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Longitudinal Changes in, and Factors Associated with, the Frequency of Condomless Sex Among People in Care for HIV Infection, HIV Outpatient Study USA, 2007–2019

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Abstract

During 2007–2019, the percentage of HIV Outpatient Study participants reporting anal or vaginal condomless sex in the past 6 months ranged from a low of 17% among heterosexual males to 59% for men who have sex with men (MSM). MSM reported having had condomless sex more frequently than heterosexual males and females and were the only group in which an increase in condomless sex was observed during the study period (from 39 to 59%). Although persons with undetectable HIV viral load have effectively no risk of transmitting HIV sexually (U = U), there is still the potential risk of transmission or acquisition of other sexually transmitted infections (STIs) when engaging in condomless sex. Continuing education about risks of HIV and STI transmission as well as ongoing screening for and treatment of STIs, retention in HIV treatment, and support for sexual health are critical components of care for people living with HIV.

Keywords

HIV; Risk behavior; Longitudinal; Condomless sex

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Declarations

Disclaimers The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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Introduction

Approximately 80% of annual HIV infections are transmitted by individuals not in care [1]. Improved levels of HIV viral suppression and reductions in anal/vaginal condomless sex among people with HIV (PWH) may substantially decrease the rates of transmission for HIV [2, 3] and other sexually transmitted infections (STIs) [4], contributing to the national goal for reducing new HIV infections outlined in the federal "Ending the HIV Epidemic" initiative and the National HIV/AIDS Strategy [1, 5–7]. Reported rates of condomless sex among PWH, including gay, bisexual and other men who have sex with men (MSM) with HIV, vary widely depending on the populations assessed, specific practices, and time frame for the data recorded, anywhere from 13 to 66% in some studies [8–11]. The findings from the HPTN052 study [12] and subsequent research [13] affirmed HIV treatment as prevention: PWH on antiretroviral therapy (ART) with an undetectable viral load have virtually no risk of sexually transmitting HIV, also referred to as U = U or undetectable equals untransmittable [7]. Across the age spectrum, sexually active people [14, 15] who have a detectable HIV viral load, however, remain at risk of transmitting HIV to their sexual partners if engaging in condomless sex, including rare instances of superinfection [16, 17]. HIV prevention efforts now also include biomedical-prevention strategies such as post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) [18-20] which are recommended for persons without HIV who are unable to use condoms or who use them inconsistently.

The characteristics and risk factors for engaging in condomless sex have been extensively studied among people without HIV. However, there are limited data exploring condomless sex behaviors and their changes over time among PWH who are under regular medical care, especially women and heterosexual men. Identifying and characterizing factors that may be associated with increases or decreases in condomless sex among PWH may lead to the development and implementation of improved interventions for reducing HIV and STI transmission [1, 21]. Using data from the HIV Outpatient Study (HOPS), we sought to address this gap in the literature and (1) determine if there were significant changes in self-reported condomless sex behaviors over time among sexually active PWH under regular medical care; and (2) explore patient- and treatment-related factors associated with these changes.

Methods

The HIV Outpatient Study (HOPS)

The HOPS is an ongoing prospective observational cohort study of adults 18 years and older diagnosed with HIV, receiving care at eight participating HIV clinics (university-based, public and private) in six U.S. cities (Chicago, IL; Denver, CO; Stony Brook, NY; Philadelphia, PA; Tampa, FL; and Washington, DC) since 1993 [22]. The HOPS is an open cohort: patients may enter the study at any point after a diagnosis of HIV infection regardless of treatment history and may leave the study at any point for a variety of reasons such as patient request or loss to follow-up [23]. Through December 2019, the HOPS had collected information on over 11,250 patients from more than 584,000 clinical encounters. Patient data, including sociodemographic characteristics, diagnoses, ART use

and other treatments, and laboratory values (including CD4+ lymphocyte cell counts/mm³ [CD4 count] and plasma HIV RNA levels (viral load, HIV VL) are abstracted from medical charts and entered into an electronic database by trained medical record abstractors with backgrounds in nursing or other healthcare-related fields. Since 2007, the HOPS has employed an optional supplemental survey for patients to also gather self-reported information on sociodemographic and behavioral measures, including sexual behaviors, substance use and adherence to ART. The survey is conducted via telephone or web-based audio-computer assisted self-interview (ACASI). All data are reviewed for quality and analyzed centrally.

Ethics

Since its inception, the HOPS protocol has been reviewed and approved annually by CDC's (Atlanta, GA, USA), Cerner Corporation's (Kansas City, MO, USA) and each local site's institutional review board. All participants provided written informed consent. The study protocol conforms to the regulations of the U.S. Department of Health and Human Services for the protection of human subjects in research.

Study Population

We analyzed medical records data from HOPS participants who received HIV care at eight U.S. HIV clinics during March 2007 through December 2019. Participants who completed at least one ACASI and reported sexual activity beyond hugging or kissing in at least one ACASI were included in the analysis. The start of observation was considered to be the date of the first ACASI taken, hereafter referred to as the baseline date. Study observation was discontinued after the date of the last ACASI completed by each participant. A total of 2193 participants were included in this study, contributing a total of 5214 completed ACASI observations.

Measurements and Definitions

Baseline demographic variables included age at survey date, sex at birth, race/ethnicity (non-Hispanic/Latino Black or African American [Black], non-Hispanic/Latino white, Hispanic/ Latino or other/unknown race/ethnicity), and HIV transmission risk (MSM, heterosexual males and females). Updated variables in the modeling analyses included CD4 count and HIV VL as well as type of insurance from the medical records, and from the ACASI survey the following items: sexual activity in the past 6 months, recreational drug use, cannabis use, alcohol use, and cigarette smoking. CD4 count was categorized as < 200, 200–349, 350–499 and 500 cells/mm³. Plasma HIV VL was characterized as undetectable or detectable, where undetectable was a VL test result less than the lower limit of detectability for the particular test used. Years elapsed since ACASI was first instituted in the HOPS (March 15, 2007) was also used as an explanatory measure, which enabled us to evaluate temporal trends in sexual behavior over time. Primary endpoint of interest was having reported anal or vaginal condomless sex during the past 6 months on an ACASI survey. Secondary endpoints of interest were anal or vaginal condomless sex with partners of HIV-negative or unknown HIV status during the past 6 months.

Statistical Analyses

Descriptive summaries of the data were generated for single-time observations per subject at baseline. Categorical and continuous measures were compared using the likelihood ratio chi-square test, and Wilcoxon rank-sum test, respectively. Expected cell counts for this test were verified to be at least five for at least 80% of cells for each of these tests. Generalized linear mixed model analyses (GLMMs) were used to evaluate longitudinal trends. To account for repeated measures, we used random intercept terms that estimated a best linear unbiased predictor for each subject for these models. Our model building procedure was as follows. Initial univariable GLMMs were estimated, adjusted for observation time. Next, full multivariable models were generated including all factors from univariable models. The final multivariable models were then created by removing all factors with P values > 0.05when adjusted for other factors in the full multivariable model step. Because of our primary interest in studying temporal trends, time was also included in each model regardless of statistical significance. Separate models were estimated for MSM, heterosexual males, and females due to substantial observed differences in descriptive plots of our endpoints over time. Based on the descriptive plots, we explored trends of the annual percentages of condomless sex overall and condomless sex with partners of negative or unknown HIV status during 2008–2011 and 2011–2019, as during 2011, the percentage of MSM reporting condomless sex was at a nadir. These time windows corresponded to the period before and after the release of the results of HPTN052 study which opened the era of HIV treatment as prevention [12, 23]. For these explorations we estimated slopes using simple linear regression with the descriptive percentages (unadjusted) as the response. Due to the smaller number of ACASIs completed during 2007, the 1st year they were offered, 2007 was not included in these linear regressions. We used SAS version 9.4 (SAS Institute, Cary, NC) for our analyses. Results with P values < 0.05 were considered statistically significant.

Results

Among the 11,253 participants enrolled in HOPS as of December 31, 2019 (Fig. 1), we identified 2856 participants who completed one or more ACASI assessments and had at least one VL test result recorded. Of these, 2193 reported sexual activity beyond hugging or kissing in at least one ACASI and were included in the analysis. Of these participants, 65% (N = 1429) were MSM, 16% (N = 352) were heterosexual males, and 19% (N = 428) were female (Table 1). Overall, the median age at first assessment was 45 years (interquartile range [IQR] 39–52 years), 54.5% (N = 1195) were non-Hispanic/Latino white, 30.8% (N = 675) non-Hispanic/Latino Black, 11.3% (N = 248) Hispanic/Latino and 3.4% (N = 75) were persons of other or unknown race/ethnicity. Median follow-up for those who completed > 1 ACASI was 4.6 years (IQR 2.6–6.4 years). In terms of the number of surveys completed during 2007–2019, 864 (39%) participants contributed only one ACASI, 498 (23%) contributed two, 301 (14%) contributed three, 199 (9%) contributed four, and 331 (15%) contributed five or more ACASIs.

Participants who did not complete any ACASIs (n = 2961) and were thus excluded from the analyses, were more likely to be > 40 years of age, not have MSM HIV risk, not be of white non-Hispanic/Latino race/ethnicity, not be privately insured, have detectable HIV viral

In terms of the characteristics of the three demographic subsets of participants we studied (Table 1), compared with heterosexual males and females, MSM were more likely to have completed the assessment during 2007–2010, be white, non-Hispanic/Latino persons, be privately insured, have CD4 count 500 cells/mm³, have undetectable viral load, have had any sex beyond hugging and kissing, used poppers, methamphetamine, club drugs, erectile dysfunction drugs (EDD), cannabis or alcohol, but less likely to use heroin or be a current smoker.

Trends in Condomless Sex Over Time

The percentage of ACASI surveys indicating anal or vaginal condomless sex in the past 6 months by HIV transmission risk group and calendar year ranged from a low of 17% among heterosexual males in 2012 to 59% for MSM in 2017 (Fig. 2a). MSM reported having had condomless sex more frequently than heterosexual males and females, and that trend held over time. Additionally, the levels of condomless sex among females and heterosexual males tended to be similar over time. Using general linear modeling to look at years 2008-2011 and 2011–2019, only among MSM did the percentages of those engaging in either condomless sex overall or condomless sex with partners of negative or unknown HIV status, change over time. During 2008–2011, the estimated rate ratios for MSM were 0.83 per calendar year (95% confidence interval [CI] 0.74–0.93) and 0.77 (CI 0.69–0.87) per calendar year for engaging in condomless sex overall or condomless sex with partners of negative or unknown HIV status, respectively, indicating a temporal decrease in these activities during this period. In contrast, during 2011–2019, the estimated rate ratios for MSM were 1.53 per calendar year (CI 1.26–1.86) and 1.65 (CI 1.34–2.03) for engaging in condomless sex overall or condomless sex with partners of negative or unknown HIV status, respectively, indicating an increase in these activities during this period (Fig. 2a, b).

Among 1429 MSM who completed two or more ACASI surveys, 370 (26%) reported having had condomless sex in the past 6 months on all of their surveys, 743 (52%) reported not having had condomless sex on all surveys, and 316 (22%) had mixed responses. Among 352 heterosexual males who had two or more ACASI surveys, 39 (11%) reported having had condomless sex in the past 6 months on all of their surveys, 248 (70%) reported not having had condomless sex on all surveys, and 65 (18%) had mixed responses. Among 412 female participants who had two or more ACASI surveys, 51 (12%) reported having had condomless sex in the past 6 months on all of their surveys, 277 (67%) reported having had condomless sex on all surveys, and 84 (20%) had mixed responses.

Correlates of Condomless Sex in Longitudinal Analyses

In the final multivariable GLMM analysis, among 1429 MSM who completed a total of 3342 surveys (Table 2), the overall frequency of reporting condomless sex increased over time (odds ratio [OR] 1.06 per year, 95% CI 1.03–1.09). Younger MSM had substantially higher odds of having had condomless sex than those aged 50 and older (Table 2). Other independent correlates of condomless sex included having private rather than public

insurance (OR 1.74), using cocaine (OR 2.42), poppers (OR 3.41), methamphetamine (OR 2.99), EDD (OR 2.49), injecting drugs (OR 2.43), and using alcohol (OR 1.34). MSM with CD4 counts in all strata < 500 cells/mm³ were less likely to have had condomless sex than those with CD4 500 cells/mm³ (Table 2). As compared with non-Hispanic/Latino white MSM, those of Hispanic/Latino race/ethnicity were less likely to have had condomless sex (OR 0.59), and those of non-Hispanic/Latino Black MSM did not differ in their odds of engaging in that behavior after adjusting for other covariates.

Among 353 heterosexual males who completed a total of 844 surveys (Table 3), engagement in condomless sex did not change over time (OR 1.03 per year; 95% CI 0.97–1.10). Those who were more likely to engage in condomless sex included participants who were 30–39 (OR 2.32) and 40–49 (OR 1.66) years old as compared with older, and those reporting use of cocaine (OR 2.75), poppers (OR 3.90), or EDD (OR 2.71). Heterosexual men of Black race (OR 0.51) were less likely to report engaging in condomless sex over time than heterosexual white men.

For 411 females who completed a total of 1028 surveys (Table 4), engagement in condomless sex did not change over time (OR 0.99 per year; 95% CI 0.94–1.04). Those who were more likely to engage in condomless sex over the period of observation included females who were 29 years of age (OR 3.72), 30–39 (OR 2.42) and 40–49 (OR 1.68) as compared with older, and those reporting use of cannabis (OR 1.67) or alcohol (OR 1.79).

Secondary Analyses

In analyses with the outcome of condomless anal or vaginal sex with negative/unknown HIV status partners, similar trends over time were observed for the three demographic subsets, except that the frequency of condomless sex was lower (Fig. 2b). In the GLMMs for MSM, age < 50 years, having either private insurance, CD4 cell count 500 cells/mm³, using cocaine, poppers, methamphetamine, or EDD were associated with having condomless sex with negative/unknown HIV status partners, and such sexual encounters increased during the observation (data not shown). Viral load was not associated with this outcome. For females, only cocaine use was associated with this outcome; for heterosexual males, use of cocaine, poppers, methamphetamine, and EDD was associated with this outcome and such sexual encounters increased during observation (data not shown).

Similar sensitivity analyses were performed with age group and race/ethnicity included in the models (regardless of statistical significance) to adjust for any residual confounding, with the outcome being condomless sex with negative/unknown HIV status partners (data not shown). The results from the models for MSM and heterosexual men were qualitatively similar to those from the main analyses and independent correlates remained the same. For female participants, being of Hispanic/Latina or other/unknown race/ethnicity was associated with the outcome, but such sexual encounters did not increase during observation.

Discussion

In this prospective cohort of adult PWH in care, the frequency of reported anal or vaginal condomless sex in the past 6 months ranged from 31 to 59% among MSM and it ranged

from 13 to 45% for heterosexual females and males. MSM reported having had condomless sex more frequently than heterosexual males and females, and that trend held over time. Modest increases in the frequency of condomless sex were observed for MSM, coinciding with the growing evidence for HIV treatment as prevention, but such increases were not seen for females or heterosexual males. In this report, we were specifically interested in the frequency and correlates of self-reported condom use among sexually active adults; consequently about one-quarter of HOPS participants without any reported sexual activity in the previous 6 months were excluded from the analysis, but could be considered in a future focused investigation around sexual health.

Other published studies have reported variable rates of self-reported condomless sex among study participants depending on the time frame and definitions for ascertaining sex. A large cross-sectional multicenter survey of HIV positive MSM in the UK seen at HIV clinics in 2011–2012 reported 38% of its respondents had engaged in any condomless sex in the 3 months prior to survey response [24]. A systematic literature review of 37 studies published from 2004 to 2015 examining trends in sexual risk behaviors found a decreasing trend in condom use among MSM over time including condomless sex with negative or unknown status partners [25]. In an analysis of CDC's National HIV Behavioral Surveillance data, among 5371 HIV-positive MSM, there were increases in discordant condomless sex (15–19%, P < 0.001). [26].

We identified several factors associated with changes in condom use behavior over time. Younger HOPS participants under the age of 50 years were more likely to have condomless sex compared with their older counterparts, a trend which has also been reported elsewhere [27, 28]. This finding may be due to older participants having fewer sexual partners, being more cautious than their younger counterparts, or other reasons. Recreational substance use was associated with increased condomless activity over time, consistent with reports from earlier studies [29]. Substance use may provide individuals with a method to cope with their HIV infection or it may be used to reduce inhibitions or enhance sexual pleasure. Secondary analyses indicated that among those who had condomless sex with partners of HIV-negative or unknown status, the frequency of reported condomless sex increased over time for males, both MSM and heterosexual; increasing trends were noted after the release of HPTN052 study results which affirmed the role of HIV treatment for prevention. However, in these secondary analyses, we did not detect an association between condomless sex and having an undetectable VL.

Our results should be interpreted in light of some caveats and limitations. The data collected via the ACASI survey are from a convenience sample of volunteer participants from the larger HOPS cohort. Although the survey is offered to participants on an annual basis, persons may elect to not participate or delay participation. Therefore, the study is subject to some bias due to missing data if that missingness is informative, and potentially with respect to both the estimates of the frequency of condomless sex and the trends over time. Although the ACASI method has been established as a good way of capturing quality data containing sensitive information [30–32], the survey non-participation (see Fig. 1) and social desirability bias may still affect the reporting of certain behaviors. We did not collect individual partner-level information using ACASI, and instead queried about the

total number of partners during the period of observation and whether or not the HOPS study participant engaged (in aggregate) in specific behaviors with sexual partners who were HIV-negative, HIV-positive or of an unknown HIV status in the past 6 months. We were unable ascertain if condomless sex acts were protected with the use of PrEP by HIV-negative partners. With the brief survey and medical records data in the HOPS, we also did not have information on psychosocial and structural factors that may have contributed to condomless sex, including stigma, exchanging sex for money or drugs and the like [33, 34]. Finally, because nearly half of the HOPS cohort participants are white non-Hispanic/Latino MSM, findings may be less robust for other racial/ethnic groups and not be generalizable to other PWH (i.e., people not in routine HIV medical care). Despite the limitations noted, the strength of this study lies in the demonstrated ability to link clinical (i.e., HIV viral load and CD4 cell count) and behavioral data, and the consistent longitudinal data collection which enables us to explore the longer-term changes in sexual risk behavior. Identifying and characterizing changes in and correlates of condomless sexual activity among PWH may lead to further development and implementation of more tailored HIV prevention interventions addressing factors such as reducing condomless sex with HIV-negative or unknown status partners [35-37], limiting the number of sexual partners [38], or reducing substance use [39].

In conclusion, throughout their observation in this cohort, sexually active persons in HIV care continued to report engaging in condomless anal and vaginal sex, including with partners of HIV-negative or unknown status. The frequency of reported condomless sex increased among MSM but appeared stable for heterosexual males and females over time. Although persons with undetectable HIV viral load have effectively no risk of sexually transmitting HIV to others, there is still the potential risk of transmission or acquisition of other STIs [40]; effective interventions are available to assist persons living with HIV to link to care and achieve and maintain viral suppression thus protecting their health and that of their sexual partners [1]. Coordinated services and programming by clinical, community and federal and local health department partners, that support comprehensive care and sexual health for persons with HIV, will be instrumental for ending the HIV epidemic in the United States [1, 5, 6].

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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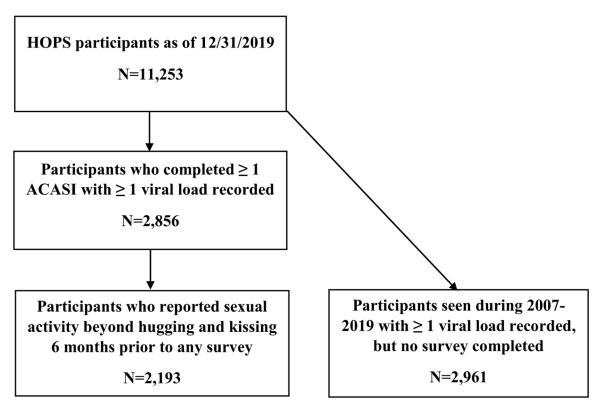


Fig. 1.

Selection steps outlining patients included in the current analysis, HIV Outpatient Study 2000–2019, USA, (N = 2193)

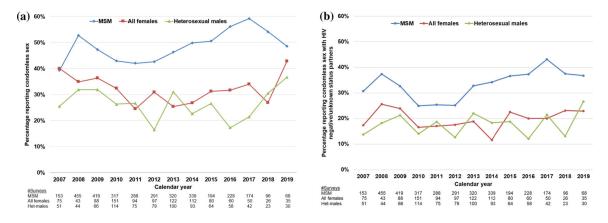


Fig. 2.

Reported frequency of condomless anal or vaginal sex by sociodemographic group and calendar year with **a** partners of any HIV status and **b** partners of HIV negative/unknown status, HIV Outpatient Study, USA, 2007–2019 (N = 2193). **a** Linear regressions of the frequency of condomless sex by MSM during 2008–2011 and 2011–2019 were the following: 0.83 (95% CI 0.74–0.93, P = 0.001), and 1.53 (95% CI 1.26–1.86, P < 0.001), respectively. Similar linear regression results for heterosexual males and all females were not statistically significant. *Het* heterosexual; *MSM* men who have sex with men. **b** Linear regressions of the frequency of condomless sex with partners of negative or unknown HIV status by MSM during 2008–2011 and 2011–2019 were the following: 0.77 (95% CI 0.69–0.87, P < 0.001), and 1.65 (95% CI 1.34–2.13, P < 0.001), respectively. Similar linear regression results for heterosexual males and all females were not statistically significant.

Table 1

Characteristics at first assessment among patients with one or more Audio Computer Assisted Self Interview, HIV Outpatient Study, USA, 2007–2019 (N = 2193)

Durham et al.

Patient characteristics at first ACASI completed: N (%) or median (IQR)	MSM N = 1429 (65.2%)	Heterosexual males N = 352 (16.0%)	Females N = 412 (18.8%)	P value	Chi-square [‡]	All participants N = 2193 (100.0%)
Year range first ACASI completed				< 0.001	25.5	
2007–2010	889 (62.2)	196 (55.7)	240 (58.3)			1325 (60.4)
2011–2014	326 (22.8)	114 (32.4)	131 (31.8)			571 (26.1)
2015–2019	214 (15.0)	42 (11.9)	41 (10.0)			297 (13.5)
Age group (years) at first ACASI				< 0.001	27.4	
29	120 (8.4)	19 (5.4)	30 (7.3)			169 (7.7)
30–39	279 (19.5)	49 (13.9)	102 (24.8)			430 (19.6)
40-49	552 (38.6)	145 (41.2)	173 (42.0)			870 (39.7)
50	478 (33.5)	139 (39.5)	107 (26.0)			724 (33.0)
Median age (IQR) at first ACASI	45 (39–52)	48 (42–54)	43 (38–50)	< 0.001	30.5	45 (39–52)
Race/ethnicity				< 0.001	439.2	
White, non-Hispanic/Latino	998 (69.8)	96 (27.3)	101 (24.5)			1195 (54.5)
Black, non-Hispanic/Latino	251 (17.6)	179 (50.9)	245 (59.5)			675 (30.8)
Hispanic/Latino	134 (9.4)	60 (17.0)	54 (13.1)			248 (11.3)
Other/unknown	46 (3.2)	17 (4.8)	12 (2.9)			75 (3.4)
Insurance payer at first ACASI				< 0.001	324.9	
Private	989 (69.2)	122 (34.7)	106 (25.7)			1217 (55.5)
Public/None	440 (30.8)	230 (65.3)	306 (74.3)			976 (44.5)
CD4 cell count (cells/mm 3) *				< 0.001	70.9	
< 200	86 (6.0)	45 (12.8)	55 (13.3)			186 (8.5)
200–349	179 (12.5)	75 (21.3)	65 (15.8)			319 (14.5)
350-499	284 (19.9)	69 (19.6)	58 (14.1)			411 (18.7)
500	835 (58.4)	143 (40.6)	217 (52.7)			1195 (54.5)
Unknown/Missing	45 (3.2)	20 (5.7)	17 (4.1)			82 (3.7)
HIV RNA viral load *				< 0.001	39.3	
Undetectable	1063 (74.4)	228 (64.8)	246 (59.7)			1537 (70.1)
Detectable	319 (22.3)	105 (29.8)	149 (36.2)			573 (26.1)

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Patient characteristics at first ACASI completed: N (%) or median (IQR)	MSM N = 1429 (65.2%)	Heterosexual males N = 352 (16.0%)	Females N = 412 (18.8%)	P value	Chi-square [‡]	All participants N = 2193 (100.0%)
Missing	47 (3.3)	19 (5.4)	17 (4.1)			83 (3.8)
Any sex, prior 6 months				< 0.001	27.4	
Yes	1329 (93.0)	304 (86.4)	353 (85.7)			1986 (90.6)
No	100 (7.0)	48 (13.6)	59 (14.3)			207 (9.4)
Recreational drug use, past 6 months $\dot{\tau}$						
Poppers	462 (32.3)	23 (6.5)	5 (1.2)	< 0.001	307.3	490 (22.3)
Injection drug use	46 (3.2)	8 (2.3)	6 (1.5)	0.10	4.5	60 (2.7)
Heroin	7 (0.5)	15 (4.3)	9 (2.2)	< 0.001	26.5	31 (1.4)
Methamphetamine	125 (8.7)	10 (2.8)	3 (0.7)	< 0.001	56.2	138 (6.3)
Club drugs	86 (6.0)	5 (1.4)	3 (0.7)	< 0.001	38.0	94 (4.3)
Cocaine	113 (7.9)	31 (8.8)	37 (9.0)	0.72	0.6	181 (8.3)
Erectile dysfunction drugs, past 6 months (whether prescribed or not)				< 0.001	196.9	
Yes	398 (27.9)	73 (20.7)	4 (1.0)			475 (21.7)
No	1031 (72.2)	279 (79.3)	408 (99.0)			
Cannabis use, past 6 months \vec{r}				< 0.001	14.9	
Yes	479 (33.5)	101 (28.7)	99 (24.0)			679 (31.0)
No	950 (66.5)	251 (71.3)	313 (76.0)			1514 (69.0)
Alcohol use, prior 30 days				< 0.001	117.4	
Yes	1113 (77.9)	212 (60.2)	215 (52.2)			1540 (70.2)
No	316 (22.1)	140 (39.8)	197 (47.8)			653 (29.8)
Current cigarette smoker				< 0.001	94.7	
Yes	316 (22.1)	145 (41.2)	177 (43.0)			638 (29.1)
No	1113 (77.9)	207 (58.8)	235 (57.0)			1555 (70.9)

responses not 2 ZD SD shown would include those who answered "no" or did not answer the question regarding the specific substance in question upcett or une unee gro alues are lor me

ACASI audio-computer assisted self-interview; ART antiretroviral therapy; IQR interquartile range; MSM men who have sex with men; PWID persons who inject drugs

 $_{\star}^{*}$ Closest CD4 or viral load measurement within 365 days of date of ACASI survey, obtained from the medical records

 $\overset{\star}{\mathcal{T}}$ During the 6 months preceding date of ACASI survey

[‡]Test statistic is likelihood ratio chi-square for categorical variables, and Kruskal-Wallis chi-square for continuous variables

Table 2

Repeated measures GLMM analyses of factors associated with condomless sex among MSM (N = 1429 participants and 3342 ACASIs), HIV Outpatient Study, USA, 2007–2019

Participant characteristics	Univariable OR (95% CI)	Full multivariable OR (95% CI)	Final multivariable OR (95% CI)
Age, years			
29	$3.40 \left(2.18{-}5.29 ight)^{**}$	$11.85 (5.79-24.24)^{**}$	5.36 (3.29–8.73) ^{**}
30–39	2.70 (2.01–3.65) ^{**}	5.33 (3.31–8.58)**	3.38 (2.43–4.70) ^{**}
40-49	$2.10\left(1.67{-}2.63 ight)^{**}$	3.24 (2.31–4.54) ^{**}	$2.32 (1.82 - 2.96)^{**}$
50	Referent	Referent	Referent
Race/ethnicity			
White, non-Hispanic/Latino	Referent	Referent	Referent
Black, non-Hispanic/Latino	$0.69 \left(0.51 {-} 0.93\right)^{*}$	0.76 (0.47–1.25)	0.86 (0.62–1.20)
Hispanic/Latino	$0.67 \left(0.46 – 0.98\right)^{*}$	$0.48\ (0.26-0.86)^{*}$	$0.59 \left(0.39 {-} 0.88 ight)^{*}$
Other/Unknown	1.23 (0.64–2.35)	1.17 (0.44–3.11)	1.09 (0.55–2.13)
Insurance			
Private	2.12 (1.67–2.68) ^{**}	$2.46 \left(1.65 - 3.65\right)^{**}$	$1.74 (1.35 - 2.26)^{**}$
Public/none	Referent	Referent	Referent
CD4 cell count (cells/mm ³)			
< 200	$0.50 \left(0.32 {-} 0.78 ight)^{*}$	$0.48 (0.24 - 0.96)^{*}$	$0.60 {\left(0.37 - 0.98 ight)}^{*}$
200–349	$0.50 \left(0.37 {-} 0.69 ight)^{**}$	$0.38 \left(0.24 0.61 \right)^{**}$	0.52 (0.37–0.72)**
350-499	$0.77~(0.60-0.98)^{*}$	$0.64 \left(0.45 {-} 0.91 ight)^{*}$	$0.73 \left(0.56 {-} 0.95 ight)^{*}$
500	Referent	Referent	Referent
Unknown/Missing	$0.97\ (0.47 - 1.98)$	2.21 (0.23–21.21)	0.98 (0.45–2.13)
HIV RNA viral load (copies/mL)			
Undetectable	1.08 (0.86–1.35)	1.00 (0.72–1.40)	
Detectable	Referent	Referent	
Unknown/Missing	1.11 (0.53–2.32)	$0.41 \ (0.04 - 4.01)$	
Cocaine	3.49 (2.29–5.30)**	$3.54 \left(1.88 - 6.68\right)^{**}$	2.42 (1.53–3.83) **
Poppers	$12.38 \left(8.56{-}17.91 ight)^{**}$	6.05 (4.22–8.67) **	3.41 (2.66–4.37) **

Injection drug use $5.84 (2.98-11.45)$ ** $3.46 (1.20-9.97)$ * $2.43 (1.09-5.44)$ *Methamphetamine $8.20 (5.19-12.94)$ ** $4.73 (2.30-9.76)$ ** $2.99 (1.78-5.01)$ *Club drugs $6.44 (3.62-11.45)$ ** $1.76 (0.75-4.15)$ $2.99 (1.78-5.01)$ *Erectile dysfunction drugs $2.87 (2.30-3.58)$ ** $3.62 (2.58-5.07)$ ** $2.49 (1.96-3.18)$ *Canabis use $1.77 (1.43-2.18)$ ** $1.45 (1.05-2.00)$ * $1.24 (0.99-1.56)$ *Alcohol use $1.77 (1.37-2.18)$ ** $1.45 (1.05-2.00)$ * $1.24 (0.99-1.56)$ *Alcohol use $1.71 (1.37-2.15)$ ** $1.35 (0.92-1.97)$ * $1.34 (1.05-1.70)$ *Alcohol use $1.77 (1.37-2.15)$ ** $1.35 (0.92-1.97)$ * $1.34 (1.05-1.70)$ *Alcohol use $1.71 (1.37-2.15)$ ** $1.35 (0.92-1.97)$ * $1.34 (1.05-1.70)$ *Alcohol use $1.77 (1.37-2.15)$ ** $1.35 (0.92-1.19)$ * $1.34 (1.05-1.70)$ *Alcohol use $1.71 (1.37-2.15)$ ** $1.35 (0.92-1.19)$ * $1.34 (1.05-1.70)$ *Alcohol use $1.71 (1.37-2.15)$ ** $1.35 (0.92-1.19)$ * $1.34 (1.05-1.10)$ *Alcohol use $1.71 (1.37-2.15)$ ** $1.35 (0.92-1.19)$ * $1.34 (1.05-1.10)$ *Alcohol use $1.78 (0.99-1.64)$ * $1.35 (0.92-1.19)$ * $1.34 (1.05-1.10)$ *Alcohol use $1.78 (0.99-1.64)$ * $1.35 (0.92-1.19)$ * $1.06 (1.03-1.09)$ *Time since $3/15/2007$, per year $1.38 (0.99-1.64)$ * $1.08 (1.03-1.12)$ * $1.06 (1.03-1.09)$ *Alcohol use $1.14 (1.11-2.15)$ * $1.08 (1.03-1.12)$ * $1.06 (1.03-1.10)$ * <tr< th=""><th>Participant characteristics</th><th>Univariable OR (95% CI)</th><th>Full multivariable OR (95% CI)</th><th>Univariable OR (95% CI) Full multivariable OR (95% CI) Final multivariable OR (95% CI)</th></tr<>	Participant characteristics	Univariable OR (95% CI)	Full multivariable OR (95% CI)	Univariable OR (95% CI) Full multivariable OR (95% CI) Final multivariable OR (95% CI)
Methamphetamine 8.20 (5.19–12.94) ** 4.73 (2.3) Club drugs 6.44 (3.62–11.45) ** 1.76 (0.5) Erectile dysfunction drugs 2.87 (2.30–3.58) ** 3.62 (2.5) Cannabis use 1.77 ($1.43-2.18$) ** 1.45 (1.6 Cannabis use 1.77 ($1.43-2.18$) ** 1.45 (1.6 Alcohol use 1.71 ($1.37-2.18$) ** 1.45 (1.6 Alcohol use 1.71 ($1.37-2.18$) ** 1.35 (0.5 Current cigarette smoker 1.28 ($0.99-1.64$) 1.35 (0.5 Time since $3/15/2007$, per year 1.28 ($0.99-1.64$) 1.35 (0.5 Time since $3/15/2007$, per year 1.28 ($0.99-1.64$) 1.35 (0.5 Time since $3/15/2007$, per year 1.08 (1.6 1.60 (1.6 Aconfidence interval; $GLMM$ generalized linear mixed model analyses; MSM men 1.08 (1.6 ** indicates P-value < 0.05 and 1.28 ($0.99-1.64$) 1.38 (0.6)		5.84 (2.98–11.45) ^{**}	$3.46\left(1.20 extsf{-}9.97 ight)^{*}$	$2.43 (1.09-5.44)^{*}$
Club drugs $6.44 (3.62-11.45)^{**}$ $1.76 (0.7)^{*}$ Erectic dysfunction drugs $2.87 (3.62-11.45)^{**}$ $3.62 (2.2)^{*}$ Cannabis use $1.77 (1.43-2.18)^{**}$ $1.45 (1.1)^{*}$ Cannabis use $1.77 (1.37-2.15)^{**}$ $1.45 (1.1)^{*}$ Alcohol use $1.71 (1.37-2.15)^{**}$ $1.45 (1.1)^{*}$ Alcohol use $1.71 (1.37-2.15)^{**}$ $1.35 (0.1)^{*}$ Current cigarette smoker $1.28 (0.99-1.64)^{*}$ $1.35 (0.1)^{*}$ Time since $3/15/2007$, per year $1.28 (0.99-1.64)^{*}$ $1.08 (1.1)^{*}$ Trime since $3/15/2007$, per year $1.08 (1.0)^{*}$ $1.08 (1.1)^{*}$ Trime since $3/15/2007$, per year $1.08 (1.0)^{*}$ $1.08 (1.0)^{*}$ Time since $3/15/2007$, per year $1.08 (1.0)^{*}$ $1.08 (1.0)^{*}$ Time since $3/15/2007$, per year $1.08 (1.0)^{*}$ $1.08 (1.0)^{*}$ Trime since $3/15/2007$, per year $1.08 (1.0)^{*}$ $1.08 (1.0)^{*}$ Time since $3/15/2007$, per year $1.008 (1.0)^{*}$ $1.08 (1.0)^{*}$ Time since $3/15/2007$, per year $1.08 (1.0)^{*}$ $1.08 (1.0)^{*}$ Time since $3/15/2007$, per year 1.000^{*} 1.00^{*} <tr< td=""><td></td><td>8.20 (5.19–12.94) **</td><td>4.73 (2.30–9.76) **</td><td>$2.99 (1.78 - 5.01)^{**}$</td></tr<>		8.20 (5.19–12.94) **	4.73 (2.30–9.76) **	$2.99 (1.78 - 5.01)^{**}$
Erectile dysfunction drugs $2.87 (2.30-3.58)^{**}$ $3.62 (2.5)^{**}$ Cannabis use $1.77 (1.43-2.18)^{**}$ $1.45 (1.6)^{**}$ Alcohol use $1.71 (1.37-2.15)^{**}$ $1.54 (1.5)^{**}$ Alcohol use $1.71 (1.37-2.15)^{**}$ $1.54 (1.5)^{**}$ Current cigarette smoker $1.28 (0.99-1.64)^{*}$ $1.35 (0.5)^{*}$ Time since $3/15/2007$, per year $1.28 (0.99-1.64)^{*}$ $1.35 (0.5)^{*}$ Time since $3/15/2007$, per year $1.08 (1.6)^{*}$ $1.08 (1.6)^{*}$ Cronfidence interval; $GLMM$ generalized linear mixed model analyses; MSM men $*^*$ Indicates P-value < 0.05 and		6.44 (3.62–11.45) ^{**}	1.76 (0.75–4.15)	
Cannabis use $1.77 (1.43-2.18)^{**}$ $1.45 (1.63)^{-1}$ Alcohol use $1.71 (1.37-2.15)^{**}$ $1.54 (1.1)^{-1}$ Alcohol use $1.71 (1.37-2.15)^{**}$ $1.54 (1.1)^{-1}$ Current cigarette smoker $1.71 (1.37-2.15)^{**}$ $1.54 (1.1)^{-1}$ Current cigarette smoker $1.28 (0.99-1.64)^{-1}$ $1.35 (0.5)^{-1}$ Time since $3/15/2007$, per year $1.28 (0.99-1.64)^{-1}$ $1.35 (0.5)^{-1}$ Time since $3/15/2007$, per year $1.28 (0.99-1.64)^{-1}$ $1.35 (0.5)^{-1}$ Time since $3/15/2007$, per year $1.28 (0.99-1.64)^{-1}$ $1.35 (0.5)^{-1}$ Time since $3/15/2007$, per year $1.28 (0.99-1.64)^{-1}$ $1.35 (0.5)^{-1}$ Time since $3/15/2007$, per year $1.28 (0.99-1.64)^{-1}$ $1.38 (0.1)^{-1}$ Cronfidence interval; $GLMM$ generalized linear mixed model analyses; MSM men $*^*$ Indicates P-value < 0.001		2.87 (2.30–3.58) ^{**}	3.62 (2.58–5.07) **	2.49 (1.96–3.18) **
Alcohol use $1.71 (1.37-2.15)^{**}$ $1.54 (1.1)^{*}$ Current cigarette smoker $1.28 (0.99-1.64)$ $1.35 (0.5)^{*}$ Time since $3/15/2007$, per year $1.28 (0.99-1.64)$ $1.08 (1.6)^{*}$ Time since $3/15/2007$, per year $1.08 (1.6)^{*}$ $1.08 (1.6)^{*}$ Cronfidence interval; $GLMM$ generalized linear mixed model analyses; MSM men $*^{*}$ Indicates P-value < 0.05 and		1.77 (1.43–2.18) ^{**}	$1.45 (1.05 - 2.00)^{*}$	1.24 (0.99–1.56)
Current cigarette smoker $1.28 (0.99-1.64)$ $1.35 (0.92) = 1.35 (0.92)$ Time since $3/15/2007$, per year $1.08 (1.02) = 1.08 (1.02) = 1.08 (1.02)$ Cronfidence interval; $GLMM$ generalized linear mixed model analyses; MSM ment**Indicates P-value < 0.001	Se	1.71 (1.37–2.15)**	1.54 (1.11–2.15)*	$1.34 \left(1.05{-}1.70 ight)^{*}$
Time since 3/15/2007, per year 1.08 (1.0 C7 confidence interval; GLMM generalized linear mixed model analyses; MSM men ** indicates P-value < 0.001	garette smoker	1.28 (0.99–1.64)	1.35 (0.92–1.97)	
<i>CI</i> confidence interval; <i>GLMM</i> generalized linear mixed model analyses; <i>MSM</i> men [*] Indicates P-value < 0.05 and ** indicates P-value < 0.001	e 3/15/2007, per year		$1.08(1.03-1.12)^{**}$	$1.06 \left(1.03 - 1.09\right)^{**}$
* Indicates P-value < 0.05 and ** indicates P-value < 0.001	ce interval; GLMM genera	dized linear mixed model ana	lyses; MSM men who have sex with 1	nen; OR odds ratio
** indicates P-value < 0.001	\sim value < 0.05 and			
	P-value < 0.001			

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Repeated measures GLMM analyses for heterosexual males, with outcome being condomless-sex (N = 353 participants and 844 ACASIs), HIV Outpatient Study, USA, 2007–2019

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Participant Characteristics	Univariable OR (95% CI)	Full multivariable OR (95% CI)	Final multivariable OR (95% CI)
Age, years			
29	1.78 (0.60–5.25)	2.62 (0.57–12.01)	2.55 (0.86–7.54)
30–39	1.72 (0.87–3.39)	$3.08 \left(1.16 {-} 8.18\right)^{*}$	$2.32 \left(1.16 - 4.63\right)^{*}$
40-49	$1.59 \left(1.00 {-}2.52 ight)^{*}$	$2.07 (1.08 - 3.98)^{*}$	$1.66\left(1.03{-}2.67 ight)^{*}$
50	Referent	Referent	Referent
Race/Ethnicity			
White, non-Hispanic/Latino	Referent	Referent	Referent
Black, non-Hispanic/Latino	$0.48 \left(0.28 {-} 0.81 ight)^{**}$	$0.39\ (0.17-0.91)^{*}$	$0.51 \left(0.29 {-} 0.87 ight)^{*}$
Hispanic/Latino	0.67 (0.34–1.34)	0.64 (0.22–1.84)	0.68 (0.34–1.37)
Other/Unknown	0.88 (0.29–2.63)	0.79 (0.15-4.23)	0.71 (0.23–2.24)
Insurance			
Private	1.30(0.81 - 2.10)	$0.83\ (0.38-1.83)$	
Public/None	Referent	Referent	
CD4 cell count (cells/mm ³)			
< 200	0.63(0.29-1.39)	$0.53\ (0.17-1.63)$	
200–349	$0.82\ (0.47 - 1.45)$	0.70 (0.32–1.54)	
350-499	1.03 (0.62–1.72)	1.09 (0.55–2.18)	
500	referent	referent	
Unknown/Missing	$0.58\ (0.18-1.90)$	7	
HIV RNA viral load (copies/mL)			
Undetectable	$0.95\ (0.61{-}1.47)$	0.91 (0.50–1.68)	
Detectable	referent		
Unknown/Missing	0.65 (0.19–2.22)	+	
Cocaine	$3.59 \left(1.21 {-}10.63 ight)^{*}$	$3.39 \left(1.12 {-}10.31 ight)^{*}$	2.75 (1.27–5.96)*
Poppers	$4.75 \left(2.15{-}10.50 ight)^{**}$	$5.03 \left(1.63 - 15.53\right)^{*}$	$3.90 \left(1.72 - 8.84\right)^{*}$
Injection drug use	1.30 (0.38-4.52)	1.09 (0.17–7.17)	

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Participant Characteristics	Univariable OR (95% CI)	Full multivariable OR (95% CI)	Univariable OR (95% CI) Full multivariable OR (95% CI) Final multivariable OR (95% CI)
Methamphetamine	$3.99\ (1.10{-}14.53)^{*}$	1.73 (0.20–15.25)	
Club drugs	$8.24 \ (1.05-64.91)^{*}$	1.12 (0.08–16.30)	
Erectile dysfunction drugs	4.47 (2.22–9.00) **	3.66 (1.84–7.26)**	$2.71 \left(1.64 - 4.46\right)^{**}$
Cannabis use	$1.76 \left(1.13 – 2.74 ight)^{*}$	1.69 (0.87–3.28)	
Alcohol use	$1.57 \left(1.03 {-}2.38 ight)^{*}$	1.33 (0.72–2.44)	
Current cigarette smoker	0.82 (0.53–1.26)	0.68 (0.36–1.26)	
Time since 3/15/2007, per year		1.03 (0.94–1.12)	1.03 (0.97–1.10)
	eralized linear mixed model ana	yses; <i>OR</i> odds ratio	
* Indicates P-value < 0.05 and			

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 \dot{f} participant numbers too small to calculate ORs and CIs in the full multivariable analyses

** indicates P-value < 0.001

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	Univariable OR (95% CI)	Full multivariable OR (95% CI)	Final multivariable OR (95% CI)
Age, years			
29	4.64 $(2.07 - 10.37)$ **	7.67 (2.42–24.33)**	$3.72~{(1.65-8.39)}^{*}$
30–39	2.93 (1.72–4.98) ^{**}	$3.19 \left(1.53 {-}6.68 ight)^{*}$	$2.42 \left(1.42 - 4.14\right)^{*}$
40-49	$1.93\left(1.25{-}2.98 ight)^{*}$	$1.91 \; {(1.06 – 3.44)}^{*}$	$1.68 \left(1.08 {-} 2.61 ight)^{*}$
50	Referent	Referent	Referent
Race/Ethnicity			
White, non-Hispanic/Latino	Referent		
Black, non-Hispanic/Latino	$0.96\ (0.61 - 1.51)$	0.99 (0.51–1.90)	
Hispanic/Latino	1.02 (0.53–1.99)	1.29 (0.50–3.32)	
Other/Unknown	$1.04\ (0.31 - 3.51)$	1.04(0.20-5.49)	
Insurance			
Private	1.44 (0.94–2.21)	1.50 (0.78–2.85)	
Public/None	Referent	Referent	
CD4 cell count (cells/mm ³)			
< 200	$0.70\ (0.38{-}1.30)$	0.60 (0.26–1.39)	
200–349	0.98 (0.60–1.61)	1.06 (0.55–2.02)	
350-499	$0.83\ (0.50{-}1.36)$	0.75 (0.39–1.43)	
500	Referent	Referent	
Unknown/Missing	1.40(0.48 - 4.13)	0.97 (0.05–19.79)	
HIV RNA viral load (copies/mL)			
Undetectable	1.14(0.79-1.63)	1.21 (0.74–1.98)	
Detectable	Referent		
Unknown/Missing	1.64 (0.54–5.00)	1.05 (0.05–23.72)	
Cocaine	1.82 (0.74-4.48)	1.75 (0.67–4.58)	
Poppers	4.87 (0.68–35.02)	$0.99\ (0.04-22.10)$	
Injection drug use	$3.30\left(1.01{-}10.78 ight)^{*}$	4.30 (0.80–23.17)	
Methamphetamine	$12.23 (1.03 - 144.79)^{*}$	16.93 (0.55–525.28)	
Club drugs	+		

	Univariable OR (95% CI)	Univariable OR (95% CI) Full multivariable OR (95% CI) Final multivariable OR (95% CI)	Final multivariable OR (95% (
Erectile dysfunction drugs	22.62 (0.73–698.83)	19.46 (0.46–833.36)	
Cannabis use	$2.09(1.39-3.13)^{**}$	$2.00 \left(1.15 - 3.50\right)^{*}$	$1.67 (1.11 - 2.52)^{*}$
Alcohol use	2.11 (1.50–2.98)**	$2.30 \left(1.43 - 3.69\right)^{**}$	$1.79 \left(1.26 - 2.54\right)^{*}$
Current cigarette smoker	0.80 (0.56–1.15)	0.66 (0.39–1.10)	
Time since 3/15/2007, per year		0.97 (0.91–1.05)	0.99 (0.94–1.04)
HIV Outpatient Study, USA, 2007-2019	2019		
CI confidence interval; GLMM generalized linear mixed model analyses; OR odds ratio	sralized linear mixed model ana	ldyses; OR odds ratio	
* Indicates P-value < 0.05 and			
** indicates P-value < 0.001			
$\mathring{r}_{\rm Participant}$ numbers too small to calculate ORs and CIs in the univariable analyses	ulculate ORs and CIs in the univ	ariable analyses	

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