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Willingness to participate in HIV vaccine trials among a sample of men who have sex with men, with and without a history of commercial sex, Rio de Janeiro, Brazil

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Abstract *The study objective was to assess willingness of men who have sex with men (MSM) enrollled in a vaccine preparedness study ('Projeto Rio') to participate in phase III anti-HIV/AIDS vaccine trials. Overall, 57% of Projeto Rio participants stated they would participate in a putative vaccine trial. MSM who reported commercial sex work were significantly ($p < 0.05$) more likely to engage in risky behaviours than others. In bivariate analysis, commercial sex workers (CSWs) were significantly ($p < 0.05$) more likely than non-commercial sex workers (NCSWs) to be willing to participate in vaccine trials (62.6% versus 51.4%). Among those willing, CSWs reported significantly more often ($p < 0.05$) (50.5%) than NCSWs (38.0%) that they would enroll to protect themselves from HIV. In multivariate analyses, variables associated with willingness to participate (WTP) were lower educational level, positive serology for syphilis, and 'engagement, under the influence of alcohol, in risky sexual practices that would normally be avoided', but not commercial sex work. The potential enrollment in vaccine trials of MSM CWSs, as well as participants of low socio-economic status and high risk, seems thus to be possible.*

Introduction

The World Health Organization (WHO) and United Nations AIDS (UNAIDS) established a comprehensive programme to coordinate vaccine preparedness studies/vaccine trials in developing countries in different geographic areas (Esparza *et al.*, 1991; Heyward *et al.*, 1994). Brazil was one of the countries selected to implement such studies, after consultations evaluating the nature and extent of the epidemic in the country, as well as its scientific infrastructure and local coordinating capacity (Heyward *et al.*, 1996). Extensive evaluations of

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sociodemographic and behavioural aspects of vaccine preparedness studies are as yet preliminary in Brazil (Carneiro *et al.*, 2000; Harrison *et al.*, 1999; Hofer *et al.*, 2000; Lignani *et al.*, 2000; Périssé *et al.*, 2000; Souza *et al.*, 1999, 2002; Sutmöller *et al.*, 1997). The Brazilian effort has so far comprised the establishment of four cohorts of men who have sex with men (MSM), three of them sponsored by the Brazilian Ministry of Health and WHO/ UNAIDS, in the cities of Sao Paulo, Belo Horizonte and Rio de Janeiro, as well as one in Rio de Janeiro sponsored by the National Institutes of Health (NIH) ('Projecto Praça Onze').

Recently, Souza *et al.* (1999) published a paper addressing sociodemographic and behavioural characteristics, as well as perception of vulnerability to HIV infection, among 295 volunteers enrollled in Projeto Rio between January 1994 and March 1997. Exploratory analyses indicated striking differences between volunteers who reported engagement in commercial sex (male prostitutes—locally known as 'michês'—and male transvestites engaged in commercial sex) and those who did not. Male commercial sex workers (CSWs) seem to be particularly vulnerable to HIV infection, both in the Brazilian context (Parker *et al.*, 1992) and in other settings in both developed (Boles & Elifson, 1994; Elifson *et al.*, 1993a,b, 1999; de Graaf *et al.*, 1995; Miller *et al.*, 1998) and developing countries (Baqi *et al.*, 1999; Lubis *et al.*, 1997). Previous reports (Parker *et al.*, 1992) indicate that Brazilian male CSWs quite frequently engage in unprotected sex with both male and female partners, indicating that this population may act as a core group with respect to further spread of HIV both within the gay community as well as to women. Enrollment of male CSWs in vaccine trials is, therefore, extremely important. This paper presents data from baseline interviews of a large sample of 675 MSM enrollled in the Projeto Rio. Characteristics of MSM engaged in commercial sex, or not, and analyses of factors associated with willingness to participate in HIV vaccine trials among study participants are presented.

Methods

Study procedures and preliminary findings have been reported elsewhere (Souza *et al.*, 1999, 2002; Sutmöller *et al.*, 1997) and are briefly described here.

Study population

Entry criteria for this study was being a man who had had sex with other men, HIV-negative and between 18–50 years of age.

Procedures

Volunteers were recruited through a combined strategy mainly involving outreach activities, e.g. recruitment by study volunteers themselves ('snowballing') and by non-governmental organizations (NGOs), as well as through media advertising and referrals from health care facilities (Souza *et al.*, 1999, 2002; Sutmöller *et al.*, 1997).

At the first recruitment basic sociodemographic and behavioural data were obtained, and the Projeto Rio study was explained. The volunteers were then given pre-test counselling, with subsequent blood sample collection for HIV, syphilis (VDRL, confirmed by TPHA) and hepatitis B (anti-HBc, anti-HBs, HBsAg) testing. On their return one week later, the volunteers received their HIV and other test results during a session of post-test counselling. The HIV-positive individuals were referred to public health care facilities for follow-up care

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and those who were HIV-negative were asked to enroll in the study after signing the informed consent form. A detailed questionnaire was administered on enrollment.

Instruments

A standardized questionnaire was developed and administered by trained interviewers. The questionnaire consisted of approximately 100 (mainly closed) questions on: sociodemographic characteristics, knowledge of HIV transmission routes and prevention strategies, beliefs and attitudes towards AIDS and sexual life, sexual practices and STD/AIDS preventive initiatives.

Willingness to participate in a putative HIV vaccine trial was evaluated through a simple question, 'Would you be willing to participate in HIV vaccine trials?', answers being 'yes', 'no', 'it depends' and 'do not know'. Willingness to participate was defined for our purposes as the equivalent of a 'yes' answer and the remaining alternatives ('no', 'it depends', 'do not know') were defined, for our purposes, as unwillingness. Previous engagement in commercial sex was defined by the question, 'Have you accepted money/goods in exchange for sex during the last six months?' Volunteers answering 'often', 'sometimes' or 'rarely' were considered to have a history of commercial sex. Exploratory analyses were carried out stratifying those engaged in commercial sex on a regular ('always' or 'often') or irregular ('sometimes' or 'rarely') basis during the six months prior to interview; since both sub-categories differed markedly from people not reporting any engagement in commercial sex (data not shown), they were considered together for the purpose of the present analyses.

Statistical analysis

Only baseline date was analyzed. In the bivariate analyses, differences in characteristics between MSM with and without a history of commercial sex, as well as variables associated with willingness to participate in HIV vaccine trials, were assessed through contingency table statistics. *P*-values less than 0.05 were considered statistically significant.

To further assess the role of the different variables associated with willingness to participate in HIV vaccine trials, a stepwise logistic regression was carried out with 'willingness to participate in HIV vaccine trials' as the dependent variable. All variables significantly associated with the response variable ($p < 0.05$) as well as borderline associations formerly mentioned in the literature were entered in the model. The stepwise procedures were performed in two different ways: (1) all covariates were tested for inclusion at once, without controlling for reported engagement in commercial sex and (2) the covariate 'reported engagement in commercial sex' was included in the first step of the procedure and then the other covariates were tested for inclusion.

Forty-eight (7.11%) volunteers were excluded from the analyses due to missing data for core variables. Analyses here described refer to a total sample of 675 subjects, of whom 294 reported engagement in commercial sex in the six months prior to the interview.

Results

Sociodemographics and behaviours

The majority of volunteers were single (82.9%), young adults (mean age = 27.4, SD = 7.11 years), currently employed (66.3%) (Table 1). Roughly 63% earned less than US$ 250.00 a month (corresponding to the second tercile for income, considered poverty level (as defined

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Table 1. *Sociodemographic and behavioural characteristics of 627 participants (non-commercial sex work and reporting commercial sex work) of Projeto Rio, according to baseline interview (Rio de Janeiro, 1994–1999)*

Variables	NCSW $n = 333$ (%)	CSW $n = 294$ (%)
Age (mean in years; SD)	**28.1; 7.21**	**26.7; 6.92**
Marital status		
Single	**289 (86.8)** [a]	**231 (78.6)**
Married/ divorced [b]	**43 (12.9)**	**63 (21.4)**
Employment		
Formally employed	**242 (72.7)** [a]	**174 (59.2)**
Unemployed/alike [c]	**82 (24.6)**	**118 (40.1)**
Income		
< U$250.00	**184 (55.3)** [a]	**209 (71.1)**
≥ U$250.00	**134 (40.2)**	**68 (23.1)**
Race		
White	**186 (55.9)** [a]	**117 (39.8)**
Non-white	**137 (41.1)**	**171 (58.2)**
Educational level		
Fundamental	**123 (36.9)** [a]	**218 (74.1)**
High school/college	**204 (61.3)**	**75 (25.5)**
Unprotected Sexual Practices [d]		
With males		
Regular partners	**215 (64.6)**	**119 (40.5)**
Anal receptive	88 (40.9)	42 (35.3)
Anal insertive	86 (40.0)	49 (41.2)
Casual partners	**177 (53.2)**	**232 (78.9)**
Anal receptive	**49 (27.7)**	**43 (18.5)**
Anal insertive	**50 (28.2)**	**89 (38.4)**
With Females		
Regular partners	**46 (13.8)**	**111 (37.8)**
Vaginal	34 (74.0)	87 (78.4)
Anal	15 (32.6)	51 (45.9)
Casual partners	**36 (10.8)**	**135 (45.9)**
Vaginal	16 (44.4)	87 (64.4)
Anal	**10 (27.8)**	**66 (48.9)**
Other behavioural and attitudinal		
Behavioural change after AIDS	**163 (48.9)**	**113 (38.4)**
Engaged in risky sexual practices that normally would be avoided, under the influence of alcohol	34 (10.2)	46 (15.6)
Engaged in risky sexual practices that normally would be avoided, under the influence of drugs	**7 (2.1)**	**22 (7.5)**
Laboratory data		
Serology (+) for syphilis	**84 (25.2)**	**96 (32.7)**
Serology (+) for hep. B	**97 (29.1)**	**113 (38.4)**

[a] Total different from 100% due to invalid answers; [b] Refers to the civil status of men not reporting engagement in commercial sex, married with women. Brazilian law does not recognize the civil union of gay couples; [c] Includes living from social security, informal sources of income, etc.; [d] Data refer to those engaged in each one of these partnerships in the last six months.

** in bold = statistically significant differences ($p < 0.05$).

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by Brazilian standards). Close to half of the interviewees (49.1%) had less than eight years of regular education and half of the sample was white.

Comparison between men reporting and not reporting involvement in commercial sex in the six months prior to interview revealed some statistically significant ($p < 0.05$) differences. CSWs were more likely than NCSWs to be younger (26.7 versus 28.1 years old for NCSWs), more frequently married (21.4% versus 12.9%), unemployed (40.1 versus.6), poorer (71.1% of CSWs earned less than US$ 250.00 versus 55.3% for NCSWs), non-white (58.2% of CS and 41.1% of NCS) and less well-educated (74.1% of CS had less than eight years of education, compared with 36.9% of NCSWs) (Table 1).

A high proportion of the interviewees reported risky sexual practices with both regular and casual male partners (Table 1). A comparison of CSWs and NCSWs revealed that the proportions reporting unprotected receptive and insertive anal sex with regular male partners were not significantly different. Regarding casual male partners, unprotected oral and receptive anal sex were more frequently reported by NCSWs (27.7%) than CSWs (18.5%). On the other hand, unprotected insertive anal sex with casual male partners was more frequently reported by CSWs (38.4%) than NCSWs (28.2%). Higher frequencies of unprotected (insertive) anal sex with casual female partners were also reported by CSWs than NCSWs (48.9% versus 27.8%). No other statistically significant differences in sexual behaviour were found between the two sub-groups.

With regard to other behaviours, NCSWs more frequently reported behavioural change as a result of the AIDS epidemic than CSWs (48.9% versus 38.4%). The engagement, under the influence of alcohol, in risky sexual practices that would normally be avoided was reported by 12.8% of the volunteers. No significant difference was found in this respect between CSWs and NCSWs. On the other hand, engagement in risky sexual practices that would normally be avoided, under the influence of (illicit) drugs, was more significantly frequently reported by CSWs than by NCSWs (7.5% versus 2.1%, respectively). This association was further explored in a recent paper (Souza *et al*., 2002). Overall, 28.7% and 33.5% of the volunteers were seropositive for syphilis and hepatitis B, respectively. Both prevalences were higher for CSWs, when compared with NCSWs (32.7% versus 25.2% and 38.4% versus 29.1%, respectively).

Willingness to participate in vaccine trials

Roughly 57% of the volunteers of Projeto Rio stated they would like to participate in a putative vaccine trial, with a higher percentage of CSWs than NCSWs stating that they would participate (62.6% versus 51.4%). Among those willing to participate, 'humanitarian concerns/solidarity' was the chief motivation, and was mentioned significantly more frequently by NCSWs than CSWs (73.7% versus 49.0%) (Table 2). The second reason most frequently given ('to protect [myself] against HIV-infection') was mentioned significantly less often by CSWs than NCSWs (50.0% versus 38.0%, respectively).

For those MSM who did not manifest willingness to participate in an HIV vaccine trial, roughly one-third of the interviewees alleged 'not having enough information about vaccines', with no significant differences between CSWs and NCSWs. 'Concern about possible adverse effects of the vaccine' was mentioned by 33.8% of interviewees in the total sample, with a significantly higher proportion for those who did not report commercial sex, compared with those who did (40.0% versus 24.5%). Other reasons mentioned by a significant proportion of volunteers were: 'afraid to get AIDS after vaccination' (25.3%), the former motive particularly by NCWs.

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Table 2. *Main responses (multiple answers allowed) for willingness and unwillingness to participating in HIV vaccine trials among the cohort participants*

Responses	ALL ($n = 627$) (%)	NCSW ($n = 333$) (%)	CSW ($n = 294$) (%)
Willingness	355 (56.6)	171 (51.4)	184 (62.6)
Human concerns/solidarity	216 (60.8)	126 73.7)	90 (49.0)
To protect [myself] against HIV-infection	157 (44.2)	65 (38.0)	92 (50.0)
To enjoy sex without being concerned with AIDS	51 (14.4)	29 (17.0)	22 (12.0)
I trust scientific achievements	67 (18.9)	39 (22.8)	28 (15.2)
Unwillingness	272 (43.4)	162 (48.6)	110 (37.4)
Afraid to be used as a guinea pig	36 (13.2)	23 (14.2)	13 (11.8)
Concern about possible adverse effects of the vaccine	92 (33.8)	65 (40.0)	27 (24.5)
Afraid to get AIDS after vaccination	57 (21.0)	41 (25.3)	16 (14.5)
Not having enough information about vaccines	94 (34.6)	59 (34.4)	35 (31.8)

* In bold = statistically significant associations ($p < 0.05$).

The final multiple logistic regression model, controlling for reported engagement in commercial sex (model chi-square = 13.71, $p = 0.003$), identified as factors independently associated with 'willingness to participate in HIV vaccine trials', 'positive serology for syphilis' (adjusted OR = 1.52, 95% CI 1.04–2.22) and 'engagement, under the influence of alcohol, in risky sexual practices that would normally be avoided' (adjusted OR 1.83, 95% CI = 1.05–3.20). Commercial sex work was not significantly associated with willingness to participate in vaccine trials.

The final multiple logistic regression model not controlling for previous history of commercial sex (model chi-square = 15.28, $p = 0.002$) identified as factors predictive of the willingness to participate in HIV vaccine trials: 'lower educational level' (defined as an ordinal variable, with a cut-off point of eight years of regular school attendance; adjusted OR 1.47, 95% CI 1.03–2.11); a 'positive serology for syphilis' (adjusted OR = 1.48, 9%% CI 1.01–2.16) and 'engagement, under the influence of alcohol, in risky sexual practices that would normally be avoided' (adjusted OR = 1.85, 95% CI 1.06–3.23) (Table 3).

Table 3. *Variables associated with willingness to participate in HIV vaccine trial as made evident by the final multiple logistic regression model*

Selected variables	Ajusted OR	95% CI
Controlling for CSW		
Positive serology for syphilis (1 = yes, 0 = no)	1.52	1.04–2.22
Engaged in risky sexual practices that normally would be avoided, under the influence of alcohol	1.83	1.05–3.20
Not controlling for CSW		
Lower educational level (ordinal)	1.47	1.03–2.11
Positive serology for syphilis (1 = yes, 0 = no)	1.48	1.01–2.16
Engaged in risky sexual practices that normally would be avoided, under the influence of alcohol	1.85	1.06–3.23

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Discussion

The Projeto Rio recruited men who have sex with men (MSM), most of them belonging to the low middle class and lower social strata, including a sizeable number of men reporting commercial sex. Volunteers with and without a history of commercial sex differ substantially in many sociodemographic and behavioural aspects. Overall, more than half (57%) of the participants stated they were willing to participate in vaccine trials and CSWs were more willing to participate than NCSWs, although this difference was not significant in multi-logistic regression.

Most studies on MSM carried out in different contexts have pointed to a strong willingness of such populations to participate in vaccine trials, with a moderate variance. Koblin *et al*. (1998) found that 76.2% of the volunteers enrollled in cohorts from eight American states stated they would like to participate in vaccine trials. Similar results (70–74% having stated they would like to participate) were found by Scheer *et al*. (1999) in the CDC Collaborative HIV Seroincidence Study in Chicago, IL, Denver, CO and San Francisco, CA. A slightly lower percentage (68.0%) was seen in the Project ACHIEVE and in cohorts from Boston (65.0%), as reported by Gross *et al*. (1996).

The overall proportion in our study willing to participate in the vaccine trials was slightly higher than the 50% reported for a similar study carried out in Belo Horizonte, Minas Gerais, Brazil (Carneiro *et al*., 2000), but substantially lower than the 69.8% reported in the other vaccine preparedness study implemented in Rio de Janeiro (Périssé *et al*., 2000). We must observe, however, that the other studies (Projects 'Horizonte', in Belo Horizonte, and 'Praça XV', in Rio de Janeiro) enrollled few MSM with a history of commercial sex, and in this sense differ substantially from our study in terms of the sociodemographic and behavioural characteristics of their volunteers.

Men with a history of commercial sex enrollled in Projeto Rio frequently reported sex with both men and women, corroborating previous findings by Parker *et al*. (1992), in a study targeting male prostitutes recruited from gay meeting places in the streets of Rio de Janeiro. Given the high levels of unprotected sex reported by those men, irrespective of the nature of their partnerships, they have probably functioned as a bridging population for HIV transmission between the gay community and women and thus are a very important group to recruit for vaccine trials.

To the best of our knowledge, no other vaccine preparedness study has recruited such a large proportion of volunteers reporting commercial sex (Bartholow *et al*., 1997; Gross *et al*. 1996; Harrison *et al*., 1999; Koblin *et al*., 1996, 1997, 1998; Scheer *et al*., 1999). In two vaccine preparedness studies carried out in the USA, one in San Francisco, CA (Gross *et al*., 1996) and the other in New York (Koblin *et al*., 1997), a history of commercial sex was shown to be associated with willingness to participate in vaccine trials. The small number of volunteers reporting commercial sex (less than 8% in the Project ACHIEVE, in New York, and a negligible percentage of the volunteers in San Francisco) precluded, in both studies, the inclusion of these men in multivariate analyses.

Various studies (Buchbinder *et al*., 1996; Gross *et al*., 1996; Périssé *et al*., 2000; Scheer *et al*., 1999) have shown that volunteers at particular risk of infection (for instance, those reporting unprotected sex with HIV-infected partners) state more frequently they would like to participate in vaccine trials. A low educational level has been shown to be associated with willingness to participate in vaccine trials (Bartholow *et al*., 1997; Gross *et al*., 1996; Koblin *et al*., 1996, 1997, 1998; Périssé *et al*., 2000). In our study, when the whole sample was considered, lower educational level was consistently associated with willingness to participate in vaccine trials. This association did not remain in multivariate models that controlled

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for a history of commercial sex, probably due to the striking differences in SES (socio-economic status) between NCSWs and CSWs. This is important, since dispossessed and underserved populations are currently being increasingly infected by HIV in Brazil (Fonseca *et al*., 2000).

Hays and Kegeles (1999), analyzing data from a cohort of 390 young gay/bisexual men recruited from three communities on the West Coast of the USA (Eugene, OR; Santa Cruz, CA; Santa Barbara, CA), found that willingness to participate in vaccine trials was associated with alcohol and (illicit) drug consumption, and with the perception of interviewees that under the influence of such substances they tended to adopt risky sexual practices. Alcohol consumption patterns were assessed only indirectly in the present study, which limits itself to data relative to the relationship between alcohol (and drug) consumption patterns and sexual intercourse. Nevertheless, we found alcohol users were significantly more likely to report willingness to participate in vaccine trials even after controlling for other variables. We could hypothesize that MSM reporting difficulty in initiating/maintaining safer behaviours under the influence of alcohol perceive themselves to be at higher risk of HIV infection, and thus are most likely to take part in vaccine trials.

The main reasons given by the volunteers in our study as to why they would enrolll in vaccine trials—'humanitarian concerns/solidarity' and 'to protect [myself] against HIV-infection'—have been reported by other national (Carneiro *et al*., 2000; Harrison *et al*., 1999; Périssé *et al*., 2000) and international studies (Gross *et al*., 1996; Hays & Kegeles, 1999; Koblin *et al*., 1997, 1998). Interviewees with a history of commercial sex more frequently stated 'to protect [myself] against HIV-infection' as their motivation than those without such a history, a perception that could reflect the increased risks that such populations are exposed to. However, it should be noted that these same risky populations may see vaccine trials as preventive and increase risky behaviours once enrollled in these trials.

The main motives for unwillingness to participate in vaccine trials given by study participants were similar to those in other national and international studies. For instance, in Project 'Horizonte', 30% of the interviewees said they 'were insecure and needed more information on the subject before a final decision' (Carneiro *et al*., 2000) and, in Project 'Praça XI', the main alleged reasons given were: 'fear of becoming HIV infected from the vaccine itself', 'fear of vaccine-induced positive HIV serological test result' and 'do not want to be a human guinea pig' (Périssé *et al*., 2000).

There are some limitations to our study. First, subjects in our study received, before they signed the informed consent and answered the baseline interview, results for syphilis, hepatitis B and HIV infection. Whereas the latter constituted one of the exclusion criteria for enrollment in the cohort, volunteers found to be positive for syphilis and hepatitis were informed immediately before they were interviewed that they had a medical condition, explicitly linked, in the counselling sessions, to risky sexual behaviour. These volunteers may have more frequently reported interest in participating in a future vaccine trial because they felt they were at great risk for infection. Second, financial incentives, although modest (USD $10.00), could influence reported willingness to participate in vaccine trials, especially for those reporting commercial sex, most of whom are poor and underserved (Koblin *et al*., 1998).

Third, because sampling included referrals by participants, we may have not recruited a representative sample of MSM from Rio de Janeiro but instead a specific network. However, we tried to avoid this by using a variety of methods to recruit participants. Fourth, social desirability may have influenced participants to have reported they were willing to participate in vaccine trials. Finally, our sample was the baseline of a cohort study and we could only measure willingness to participate; further research on follow-up data from the cohort is

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needed to examine whether or not there are differences in incidence and retention rates between CSWs and NCSWs.

Summarizing, our results indicate that MSM engaged in commercial sex are willing to participate in vaccine trials. The fact that those interviewees and/or volunteers with lower educational levels, higher prevalence for syphilis or reported difficulties in maintaining safer behaviours under the influence of alcohol and drugs were significantly more likely than others to report willingness to participate in vaccine trials is encouraging. Beyond the specific scope of vaccine preparedness studies, MSM engaged in commercial sex, as a population highly vulnerable to HIV infection, should be the target of comprehensive preventive efforts.

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Participants of Projeto Rio include: Frits Sutmöller (coordinator), Claudia Teresa Vieira de Souza, Amilton Xavier Junior, Helena Santos Martins, Dionne Peluso de Oliveira Costa, Paulo Starling Brandão Junior and Therezinha Lucy Penna.

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