1587)*
Shared a needle with someone known HIV-positive	0.2
Number of regular partners	
0	18.8
1	42.5
2–5	33.9
$\geq 6$	4.8
Number of casual partners	
0–5	68.2
6–49	29.0
$\geq 50$	2.8
Had unprotected receptive anal sex	28.8
Had unprotected insertive anal sex	32.1
Had unprotected anal sex	38.5
Had unprotected anal sex with HIV serodiscordant/casual partners	18.6
Had unprotected anal sex with HIV seroconcordant regular partners	24.6

\*Numbers entered in the analyses do not always equal total number of participants because of missing values.  
HIV indicates human immunodeficiency virus.

gonorrhea 1.6%, chlamydia 1.0%, syphilis 0.16%, herpes 0.83%, genital warts 2.0%, and genital ulcers 0.03%. An increasing trend was observed only for chlamydia (1.1% in 1999–2003 vs. 0.5% in 1997–1998,  $P = 0.02$ ). Finally, we observed only 3 confirmed (1 in each of 2000, 2001, and 2003) and 1 possible (in 1997) new syphilis infections through direct testing.

#### Sexual Behaviors Associated With Seroconversion

Table 3 displays results of the multivariate Cox regression analyses for sexual behaviors predicting HIV seroconversion with time-dependent variables. The following risk factors in the preceding 6-month period were found to be significantly and independently associated with seroconversion: (a) increased number of casual partners; (b) all anal sex-related behaviors with a serodiscordant/casual partner, including the anal sex always protected by condoms, the exclusive practice of unprotected insertive anal sex, the exclusive practice of unprotected receptive anal sex, and the practice of both unprotected insertive and receptive anal sex; and (c) needle sharing with someone HIV-positive. The results for risky oral sex revealed a borderline statistically significant association with seroconversion. It is noteworthy that 3 seroconverters reported having had unprotected receptive oral sex with a serodiscordant/casual partner but no anal sex during the 6 months preceding their seroconversion. None of the risky behaviors with a seroconcordant regular partner was predictive of HIV seroconversion. None of the other covariates for which the model was adjusted was found to have a confounding effect, including time since study started, which did not show any cohort effect. The test for proportionality in the final model revealed that the assumption was respected (data not shown). Finally, the following variables were considered for inclusion in the multivariate models because they had a  $P$  value  $< 0.25$  in the univariate Cox models, but they were not kept in the final model because they were not statistically significant nor confounding the other associations: age, low education level, low income, STI history, alcohol or drug use before anal sex with a serodiscordant/casual partner, anal bleeding and condom failure during anal sex with such partners, and history of prostitution involvement.

#### Discussion

This cohort study, the first reporting on HIV incidence and associated risk factors among MSM in the province of Quebec, revealed a relatively low incidence of 0.62 per 100 py. This is much lower than HIV incidence rates reported elsewhere in Canada and in other industrialized countries since the mid 1990s.<sup>12–15</sup> This lower incidence among Montreal's MSM may be due in part to differences in study populations, selection of participants, or incidence estimation methods. Differences in the dynamics of the initial stage of the HIV epidemic between MSM in Montreal and in other large Canadian cities may also explain the lower incidence in this community.<sup>16</sup> However, Montreal is the only major urban centre in Canada with an organization dedicated solely to HIV prevention among MSM (Action Séro Zéro) and may have a more sustained, coordinated HIV prevention effort among MSM than other North American cities, resulting in the lower incidence observed.<sup>2</sup> Finally, a recent venue-based cross-sectional study of Montreal's MSM found that 84% of participants had ever been tested for HIV<sup>17</sup> and that 75% of HIV-positive men received antiretroviral treatment.<sup>18</sup> These high levels of testing and treatment may also have contributed to the low HIV incidence rate by lowering the viral load of HIV-infected subjects, thus reducing the likelihood that they will transmit the virus to their sexual partners.<sup>19</sup>

TABLE 3. Time-Dependent Cox Proportional Hazard Models of Factors Associated With HIV Seroconversion Among Men Who Have Sex With Men Who Had at Least One Follow-Up Visit in the Omega Cohort Study in Montreal, 1996–2003

Behaviors Referring to the Preceding 6-Month Period	Univariate HR (95% CI)	Multivariate HR (95% CI)	Multivariate P value
No. casual partners			0.0045*
0–5	1	1	—
6–49 <sup>†</sup>	3.1 (1.4–6.5)	1.8 (0.82–4.2)	—
50+ <sup>†</sup>	9.8 (3.5–27.8)	5.1 (1.7–15.5)	—
Anal sex (AS) practices with serodiscordant/casual partners (SDCP)			
No AS with a SDCP or no SDCP	1	1	—
AS always protected <sup>‡</sup>	5.1 (1.6–16.3)	3.4 (1.1–11.1)	0.042
AS unprotected			
Both insertive and receptive <sup>‡</sup>	18.8 (5.0–70.0)	8.3 (2.3–30.1)	0.0012
Insertive exclusively <sup>§</sup>	8.6 (2.2–34.6)	4.7 (1.1–20.3)	0.037
Receptive exclusively <sup>  </sup>	15.0 (4.5–49.9)	12.0 (3.1–47.1)	0.0004
AS practices with seroconcordant regular partners (SCRCP)			
No AS with a SCRCP or no SCRCP	1	1	—
AS always protected <sup>  </sup>	1.3 (0.49–3.6)	1.63 (0.60–4.5)	0.34
AS unprotected			
Both insertive and receptive <sup>  </sup>	1.5 (0.35–6.6)	0.80 (0.23–7.8)	0.73
Insertive exclusively <sup>§  </sup>	1.4 (0.32–5.9)	1.8 (0.39–7.8)	0.46
Receptive exclusively <sup>    </sup>	0.6 (0.18–2.0)	1.4 (0.32–6.2)	0.65
Other practices			
Risky oral sex <sup>#</sup>	4.1 (2.0–8.4)	2.1 (0.999–4.6)	0.0503
Needle sharing with someone HIV-positive	16.6 (2.2–122.3)	10.1 (1.3–79.2)	0.028

\*Test for trend:  $P = 0.0045$ .

<sup>†</sup>Dummy variable; reference: 0–5 casual partners.

<sup>‡</sup>Dummy variable; reference: no AS with a SDP or no SDP.

<sup>§</sup>Unprotected insertive anal sex and no unprotected receptive anal sex.

<sup>||</sup>Unprotected receptive anal sex and no unprotected insertive anal sex.

<sup>|||</sup>Dummy variable; reference: no AS with a SCP or no SCP.

<sup>#</sup>Risky oral sex: unprotected receptive oral sex with a seropositive regular or casual partner, or within the context of prostitution.

HIV indicates human immunodeficiency virus; HR, hazard ratio; CI: confidence interval.

Montreal, however, has not been spared by the syphilis epidemic that has affected many MSM communities in the industrialized world since 2000. The yearly number of reported cases of infectious syphilis among MSM of this city increased from less than 10 in 2000 to over 150 in 2005.<sup>20</sup> However, this increase mostly occurred toward the very end of our study (from 36 cases in 2002 to 118 cases in 2003) and we observed only a few syphilis seroconversions (3 confirmed and 1 possible) in our study participants. Furthermore, the reported frequency of the other STIs was also low. The 2.2-fold increase in reporting chlamydia coincided with the introduction of polymerase chain reaction testing for chlamydia in Montreal, a test with greater sensitivity than the assays used previously. The frequency of STI was thus low in our cohort and is compatible with the low HIV incidence we observed. However, we cannot exclude an increase in HIV incidence among Montreal's MSM since our study ended.

We observed that unprotected anal sex, when practised with a serodiscordant/casual partner, was the main risk factor for HIV seroconversion and that the risk was greatest for receptive unprotected anal sex. The number of casual sex partners as well as needle sharing with someone HIV-positive and possibly risky oral sex also contributed to HIV transmission. Assessment of anal sex behavior separately for serodiscordant/casual and seroconcordant regular partners clearly demonstrated that the type of partner was determinant in predicting risk. Participants having unprotected anal sex with a regular partner known to be seronegative as well as those always practicing protected anal sex with such a partner did

not experience increased HIV risk when compared with participants who had anal sex always protected with a regular seroconcordant partner or had no such partner. This pattern of serosorting, involving selective condom use depending on its partner's HIV serostatus, is similar to the practice of "negotiated safety" introduced by Kippax et al.<sup>8,9</sup> and has been presented as a risk-reduction approach.<sup>4</sup> However, some studies suggest that serosorting may not be effective in preventing HIV transmission.<sup>5,21,22</sup> This could be explained by the fact that some people believing themselves as HIV-seronegative because of a prior negative test have been infected since and may even be in the phase of primary infection, during which their infectivity is particularly high.<sup>23</sup> Consequently, in populations with a high HIV incidence, serosorting may not help to prevent HIV transmission. However, in a context of low incidence such as in Montreal, our results regarding unprotected anal sex with a regular seroconcordant partner suggest that practising serosorting with a regular partner does not increase the risk of HIV seroconversion.

In our study, subjects reporting protected anal sex with a serodiscordant/casual partner were at higher risk of HIV seroconversion. This result corroborates the findings of other researchers showing an association between protected anal sex and HIV seroconversion<sup>22</sup> and a considerable risk of condom failure.<sup>24</sup> Although condom use substantially reduces the risk of HIV transmission, it has been suggested that the risk of condom failure is 30%–40% in general and 5%–10% when used consistently.<sup>25</sup> Indeed, condom inefficacy could occur when it is used for ejaculation only, after limited unprotected penetration (delayed application), or when it

fails (breaks or leaks).<sup>26,27</sup> The association we observed for protected anal sex could also be due to social desirability, leading to a differential misclassification for this preventive behavior.<sup>7,28</sup>

The possible role of oral sex in HIV infection among some seroconverters in the cohort is another interesting finding of our study. Few studies have reported a significant association of oral sex and HIV transmission, suggesting that the risk of acquiring HIV infection through oral sex exists, but is low.<sup>7,29–33</sup> In our study, a social desirability bias leading to underreporting of anal sex (unprotected or not) by subjects practicing risky oral sex could have led to a spurious association with HIV seroconversion.

The community-based design of the Omega Cohort Study, the large number of MSM enrolled, and their relatively long follow-up allowed a reliable estimation of HIV incidence and a characterization of behavioral transmission patterns in this population. However, the small number of seroconversions observed limited the precision of risk factor hazard ratio estimates and possibly the power to detect other potential predictors such as those related to oral HIV transmission.

The HIV incidence we observed was relatively low; nevertheless, this rate translates into several hundred new HIV infections each year in the Montreal MSM community. Despite the possible social desirability bias identified, our findings confirmed that unprotected receptive anal sex remains the most important risk factor for HIV seroconversion. They also suggest that, although of significant value in reducing HIV transmission, condom use with serodiscordant/casual partners does not provide complete protection against HIV infection. Furthermore, in a low HIV incidence community such as Montreal, serosorting with regular partners appears to be an acceptable compromise between obtaining sexual fulfillment and the adoption of effective HIV prevention practices. Thus, our results provide new insights that can help inform the debate on the use of harm-reduction strategies to prevent sexual HIV transmission.

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