Published in final edited form as:

AIDS. 2010 March 27; 24(6): 891–897. doi:10.1097/QAD.0b013e32833616c7.

Treatment with Antiretroviral Therapy is Not Associated with Increased Sexual Risk Behaviour in Kenyan Female Sex Workers

R. Scott McClelland^{1,2,3,6}, Susan M. Graham^{1,6,7}, Barbra A. Richardson⁴, Norbert Peshu⁷, Linnet N. Masese², George H. Wanje⁶, Kishorchandra N. Mandaliya⁸, Ann E. Kurth⁵, Walter Jaoko⁶, and J. O. Ndinya-Achola⁶

¹Department of Medicine, University of Washington, Seattle, USA

²Department of Epidemiology, University of Washington, Seattle, USA

³Department of Global Health, University of Washington, Seattle, USA

⁴Department of Biostatistics, University of Washington, Seattle, USA

⁵School of Nursing, University of Washington, Seattle, USA

⁶Department of Medical Microbiology, University of Nairobi, Nairobi, Kenya

⁷Kenya Medical Research Institute, Kilifi, Kenya

⁸Coast Provincial General Hospital, Mombasa, Kenya

Abstract

Objective—The objective of this study was to test the hypothesis that sexual risk behaviour would increase following initiation of antiretroviral therapy (ART) in Kenyan female sex workers (FSWs).

Design—Prospective cohort study.

Setting—FSW cohort in Mombasa, Kenya, 1993–2008.

Subjects—898 women contributed HIV-1-seropositive follow-up visits, of whom 129 initiated ART.

Intervention—Beginning in March 2004, ART was provided to women qualifying for treatment according to Kenyan National Guidelines. Participants received sexual risk reduction education and free condoms at every visit.

Main Outcome Measures—Main outcome measures included unprotected intercourse, abstinence, 100% condom use, number of sexual partners, and frequency of sex. Outcomes were evaluated at monthly follow-up visits using a one week recall interval.

Address for correspondence and reprint requests: R. Scott McClelland, MD, MPH, International AIDS Research and Training Program, University of Washington, Box 359909, 325 Ninth Avenue, Seattle, WA 98104 USA, Telephone: (206) 543-4278, Fax: (206) 543-4818, mcclell@u.washington.edu.

Preliminary data from this study have been presented at the 5th International AIDS Society Conference on HIV Pathogenesis, Treatment, and Prevention, Cape Town, SA, July 19–22, 2009.

Author Contributions: RSM, BAR, NP, KNM, AEK, WJ, and JON-A conceived the question and designed the study. RSM obtained funding for the study. RSM, SMG, BAR, LNM, and GHW participated in collection and interpretation of the data. BAR conducted the data analyses. All authors participated in preparation of the manuscript and have approved the final draft for submission.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Results—Compared to non-ART-exposed follow-up, visits following ART initiation were not associated with an increase in unprotected sex (adjusted odds ratio [AOR] 0.86, 95% confidence interval [CI] 0.62-1.19, $P=0.4$). There was a non-significant decrease in abstinence (AOR 0.81, 95% CI 0.65-1.01, $P=0.07$), which was offset by a substantial increase in 100% condom use (AOR 1.54, 95% CI 1.07-2.20, $P=0.02$). Numbers of sex partners and frequency of sex were similar before versus after starting ART. A trend for decreased sexually transmitted infections following ART initiation provides additional support for the validity of the self-reported behavioural outcomes (AOR 0.67, 95% CI 0.44-1.02, $P=0.06$).

Conclusions—In the setting of ongoing risk reduction education and provision of free condoms, initiation of ART was not associated with increased sexual risk behaviour in this cohort of Kenyan FSWs.

Keywords

Antiretroviral therapy; sexual risk behaviour; human immunodeficiency virus type 1; sexually transmitted infection; Africa

Introduction

Increased access to antiretroviral therapy (ART) in resource limited settings has improved the health and survival of millions of people [1]. Because individuals with low plasma viral load may be less infectious [2], widespread use of ART might also influence the course of the global HIV-1 epidemic [3]. However, the net effect of the ART rollout on global HIV-1 epidemiology will also depend on long-term effects of treatment on sexual risk behaviour [4].

Ninety percent of people infected with HIV-1 live in developing countries [1], but few studies have examined sexual risk behaviour after ART initiation in these settings. A key finding of a 2007 systematic review was the lack of data on this topic [5]; only three studies were identified. Two cross-sectional analyses, from Uganda and Cote d'Ivoire, found no significant difference in risk behaviour in ART-treated versus ART-naïve adults [6,7]. The only prospective study demonstrated that integrated provision of home-based ART with prevention services was associated with 70% lower reported risky sexual behaviour over the first 6 months of treatment in a Ugandan cohort [8].

Few prospective studies have been published since the 2007 review. In Kenyan and South African adults, unprotected intercourse was less frequently reported one year after ART initiation compared to baseline [9,10]. In contrast, a study in Cote d'Ivoire found that unprotected intercourse increased significantly during the first 6 months of ART [11]. The differing results highlight both the complexity of the question of how ART influences risk behaviour and the need to develop a broad evidence base [5]. Studies with extended follow-up are needed to determine how ART is likely to influence the long-term course of HIV-1 epidemics.

This report presents analyses of the association between ART and risk behaviour in a cohort of Kenyan female sex workers. The pre-specified hypothesis was that ART would be associated with increased sexual risk behaviour.

Methods

Population and Procedures

This open cohort study of risk factors for HIV-1 acquisition in female sex workers was established in 1993 [12]. Women who acquired HIV-1 were invited to continue with follow-

up. All participants were asked to return for monthly follow-up including a standardized interview and physical examination. They were asked to report the number of sex partners, sexual contacts, and sexual contacts with condoms in the past week. Genital specimens were collected for diagnosis of sexually transmitted infections. At all visits, participants received individualized risk reduction education and free condoms. Beginning in 1998, HIV-1-seropositive women in the cohort had CD4 counts performed every 3 months. Women who were HIV-1-seropositive at screening were invited to enrol starting in 2001. In 2004, ART was introduced for those eligible according to Kenyan Guidelines (CD4 count <200 cells/ μ L or AIDS-defining illness). This analysis includes HIV-1-seropositive follow-up accrued from February 1993 through April 2008. Women receiving ART from other sources were excluded, as it was not possible to precisely ascertain the timing of treatment initiation. The protocol was approved by Human Subjects Committees at the Kenya Medical Research Institute, Kenyatta National Hospital, and University of Washington. All participants provided informed consent.

Serology and Microbiology

HIV-1 screening was performed by ELISA (Detect-HIV [BioChem ImmunoSystems]). Positives were confirmed using a second ELISA (Recombigen [Cambridge Biotech] or Vironostika [bioMérieux]) [13]. Culture for *Neisseria gonorrhoeae* was performed on modified Thayer-Martin media. A vaginal saline wet-mount was examined microscopically for motile *Trichomonas vaginalis* parasites. The presence of sperm was determined by microscopic examination of the vaginal wet-mount and cervical Gram-stain. CD4 lymphocyte quantitation was performed using a manual system (Cytosphere [Coulter]) from 1998 until 2004, and thereafter by an automated method (FACSCount [Becton Dickinson]).

Data Analysis

Reported sexual risk behaviours were used to define five outcomes based on a one-week recall period [14]. Women were considered to have *unprotected intercourse* if they were not abstinent and did not have 100% condom use. They were classified as *abstinent* if they reported no sexual intercourse during the past week. Among those reporting intercourse, *100% condom use* was defined as having the number of sexual contacts with a condom equal to the total number of sexual contacts. We evaluated the *number of sex partners in the past week* and *number of sexual encounters in the past week* among women who reported any sexual intercourse. Both outcomes were dichotomized at their medians.

Our primary comparison was sexual risk behaviour during ART-naïve versus ART-exposed follow-up, including visits from all 898 participants. Data were analyzed according to the intent-to-treat principle; women presenting for an ART-initiation visit were considered ART-exposed at all subsequent visits. To gain a greater understanding of how immunosuppression influenced risk behaviour, we performed additional analyses stratifying visits at which CD4 count was measured into three categories (CD4 $\geq$ 500, CD4 200-499, and CD4 <200).

We also analyzed changes in two biological outcomes, presence of an STI (surrogate marker for unprotected sex since last visit), and presence of sperm in genital secretions (surrogate marker for recent unprotected sex). Women were considered to have an STI if they had gonorrhoea, trichomoniasis, or both. Sperm were considered present if they were identified on vaginal saline wet mount, cervical Gram stain, or both.

Analyses were performed using SPSS version 15.0 and Stata version 9.2. Generalized estimating equations with a logit link and exchangeable correlation structure were used to quantify the effect of ART on risk behaviours, allowing for multiple observations per individual. Multivariate models controlled for time-dependent changes in risk behaviour in the cohort by adjusting for years since enrolment in all analyses [14,15]. Other potential

confounding factors were considered for inclusion in adjusted analyses based on known or suspected associations with risk behaviour. Analyses were adjusted for time-varying cofactors including calendar year category (1993-1996, 1997-2000, 2001-2004, and 2005-2008), age, and contraceptive method. Further adjustment for baseline educational level, marital status, workplace (bar versus nightclub), alcohol use, and Karnofsky score did not substantially change the associations between risk behaviours and ART, so these variables were not retained in the final adjusted model.

Results

Between February 1993 and April 2008, 966 women contributed HIV-seropositive follow-up visits. Of these, 68 (7%) received ART from other clinics and were excluded from further analyses. The remaining 898 women are the focus of this study. Of these, 298 (33%) acquired HIV-1 during follow-up, while the remainder were HIV-1-seropositive at screening. There were 15,926 HIV-1-seropositive follow-up visits during 2,404 woman-years of follow-up. The median number of follow-up visits per participant was 10 (interquartile range [IQR] 3-27), and the median interval between visits was 33 days (IQR 29-48). One hundred and twenty-nine women (14%) initiated ART, contributing a median of 24.6 (IQR 11.4-32.9) months following ART initiation.

Participants' baseline characteristics are shown in Table 1. These women had a median age of 31 years (IQR 26-36), and the majority had completed at least some primary education. Over 40% were using a contraceptive method other than condoms alone. The women reported a relatively low number of sex partners per week (median 1, IQR 1-2) and number of sexual encounters per week (median 2, IQR 1-2). The majority of the women reported using condoms during 100% of sexual encounters during the past week. At baseline, the 129 women who started ART during the study were similar to the other 769 women in the cohort with respect to the variables shown in Table 1, except that they were more likely to have ever been married (92, 71.3% versus 471, 61.2%; $P=0.003$), had higher parity (3, IQR 2-4 versus 2, IQR 1-3; $P<0.001$), and were less likely to be abstinent (5, 3.9% versus 122, 15.9%; $P<0.001$). Median age at ART initiation was 36 years (IQR 32-40).

Changes in Risk Behaviour

Unprotected intercourse was reported at 2,308/13,025 (17.7%) non-ART visits versus 258/2,901 (8.9%) visits following ART initiation (Table 2). After adjusting for years since enrolment [14,15], there was no evidence of increased unprotected intercourse after ART initiation (adjusted odds ratio [AOR] 0.80, 95% confidence interval [CI] 0.58-1.12). Further adjustment for potential confounding factors did not substantially alter these results (AOR 0.86, 95% CI 0.62-1.19). The absence of significant change in unprotected sex reflected divergent results in the rates of abstinence and condom use following ART initiation. Specifically, there was a trend suggesting that women on ART were less likely to be abstinent, but this was offset by a highly significant increase in 100% condom use. At visits where women reported that they were sexually active, frequency of reporting multiple sex partners and frequency of sex did not increase on ART. Restricting to the subset of 129 women who initiated ART did not substantially alter these results (Table 3).

Women on ART may be more likely to adhere to monthly visits because they require medication refills. Thus, a pre-specified secondary analysis was conducted including only the first visit for each participant in each quarter. After controlling for potential confounding factors, changes in risk following ART initiation were similar to our primary analysis for unprotected sex (AOR 0.77, 95% CI 0.54-1.10, $P=0.2$), abstinence (AOR 0.78, 95% CI 0.61-0.99, $P=0.05$), 100% condom use (AOR 1.56, 95% CI 1.09-2.22, $P=0.01$), >1 sex partner

(AOR 0.74, 95% CI 0.51-1.08, $P=0.1$), and >2 sexual encounters (AOR 1.04, 95% CI 0.77-1.42, $P=0.8$).

To determine the extent to which behavioural changes following ART initiation were independent of changes in CD4 count, we conducted an analysis adjusting for CD4 count in the 4,957 visits where these data were available (Table 4). This analysis demonstrated significantly lower likelihood of unprotected intercourse following ART initiation. Moreover, the previously observed trend suggesting decreased abstinence after ART initiation was eliminated.

To further explore the effect of disease stage on risk behaviour in the setting of ART, analyses were repeated after stratifying by CD4 count (<200 cells/ μ L, 200-499 cells/ μ L, and $\geq$ 500 cells/ μ L). Similar to the primary analysis, there was no evidence of increased risk following ART initiation (Table 5). Among women with the lowest CD4 counts, there were significant reductions in both sex with >1 partner and >2 sexual encounters in the past week.

Biological Outcomes

To complement self-reported behavioural risk data, we evaluated STI incidence and the incidence of sperm detection in genital secretions. STIs were identified at 780/13,024 (6.0%) pre-ART versus 116/2,901 (4.0%) post-ART visits. After adjustment for years since enrolment, there was a lower likelihood of STIs after ART initiation (AOR 0.62, 95% CI 0.42-0.91, $P=0.01$). Results were similar after additional adjustment for calendar year category, age, and contraceptive use (AOR 0.67, 95% CI 0.44-1.02, $P=0.06$). The presence of sperm in genital secretions, a marker for recent unprotected intercourse, was identified at 684 (5.0%) pre-ART visits versus 141 (4.9%) post-ART visits (AOR 1.01, 95% CI 0.75-1.34, $P=1.0$). Findings were similar following adjustment for calendar year category, age, and contraceptive use (AOR 0.88, 95% CI 0.65-1.19, $P=0.4$).

Discussion

In this population of high-risk Kenyan women, we found no increase in sexual risk behaviours following ART initiation. On the contrary, a highly significant >50% increase in consistent condom use was reported. Among those with advanced immunosuppression (CD4 <200 cells/ μ L), ART use was associated with significant reductions in both partner numbers and frequency of sex.

While this study did observe a statistical trend ($P=0.07$) for decreased abstinence following ART initiation, this finding must be interpreted in the context of an earlier study in this cohort, which demonstrated that women with advanced immunosuppression were significantly more likely to be abstinent compared to HIV-1-seropositive women with higher CD4 counts [14]. As health and quality of life improve following ART initiation [16], it seems plausible that sexual activity might increase to parallel the rates of sexual encounters in healthier women. In support of this hypothesis, analyses adjusting for CD4 count showed similar rates of abstinence before versus after ART initiation.

These data add to the evidence base on changes in sexual risk behaviour following ART initiation in resource-limited settings. Most prospective studies have found that sexual risk behaviour is either unchanged, or that risky behaviour decreases after ART initiation [8-10]. One exception was a study from Cote d'Ivoire [11], which reported an increase in unprotected intercourse in the ART group. Methodological differences including the selection and measurement of outcomes may contribute to differences in the results of these epidemiological studies [17]. Variations in population and program characteristics including gender, socioeconomic status, cultural beliefs, health status, duration of ART, treatment setting, and

the type, quality, and intensity of risk reduction services are also likely to influence the direction and magnitude of changes in risk behaviour following ART initiation.

This study had several strengths. First, the prospective cohort design provided ample baseline data on risk behaviour prior to ART initiation. Second, the long period of follow-up, including a median of >2 years following ART initiation, is useful for understanding how risk behaviour may change with prolonged ART. Third, in this high-risk cohort, risk reduction messages and provider time devoted to counselling were similar before and after ART initiation, reducing the potential for bias. Fourth, the study's size permitted careful control for multiple potential confounding factors. Finally, several relevant outcomes were used to assess a range of risk behaviours. The results highlight the importance of evaluating multiple outcomes to gain a comprehensive understanding of changes in sexual risk.

An important limitation in this type of study is the potential for under-reporting of risky sexual behaviour. In this context, it is reassuring that results evaluating biological outcomes were consistent with results based on self-reported behaviour. Several factors should be considered in relation to the generalizability of the findings. These women were enrolled based on self-reported transactional sex. Most supplemented income from work as barmaids with occasional payment for sex in cash or in kind. While sex workers are a special population, they also represent an important core-transmitter group [18]. As a final point, risk reduction services in research cohorts may be more intensive than in other settings, and participants' risk behaviour is likely to decrease over time [15]. To address this bias towards a finding of decreased risk with ART, all analyses were presented with adjustment for time in the cohort.

The magnitude of an HIV-1 epidemic is a function of infectivity, rate of partner change, duration of infection [19], and network-level influences [20]. Since ART prolongs life without eradicating HIV-1, the premise that treatment might decrease transmission rests on the hope that treatment will decrease infectivity without resulting in behavioural disinhibition. A modelling study based on the population in Rakai, Uganda found that the modest decreases in HIV-1 incidence resulting from decreased infectivity could be counterbalanced if ART resulted in behavioural disinhibition [4]. In the Mombasa Cohort, prior studies have demonstrated rapid and sustained suppression of plasma and genital HIV-1 following ART initiation [21,22]. The present findings provide strong evidence that risk behaviour did not increase following ART initiation in the same cohort. Taken together, these results support the potential importance of ART as one of the tools for reducing sexual HIV-1 transmission. This study also underscores the need for prevention targeting those who do not currently qualify for ART, since their viral loads and transmission risk may be considerably higher.

Acknowledgments

We wish to acknowledge the study participants, who contributed their time and effort to make this study a success. We also wish to recognize the contributions made by our clinical, laboratory, and administrative staff. We thank the Mombasa Municipal Council for providing clinical space, and Coast Provincial General hospital for providing laboratory space. This manuscript was approved for publication by the Director, Kenya Medical Research Institute.

Sponsorship: This study was supported by National Institutes of Health (grant R01-AI-58698) and by the Fogarty International Center (grant T43-TW00007 to S.M.G., L.N.M., and G.H.W.). Additional support for the Mombasa Field Site was received from the University of Washington Center for AIDS Research (grant P30-AI-27757). The contents are solely the responsibility of the authors and do not necessarily represent the official views of the NIH.

References

1. UNAIDS. Report on the Global AIDS Epidemic. Geneva, Switzerland: 2008. p. 1-357.

2. Quinn TC, Wawer MJ, Sewankambo N, Serwadda D, Li C, Wabwire-Mangen F, et al. Viral load and heterosexual transmission of human immunodeficiency virus type 1. Rakai Project Study Group. *N Engl J Med* 2000;342:921–929. [PubMed: 10738050]
3. Velasco-Hernandez JX, Gershengorn HB, Blower SM. Could widespread use of combination antiretroviral therapy eradicate HIV epidemics? *Lancet Infect Dis* 2002;2:487–493. [PubMed: 12150848]
4. Gray RH, Li X, Wawer MJ, Gange SJ, Serwadda D, Sewankambo NK, et al. Stochastic simulation of the impact of antiretroviral therapy and HIV vaccines on HIV transmission; Rakai, Uganda. *Aids* 2003;17:1941–1951. [PubMed: 12960827]
5. Kennedy C, O'Reilly K, Medley A, Sweat M. The impact of HIV treatment on risk behaviour in developing countries: a systematic review. *AIDS Care* 2007;19:707–720. [PubMed: 17573590]
6. Moatti JP, Prudhomme J, Traore DC, Juillet-Amari A, Akribi HA, Msellati P. Access to antiretroviral treatment and sexual behaviours of HIV-infected patients aware of their serostatus in Cote d'Ivoire. *Aids* 2003;17:S69–77. [PubMed: 14565612]
7. Bateganya M, Colfax G, Shafer LA, Kityo C, Mugenyi P, Serwadda D, et al. Antiretroviral therapy and sexual behavior: a comparative study between antiretroviral-naïve and -experienced patients at an urban HIV/AIDS care and research center in Kampala, Uganda. *AIDS Patient Care STDS* 2005;19:760–768. [PubMed: 16283836]
8. Bunnell R, Ekwaru JP, Solberg P, Wamai N, Bikaako-Kajura W, Were W, et al. Changes in sexual behavior and risk of HIV transmission after antiretroviral therapy and prevention interventions in rural Uganda. *Aids* 2006;20:85–92. [PubMed: 16327323]
9. Luchters S, Sarna A, Geibel S, Chersich MF, Munyao P, Kaai S, et al. Safer sexual behaviors after 12 months of antiretroviral treatment in Mombasa, Kenya: a prospective cohort. *AIDS Patient Care STDS* 2008;22:587–594. [PubMed: 18601582]
10. Eisele TP, Mathews C, Chopra M, Lurie MN, Brown L, Dewing S, Kendall C. Changes in Risk Behavior Among HIV-Positive Patients During Their First Year of Antiretroviral Therapy in Cape Town South Africa. *AIDS Behav.* 2008
11. Diabate S, Alary M, Koffi CK. Short-term increase in unsafe sexual behaviour after initiation of HAART in Cote d'Ivoire. *Aids* 2008;22:154–156. [PubMed: 18090406]
12. Martin HL Jr, Nyange PM, Richardson BA, Lavreys L, Mandaliya K, Jackson DJ, et al. Hormonal contraception, sexually transmitted diseases, and risk of heterosexual transmission of human immunodeficiency virus type 1. *J Infect Dis* 1998;178:1053–1059. [PubMed: 9806034]
13. WHO, CDC. Guidelines for Appropriate Evaluations of HIV Testing Technologies in Africa. Harare, Zimbabwe: 2001. p. 1–48.
14. McClelland RS, Hassan WM, Lavreys L, Richardson BA, Mandaliya K, Ndinya-Achola J, et al. HIV-1 acquisition and disease progression are associated with decreased high-risk sexual behaviour among Kenyan female sex workers. *AIDS* 2006;20:1969–1973. [PubMed: 16988519]
15. Baeten JM, Richardson BA, Martin HL, Nyange PM, Lavreys L, Ngugi EN, et al. Trends in HIV-1 incidence in a cohort of prostitutes in Kenya: implications for HIV-1 vaccine efficacy trials. *J Acquir Immune Defic Syndr* 2000;24:458–464. [PubMed: 11035617]
16. Jelsma J, Maclean E, Hughes J, Tinise X, Darder M. An investigation into the health-related quality of life of individuals living with HIV who are receiving HAART. *AIDS Care* 2005;17:579–588. [PubMed: 16036244]
17. van der Elst EM, Okuku HS, Nakamya P, Muhaari A, Davies A, McClelland RS, et al. Is audio computer-assisted self-interview (ACASI) useful in risk behaviour assessment of female and male sex workers, Mombasa, Kenya? *PLoS ONE* 2009;4:e5340. [PubMed: 19412535]
18. Cowan FM, Langhaug LF, Hargrove JW, Jaffar S, Mhuriyengwe L, Swarthout TD, et al. Is sexual contact with sex workers important in driving the HIV epidemic among men in rural Zimbabwe? *J Acquir Immune Defic Syndr* 2005;40:371–376. [PubMed: 16249714]
19. Anderson, RM.; May, RM. *Infectious Diseases of Humans: Dynamics and Control*. Oxford, England: Oxford University Press; 1991.
20. Morris M, Kretzschmar M. Concurrent partnerships and the spread of HIV. *Aids* 1997;11:641–648. [PubMed: 9108946]

21. Graham SM, Holte SE, Peshu NM, Richardson BA, Panteleeff DD, Jaoko WG, et al. Initiation of antiretroviral therapy leads to a rapid decline in cervical and vaginal HIV-1 shedding. *Aids* 2007;21:501–507. [PubMed: 17301569]
22. Graham, SM.; Masese, LN.; Gitau, R.; Richardson, B.; Peshu, N.; Mandaliya, K., et al. Correlates of genital HIV-1 shedding among antiretroviral naaive women initiating therapy. 16th Conference on Retroviruses and Opportunistic Infections; Montreal, Canada. February 8-12, 2009; p. 2009

Table 1
Baseline characteristics of HIV-1-seropositive women followed in a high-risk cohort in Mombasa, Kenya

Variable	Median (interquartile range) or number (%), N=898
Age (years)	31 (26-36)
Education (years)	8 (7-10)
Ever married ^a	563 (62.7%)
Works in a bar	722 (80.4%)
Parity	2 (1-3)
Contraception	
Oral contraceptive pills	81 (9.0%)
Depot medroxyprogesterone acetate	258 (28.7%)
Intra-uterine contraceptive device	10 (1.1%)
Tubal ligation	22 (2.4%)
Hysterectomy	2 (<1%)
Other ^b	13 (1.4%)
Sexual risk behaviour in past week	
Unprotected intercourse	351 (39.1%)
Abstinent	127 (14.1%)
100% condom use ^c	420 (54.5%)
>1 sex partners ^c	250 (32.4%)
>2 sexual encounters ^c	212 (27.5%)

^a Included 9 currently married and 554 widowed, divorced, or separated.

^b Other methods of contraception included N=11 using Norplant and N=2 reporting use of a method that they were unable to identify.

^c Analyzed only among 771 women reporting any sexual activity in the past week

Table 2
Sexual risk behaviour in the past week during non-antiretroviral treated follow-up and after antiretroviral initiation^a

	Pre-ART Visits	After ART Initiation		AOR ^b (95% CI) (P value)	AOR ^c (95% CI) (P value)
	Visits Reported (%)	Visits Reported (%)			
	N=13,025 Visits	N=2,901 Visits			
Unprotected intercourse	2,308 (17.7%)	258 (8.9%)		0.8 (0.58-1.12) (P=0.2)	0.86 (0.62-1.19) (P=0.4)
Abstinence	6,344 (48.7%)	1,584 (54.6%)		0.81 (0.65-1.01) (P=0.06)	0.81 (0.65-1.01) (P=0.07)
100% condom use ^d	4,372 (65.4%)	1,059 (80.4%)		1.64 (1.14-2.35) (P=0.008)	1.54 (1.07-2.20) (P=0.02)
> 1 sex partner ^d	1,375 (20.6%)	185 (14.0%)		0.89 (0.61-1.32) (P=0.6)	0.84 (0.57-1.25) (P=0.4)
>2 sex encounters ^d	1,441 (21.6%)	233 (17.7%)		1.17 (0.89-1.53) (P=0.3)	1.07 (0.80-1.43) (P=0.6)

AOR, adjusted odds ratio; ART, antiretroviral therapy

^aN = 898

^bMultivariate analyses were used to control for time since enrolment in the cohort, as high-risk behaviours have previously been shown to decrease over time among women in the Mombasa cohort [14,15].

^cMultivariate analyses were used to control for number of years since enrolment in the cohort, calendar year category (1993-1996, 1997-2000, 2001-2004, and 2005-2008), age (time varying), and any contraceptive use (time varying).

^dAnalyzed only among women reporting any sexual activity (N=6680 Pre-ART visits and N=1317 After ART visits).

Table 3
Sexual risk behaviour in the past week during pre-antiretroviral treated follow-up and following antiretroviral initiation among women who initiated antiretroviral therapy^a

	Pre-ART Visits		After ART Initiation		AOR ^b (95% CI) (P value)	AOR ^c (95% CI) (P value)
	Visits Reported (%)		Visits Reported (%)			
	N=2,751 Visits		N=2,901 Visits			
Unprotected intercourse	451 (16.4%)		258 (8.9%)		0.82 (0.56-1.19) (P=0.3)	0.89 (0.61-1.29) (P=0.5)
Abstinence	1408 (51.2%)		1584 (54.6%)		0.83 (0.66-1.05) (P=0.1)	0.79 (0.61-1.02) (P=0.08)
100% condom use ^d	892 (66.4%)		1059 (80.4%)		1.67 (1.14-2.46) (P=0.009)	1.51 (1.05-2.19) (P=0.03)
> 1 sex partner ^d	249 (18.5%)		185 (14.0%)		0.86 (0.47-1.56) (P=0.6)	0.79 (0.43-1.46) (P=0.5)
>2 sex encounters ^d	239 (17.8%)		233 (17.7%)		1.15 (0.76-1.73) (P=0.5)	1.12 (0.70-1.80) (P=0.6)

AOR, adjusted odds ratio; ART, antiretroviral therapy

^aN = 129

^bMultivariate analyses were used to control for time since enrolment in the cohort, as high-risk behaviours have previously been shown to decrease over time among women in the Mombasa cohort [14,15].

^cMultivariate analyses were used to control for number of years since enrolment in the cohort, calendar year category (1993-1996, 1997-2000, 2001-2004, and 2005-2008), age (time varying), and any contraceptive use (time varying).

^dAnalyzed only among women reporting any sexual activity (N=1,343 Pre-Art visits and N=1,317 After ART visits).

Table 4
Sexual risk behaviour in the past week during non-antiretroviral treated follow-up and after antiretroviral initiation including adjustment for CD4 lymphocyte count^a

	Pre-ART Visits	After ART Initiation		
	Visits Reported (%)	Visits Reported (%)		
	N=3,728 Visits	N=1,229 Visits	AOR ^b (95% CI) (P value)	AOR ^c (95% CI) (P value)
Unprotected intercourse	649 (17.4%)	110 (9.0%)	0.64 (0.44-0.92) (P=0.02)	0.69 (0.48-0.98) (P=0.04)
Abstinence	1928 (51.7%)	689 (56.1%)	0.91 (0.73-1.14) (P=0.4)	0.93 (0.74-1.17) (P=0.6)
100% condom use ^d	1151 (63.9%)	430 (79.6%)	1.90 (1.37-2.65) (P<0.001)	1.70 (1.21-2.40) (P=0.002)
>1 sex partner ^d	359 (19.9%)	72 (13.3%)	0.82 (0.54-1.25) (P=0.4)	0.69 (0.44-1.06) (P=0.09)
>2 sex encounters ^d	379 (21.1%)	101 (18.7%)	1.07 (0.76-1.51) (P=0.7)	0.95 (0.65-1.37) (P=0.8)

AOR, adjusted odds ratio; ART, antiretroviral therapy

^aCD4 lymphocyte analysis was performed on all HIV -seropositive women every three months beginning in April 1998. This analysis includes data from 765 women who contributed 4,957 visits at which CD4 data were available.

^bMultivariate analyses were used to control for time since enrolment in the cohort, as high-risk behaviours have previously been shown to decrease over time among women in the Mombasa cohort [14,15].

^cMultivariate analyses were used to control for number of years since enrolment in the cohort, calendar year category (1993-1996, 1997-2000, 2001-2004, and 2005-2008), age (time varying), and any contraceptive use (time varying).

^dAnalyzed only among women reporting any sexual activity (N=1800 Pre-Art visits and N=540 After ART visits).

Table 5
Sexual risk behaviour during non-antiretroviral treated follow-up and after antiretroviral initiation stratified by CD4 lymphocyte count^a

CD4 cell count group (cells/ μ L) and AORs for after ART initiation compared to pre-ART		<200	200-499	≥ 500
Unprotected Intercourse ^c				
AOR ^b		0.60 (0.38, 0.96)	0.63 (0.40, 0.99)	0.69 (0.24, 1.99)
AOR		0.63 (0.38, 1.04)	0.71 (0.45, 1.02)	0.70 (0.24, 2.04)
Abstinence				
AOR ^b		1.14 (0.85, 1.53)	0.95 (0.72, 1.26)	1.17 (0.62, 2.19)
AOR ^c		1.13 (0.82, 1.56)	0.99 (0.73, 1.33)	1.27 (0.68, 2.40)
100% Condom Use ^e				
AOR ^b		1.71 (1.05, 2.79)	1.84 (1.23, 2.75)	1.90 (0.74, 4.86)
AOR ^c		1.59 (0.93, 2.74)	1.56 (1.02, 2.39)	1.85 (0.69, 4.94)
>1 sex partner ^d				
AOR ^b		0.40 (0.22, 0.76)	0.81 (0.45, 1.48)	1.02 (0.25, 4.19)
AOR ^d		0.31 (0.16, 0.60)	0.64 (0.34, 1.19)	0.72 (0.16, 3.32)
>2 sexual encounters ^e				
AOR ^b		0.64 (0.38, 1.08)	1.30 (0.87, 1.95)	1.36 (0.61, 2.99)
AOR ^d		0.53 (0.30, 0.92)	1.13 (0.71, 1.80)	1.00 (0.43, 2.35)

AOR, adjusted odds ratio; ART, antiretroviral therapy

^a CD4 lymphocyte analysis was performed on all HIV-seropositive women every three months beginning in April 1998. This analysis includes data from 765 women who contributed 4,957 visits at which CD4 data were available.

^b Multivariate analyses were used to control for time since enrolment in the cohort, as high-risk behaviours have previously been shown to decrease over time among women in the Mombasa cohort [14,15].

^c Multivariate analyses were used to control for number of years since enrolment in the cohort, calendar year category (1997-2000, 2001-2004, and 2005-2008), age (time varying), and any contraceptive use (time varying). There were no CD4 counts in the period from 1993-1996.

^d Multivariate analyses were used to control for number of years since enrolment in the cohort, calendar year category (1997-2004 and 2005-2008), age (time varying), and any contraceptive use (time varying). There were no CD4 counts in the period from 1993-1996. Because of sparse data in the 1997-2000 category, these visits were combined with the 2001-2004 category in order for the models to converge.

^e Analyzed only among women reporting any sexual activity.