

Human immunodeficiency virus incidence and risk behavior in the 'Projeto Rio': results of the first 5 years of the Rio de Janeiro open cohort of homosexual and bisexual men, 1994–98

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Objectives: In preparation for a phase III HIV vaccine trial, we report the results of men who have sex with men (MSM) cohort ('Projeto Rio').

Methods: HIV-negative MSM were followed 6-monthly over a 3-year period.

Results: High seroprevalence for sexually transmitted disease (HIV, syphilis and hepatitis B seropositivities of 24%, 29%, and 37%, respectively) was seen in the 1165 potential volunteers, and this seroprevalence showed significant differences according to HIV serologic status. Among the 647 HIV-negative cohort participants, HIV incidence rate (IR) was 3.33 (95% CI 1.93–4.67) per 100 men-years, with 21 newly acquired HIV infections during 7572 men-months of observation. IR differences were observed in four categories: (1) non-commercial sex workers and non-transvestites who had protected sex prior to study entry (IR 1.6 per 100 men-years); (2) non-commercial sex workers and non-transvestites who had unprotected sex prior to study entry (IR 2.7 per 100 men-years); (3) commercial sex workers (IR 3.5 per 100 men-years); and (4) transvestite groups (IR 16.8 per 100 men-years). Unprotected penetrative anal sex was frequent (66%) in the 6 months before study entry, and when we take into consideration the fact that bisexual men engaged in unprotected vaginal intercourse with their female partners, the risk behavior in this group escalates to 73%. HIV seroconverters had high risk behavior prior to study entry (76%), and all but one admitted to having unprotected penetrative sex prior to infection.

Conclusions: MSM in this study had a high rate of unprotected penetrative sexual practices, which caused a significant HIV incidence rate, and, with improved study adherence, this study site could be used for future vaccine trials.

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INTRODUCTION

Behavioral change is the only available method at this time to decrease the risk of human immunodeficiency virus (HIV) transmission. As is known, this has had little impact on new acquisition of HIV infection, especially

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in developing countries. Brazil has an estimated 700 000 HIV-infected persons, and 145 000 have developed AIDS since the beginning of the epidemic.⁽¹⁾ Prevention efforts focused primarily on education and the distribution of prophylactics will have to be maintained, but these efforts will only become optimally effective when an HIV preventive vaccine becomes available. In 1992, the Brazilian Ministry of Health decided to participate in the General AIDS Program of the World Health Organization (GPA/WHO) as one of four developing countries (including Uganda, Rwanda, and Thailand) that would prepare sites that might be chosen for future HIV vaccine and sexually transmitted disease (STD) intervention protocols. These sites were expected to establish an infrastructure to generate epidemiologic data (to determine accurate incidence and prevalence rates in high-risk cohorts), to perform research on social science issues (social and behavioral aspects and the ethical issues involved), to carry out clinical investigations (execution of vaccine research protocols), and to ensure the availability of laboratory capabilities for HIV isolation and characterization, and assessment of HIV-specific immunologic responses. It was also expected that these sites chosen by the WHO would understand the importance of proactive public relations in order to stimulate

public debate concerning the acceptance of HIV vaccine trials.

The rationale, significance and feasibility of the multicenter (São Paulo, Belo Horizonte, and Rio de Janeiro) HIV incidence cohort studies for future vaccine efficacy trials in Brazil have been described elsewhere;^{2,3} these are supported financially by the STD Program of the Brazilian Ministry of Health, the United Nations Joint Program on AIDS (UNAIDS), and other organizations.

In this paper, we provide the results of the first 5 years of an ongoing open cohort of men who have sex with men (MSM) ('Projeto Rio') in Rio de Janeiro. We provide an update of the sociodemographic and STD prevalence data, observed sexual risk behavior data and HIV incidence data for the different risk groups identified in this cohort. The study period covered is from January 1994 to December 1998.

MATERIALS AND METHODS

This multicenter study was approved by the Oswaldo Cruz Research Ethics Committee. Volunteers were enrolled into the study following a discussion of the informed consent procedure, and after signing the informed consent form. The study site, study population and study procedures have been described elsewhere,⁴ and preliminary seroprevalence results have been reported.

Study site and population

The investigation was performed in the City of Rio de Janeiro (Brazil) by a multidisciplinary team at the Epidemiology Service of the Infectious Disease Clinical Investigations Unit, Center of Clinical Research, Evandro Chagas Hospital (CCR-ECH), of the Oswaldo Cruz Foundation (Ministry of Health). Study population and cohort entry criteria were as follows: men ranging in age from 18 to 50 years who engaged in sexual activity with other men (MSM), who had a negative HIV test at recruitment date, and who were interested in participating in a research protocol.

Study procedures

At the recruitment interview, the data collected consisted of basic sociodemographic information, sexual behavior data, HIV knowledge, and attitudes on health issues; information on the 'Projeto Rio' was provided to each volunteer. Volunteers were given pretest counseling, and blood specimens were subsequently collected for HIV, syphilis (venereal disease research laboratory test, with confirmation with *Treponema pallidum* hemagglutination assay or fluorescent treponemal antibody absorption test-Abs) and hepatitis B (anti-HBc, anti-HBs, HbsAg) testing. On their subsequent visit 1 week later, they received the results of their HIV test and other blood examinations, and were given post-

test counseling. The HIV-positive individuals were referred to public health care facilities for follow-up, and those who were HIV negative were invited to enroll in the study. After an informed consent form was signed, a more detailed questionnaire was administered.

Standardized questionnaires were administered by specially trained study staff. The socio-behavioral questionnaire was composed of sociodemographic information, knowledge about HIV transmission routes and prevention strategies, and beliefs and attitudes concerning AIDS and sexual life, sexual practices, and STD/AIDS preventive initiatives.

Data collection and criteria

The information analyzed in this study was obtained from the socio-behavioral questionnaire used by the multicenter investigation teams at the initial interview. The variables collected included: social and demographic data (age, income, educational level, race), sexual partner types, recent sexual practices, and volunteer's use of condoms during both oral and penetrative sex.

A steady partner was defined as the person with whom the cohort volunteer planned a new encounter, and with whom he had ongoing emotional involvement. In contrast, casual partners were those with whom the volunteer had one or more sexual encounters without making a date for a further encounter (one-night-stand partners are included in this category). Risk behavior refers to the 6 months prior to study entry and was defined as any unprotected penetrative (anal or vaginal) sexual contact during this period. The cohort was divided into an exclusively homosexual group and a bisexual group, based on sexual history.

Data analysis

Data were entered into a FoxPro (version 2.0) spreadsheet and evaluated (using EPI INFO version 5.0) with frequency tables and chi-square test for P-value calculations. Significance was defined as a P-value less than 0.05. In univariate analyses, chi-square tests were used to assess any associations with risk behavior.

For the purpose of incidence data analysis, the following points were considered. Incidence rates were calculated with the denominator being men-months at risk and the numerator the number who seroconverted to HIV. The denominator of those who seroconverted was the number of months of observation plus half the number of months between the last negative HIV test and the positive result; and the result was transformed to represent the incidence rate (IR) as the number of new cases per 100 men-years.

RESULTS

During the 5-year study period, 1165 MSM were interviewed at the CRC-ECH and asked about their willingness to participate in the cohort study. In total, 647

volunteers, all HIV negative at the time of enrollment, agreed to enter the 3-year open cohort study.

Recruitment

The source of the volunteers changed over time. In the first years of the study, recruitment came from a mixture of referrals from health services, media contact through paid advertisements, and public information disseminated with the support of non-governmental organizations (NGOs); in the last 3 years of the study, this strategy changed to include snowball recruitment (45%), specific community recruitment activities, and NGO support (33%). Since 1996, efforts have been made to include in our study male commercial sex workers (CSWs), who were recruited from prostitution areas, and transvestites.

Cohort participants were placed into two groups: bisexual men ($n=310$) and homosexual men ($n=337$). Relevant to the overall interpretation of the data is that 34% (221) of these men (representing 56% of the bisexual men) classified themselves as CSWs (as they had sex in exchange for money). The number of persons who paid for sexual favors (3%) or offered drugs (1%) in return for sex was small, as were the alcohol and drug consumption rates. Thirty-one men were transvestites, and two in this group also had sexual encounters with women in the months prior to study entry.

Cohort adherence

Sixty per cent of the volunteers who agreed to enter the study had at least one follow-up visit. The retention of these volunteers at 12, 24 and 36 months was 85%, 61% and 42%. The most common self-reported reason for their willingness to participate was a wish to know their HIV status, wanting to take part in a project that provides volunteers with preventive resources (e.g. condoms, education), and having access to the support of a multi-disciplinary team.

STD seroprevalence

Table 1 shows the results for the seroprevalence of HIV, syphilis and hepatitis B in the men who were seen at the initial visit. Of the sera tested, 281 (24.1%) were positive

for HIV, 29.5% for syphilis, and 37.2% for hepatitis B markers, with a 4% positivity for HbsAg. Although HIV-positive individuals were not eligible for study participation, high seropositivity rates were observed in this group for syphilis, hepatitis B markers, and HbsAg: 43%, 56%, and 9%, respectively. Volunteers who seroconverted for HIV during the study had respective percentages of 47%, 39%, and 6%. Those who tested HIV negative at study entry had significantly lower rates of past infections: 25%, 31%, and 4%, respectively. The risk of positive HIV serology at initial screening was 13% for those volunteers without syphilis or hepatitis, almost 2.5 times higher (33%) in those men who had at least one of these infections, and three times higher (45%) in men with syphilis and hepatitis.

Social and demographic data

A large variety of sexual practices and partnerships existed in this study.^{5,6} Information obtained during the first visits sometimes changed during follow-up, in that there was greater openness at subsequent visits, which we attributed to increased trust in the interviews. The groups in which this change was observed were the CSWs and the transvestites.

Table 2 shows the sexual partnership types and the sexual practices. The relationships varied from only steady partners to only casual partners. Homosexual men had sex mainly with their steady partners (75%), and bisexual men more with casual partners (82%); in this latter group, the relationships with women also varied extensively.

Overall, the frequency of unprotected penetrative sex in the 6 months prior to study entry was high in both the homosexual (58%) and bisexual (74%) groups, and was statistically different ($P<0.0001$) between groups. Unprotected oral sex rates (17%) were similar in both groups. The percentage of safer sex practices was higher in the homosexual group. The sexual practices and condom usage according to social and demographic data showed that no difference existed between the homo- and bisexual men under age 30, but a significant difference ($P<0.0001$) existed above age 30. In regard to income and educational level, no significance differences were observed, except in the bisexual group, where men

Table 1. Seroprevalence of syphilis and hepatitis B at time of recruitment among the potential participants in the 'Projeto Rio', according to HIV serology status (1994–98)

	HIV ⁺	%	HIV ⁻	%	OR (95% CI)	P-value ^a
No syphilis or hepatitis B	412	46.6	56	19.9	0.29 (0.20–0.40)	<0.0001
Only syphilis	116	13.1	33	11.7	0.88 (0.57–1.35)	0.6
Only hepatitis B	166	18.8	69	24.6	1.41 (1.01–1.96)	0.04
Both infections	108	12.2	89	31.7	3.31 (2.37–4.63)	<0.0001
Not tested	82	9.3	34	12.1	1.35 (0.86–2.10)	0.2
Total	884	(76%)	281	(24%)		

^aChi-square Yates corrected.

Table 2. Sexual practice and percentage of unprotected sex, according to partner type, during the 6 months prior to entry into the 'Projeto Rio' Male Homosexual Cohort Study

Sexual practice (unprotected)	Homosexual n=338	Bisexual n=310
Male partner	313	276
Steady	234	122
Oral sex	124 (78.5%)	40 (71.4%)
Anal sex	212	102
Active anal	81 (58.7%)	59 (64.8%)
Passive anal	111 (65.7)	26 (55.3%)
Casual	207	226
Oral sex	107 (68.1%)	55 (58.5%)
Anal sex	175	202
Active anal	36 (35.3%)	107 (56.3%)
Passive anal	70 (46.4%)	32 (48.5%)
Female partner	1	230
Steady	0	143
Vaginal sex	-	110 (83.3%)
Anal sex	-	60 (73.2%)
Casual	1	157
Vaginal sex	0	93 (62.4%)
Anal sex	-	70 (61.4%)

with lower educational levels were at higher risk ($P=0.003$) than men with higher educational levels. The data related to race showed no significant difference in risk behavior.

The incidence of penetrative and receptive anal sex among men, in either the homosexual group or the bisexual group, did not differ, and nor was there a statistical difference in risk behavior with regard to either vaginal or anal sex among the female partners. No differences in risk behavior were observed between the two groups with regard to oral or anal sex. However, a significant difference was observed in the variable 'steady or casual partner' for both penetrative ($P<0.0001$) and receptive ($P=0.002$) sex, showing that a higher proportion of men have unprotected sex with their fixed partners. This finding is especially relevant from an epidemiologic standpoint, when we consider that the bisexual men maintain unprotected sexual relations with their fixed female partners.

The data confirm the observations made by the study staff, that the exclusively homosexual group had more unprotected relations with steady partners, which they justified with statements such as loyalty, emotional involvement, and dislike of condom use. Although they often have individual sexual preferences, they normally accepted both penetrative and receptive anal sex. The small but important group of transvestites stated having feelings of affection for their steady partners, and clearly preferred receptive anal sex, but also engaged in penetrative anal sex when asked. Among the bisexual men, the large variety of partners and feelings of affection were observed, including their affection for the steady female partners. Many of these men are CSWs, and they claimed to practice mainly penetrative sex, but later often admitted to having receptive anal sex.

HIV incidence data

Table 3 shows the number of persons who underwent seroconversion during the study, the men-months of observation, and the incidence rates in the different groups observed in our study. Of the cohort participants, 385 had at least one follow-up visit, producing 7572 men-months of observation (=631 men-years), and an average of 19.6 months of observation per volunteer; this number was similar in both the homosexual and bisexual groups. The CSWs were observed for 17 months/person, and the transvestites for 15 months.

Of the 21 seroconverters, 16 (76%) had shown high-risk behavior prior to study entry, and all but one referred to unprotected penetrative sex prior to infection. Ten did not belong to the CSW or the transvestite groups. The overall HIV incidence rate (IR) was 3.33 per 100 person-years of observation; it was higher in the homosexual group (3.68) than in the bisexual group (2.79). Overall, the cohort participants who had unprotected penetrative sex before study entry had an IR of 4.06; the IR was higher in the homosexual men, at 5.21.

Table 3. Number of HIV seroconverters, men-months of observation and incidence rates for the cohort according to the homosexual and bisexual men risk behavior prior to study entry in the 'Projeto Rio' (1994-98)

		Bisexual men	Homosexual men	Total	
HIV seroconverters	Total cohort	7	14	21	
	Low risk	2	3	5	
	High risk	5	11	16	
	Total cohort (excluding CSWs and transvestites)	3	7	10	
	Low risk	2	1	3	
	High risk	1	6	7	
	CSWs	4	2	6	
	Transvestites	0	6	6	
	Men-months of observation	Total cohort	3012	4560	7330
		Low risk	818	2025	2843
High risk		2194	2535	4729	
Cohort, excluding CSWs and transvestites		1669	3718	5387	
Low risk		458	1793	2251	
High risk		1211	1925	3136	
CSWs		1343	581	1924	
Transvestites		37	391	428	
HIV incidence rates		Total cohort	2.79	3.68	3.33
		Low risk	2.93	1.78	2.11
	High risk	2.73	5.21	4.06	
	Cohort excluding CSWs and transvestites	2.16	2.26	2.23	
	Low risk	5.24	0.67	1.60	
	High risk	0.99	3.74	2.68	
	CSWs	3.57	4.13	3.47	
	Transvestites	-	18.41	16.82	

Further evaluation revealed that the IR difference could be better understood by dividing the study into four categories: (1) non-commercial sex workers (N-CSWs) and non-transvestites (N-TVs) who had protected penetrative sex; (2) N-CSWs and N-TVs who had unprotected penetrative sex in the 6 months prior to study entry; (3) CSWs; and (4) transvestites. In this analysis, the IRs were 1.6, 2.7, 3.5 and 16.8 per 100 men-months at risk, respectively. Although the numbers are small, the IR differences that appeared to be related to homosexuality and bisexuality seem to be smaller according to this analysis.

Willingness to participate in vaccine trials

Fifty-four per cent of our cohort participants stated that they would be willing to participate in a vaccine trial, mostly for humanitarian reasons. In public opinion polls (street polls and national television) conducted on this subject at the time of our research study, a rate of willingness to participate in HIV vaccine trials was obtained from the general public. A separate public opinion poll was done on 505 persons in different areas of Rio de Janeiro in December 1995; this survey reported that 82% considered HIV vaccine trials, which were then in progress, run by members of our project, to be important, and 53% responded that they would be willing to volunteer to participate in an HIV vaccine trial. This rate is very similar to that obtained from the opinion polls done on national TV talk shows and telephone surveys, which were also done that year.

DISCUSSION

Currently, non-vaccine interventions are the only available HIV prevention strategy; and even if a successful vaccine is found, such activities will still be necessary.

The cohort volunteers enrolled at the Rio de Janeiro site were selected from a relatively young population; in this group, high prevalence rates were found for HIV (24%), hepatitis B (33%), and syphilis (37%). These rates were higher than those observed at the other Brazilian HIV vaccine sites (Grego and Carneiro, personal communication). HIV prevalence rates among homosexual populations in other studies have generally been lower than those reported in our study,⁷⁻¹² but a few studies have shown similar rates, and a few have shown higher STD rates.¹³⁻¹⁵ The syphilis and hepatitis B rates observed in our study were also higher than those found in similar studies.^{10,12}

Sexual risk behavior was significant at the time of study entry, and was studied according to the groups who were identified in our previous evaluations. The homosexual and bisexual men have different risks of engaging in unprotected penetrative sex. In the latter group, the higher rates are the consequence of unprotected vaginal and anal sex with female partners, especially with the steady ones. Consequently, the bi-

sexual men, who were often also CSWs, increased the risk of exposure of their female partners to STD. It is possible that transmission of HIV-1 from bisexual men to female sexual partners plays a greater role in heterosexual transmission than has previously been recognized. The prevalence of unprotected penetrative sex in this study (66%) and that of multiple partnerships were higher than those found in other studies,^{10-13,16,17} where unprotected sex rates varied between 26% and 41%. In this study, we did not find the racial and class differences observed by others¹⁸⁻²⁰ as they relate to HIV risk behavior. Further evaluation will determine whether other social or psychological factors may be involved in this form of risk-taking. In our cohort,⁶ we have already observed that volunteers have a sound knowledge of how to protect themselves against HIV infection, and an association was observed between their perception of vulnerability to infection and the practice of unprotected anal sex, as well as an association between higher levels of formal education and perception of vulnerability.

Another finding from our data is that they consistently show the higher risk of engaging in unprotected sex with steady partners rather than with casual partners, as seen in Table 2; these data were confirmed by verbal information obtained in individual counseling sessions and in focus groups. Data from the HIV seroconverters confirm this observation, which is contrary to the general belief that infection is acquired through unprotected anal intercourse with casual partners. Unprotected oral sex was also observed in our study, but only one of the seroconverters referred to this practice as being an exclusive one.

The overall IR among the 21 seroconverters was 3.3 per 100 men-years of observations; this is higher than the rates found in similar studies^{16,21,22} and in other studies conducted in Brazil (Grego and Carneiro, personal communication). If we exclude the group of transvestites and CSWs, the IR comes down to 2.1, which is similar to the values found in the above-mentioned studies.

The rate of adherence to study follow-up was relatively low, primarily due to a high drop-out rate in the CSW group and the high residential mobility of the group, which made follow-up difficult. The latter factor, the low age of volunteers and other parameters were also noted in another study.²³ On the other hand, the group composed of transvestites showed strong adherence to study visits. We observed a variety of needs in the different groups that composed this cohort, including those for emotional or social support and for medical care. Some of these needs could be met by means of one-to-one counseling, discussion groups, and other activities, but other needs were beyond the scope of the study, and included requests for job placement, and reimbursement for travel expenses beyond the support that was routinely provided. The cohort participants' ability to keep appointments was unsatisfactory, and this can be attributed to local cultural factors.

The recruitment strategies that we initially used needed to be changed midway through our study, as the original reliance on health care units for volunteer referral was shown to be unsatisfactory. Even when close collaboration with physicians and health units was established, problems related to poor infrastructure in the health care system and adverse working conditions limited our success. Nonetheless, the new STD clinics that are currently being established may prove useful in the future. Information dissemination among MSMs in recreational localities (i.e. bars, discos) was ineffective, as these places were proven to be unsuitable for discussions of disease-related topics. We found that snowball recruitment was the most effective strategy, especially in combination with active NGO collaboration and with certain specific community activities, but this method must be carefully monitored in order to avoid bias in the volunteer sample.

This study, conducted in a Latin American culture, confirms many findings published on the subject of HIV risk factors in other countries and cultures. The relevant findings of this study are as follows: the high rates of comorbidity with other STDs (syphilis and hepatitis B) might prove to be a good predictor for HIV seroconversion; there was a high rate of unprotected penetrative sexual practices among our sample, especially with the steady partners, which translated into a high HIV incidence rate; the high rate of unprotected vaginal sex in the bisexual group may be of importance in the increasing spread of HIV infection in women. Our educational efforts were clearly not sufficient as preventive measures; further attention must be paid to other possible preventive interventions at the individual level.

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