HIV incidence and sexually transmitted disease prevalence associated with condom use: a population study in Rakai, Uganda

Saifuddin Ahmed, Tom Lutalo[a], Maria Wawer[b], David Serwadda[c], Nelson K. Sewankambo[c],Fred Nalugoda[a], Fred Makumbi[a], Fred Wabwire-Mangen[c], Noah Kiwanuka[a], Godfrey Kigozi[a], Mohamed Kiddugavu[a] and Ron Gray

Objective: Evidence of condom effectiveness for HIV and sexually transmitted disease (STD) prevention is based primarily on high-risk populations. We examined condom effectiveness in a general population with high HIV prevalence in rural Africa.

Methods: Data were from a randomized community trial in Rakai, Uganda. Condom usage information was obtained prospectively from 17 264 sexually active individuals aged 15–59 years over a period of 30 months. HIV incidence and STD prevalence was determined for consistent and irregular condom users, compared to non-users. Adjusted rate ratios (RR) of HIV acquisition were estimated by Poisson multivariate regression, and odds ratios of STDs estimated by logistic regression.

Results: Only 4.4% reported consistent condom use and 16.5% reported inconsistent use during the prior year. Condom use was higher among males, and younger, unmarried and better educated individuals, and those reporting multiple sex partners or extramarital relationships. Consistent condom use significantly reduced HIV incidence [RR, 0.37; 95% confidence interval (CI), 0.15–0.88], syphilis [odds ratio (OR), 0.71; 95% CI, 0.53–0.94] and gonorrhea/Chlamydia (OR, 0.50; 95% CI, 0.25–0.97) after adjustment for socio-demographic and behavioral characteristics. Irregular condom use was not protective against HIV or STD and was associated with increased gonorrhea/Chlamydia risk (OR, 1.44; 95% CI, 1.06–1.99). The population attributable fraction of consistent use for prevention of HIV was −4.5% (95% CI, −8.3 to 0.0), due to the low prevalence of consistent use in the population.

Conclusions: Consistent condom use provides protection from HIV and STDs, whereas inconsistent use is not protective. Programs must emphasize consistent condom use for HIV and STD prevention.

AIDS 2001, **15**:2171–2179

Keywords: Africa, condom, effectiveness, HIV, prevention, sexually transmitted disease

From the Johns Hopkins University School of Public Health, Baltimore, Maryland, USA, [a] Rakai Project, Uganda Virus Research Institute, Entebbe, Uganda, the [b] Center for Population and Family Health, Columbia University School of Public Health, New York, USA, and the [c] Department of Medicine and Clinical Epidemiology Unit and the Institute of Public Health, Makerere University, Kampala, Uganda.

Requests for reprints to: S. Ahmed, Johns Hopkins University School of Public Health, 615 North Wolfe Street 4030, Baltimore, MD 21205, USA.

Received: 2 February 2001; revised: 18 June 2001; accepted: 2 July 2001.

Introduction

It is estimated that more than 36 million adults are infected with HIV worldwide, acquired primarily via heterosexual contact [1]. Other sexually transmitted diseases (STD), especially gonorrhea, syphilis, trichomoniasis, Chlamydia, and genital herpes infections are also important causes of morbidity and it is estimated that 333 million new cases of curable STD are diagnosed among adults annually. STDs are ranked among the top five causes for which adults seek health care services in developing countries [2].

Acceptance and use of condoms has been promoted to prevent the sexual transmission of HIV and STDs [2,3]. Latex condoms are effective in blocking the passage of HIV [4–8] and STDs [6,9]. Model-based estimates suggest that even occasional condom use with high-risk partners may reduce HIV transmission [10] and in Thailand the 100% condom use program reduced STD [11] and HIV infection [12–14]. A recent meta-analysis of studies of HIV serodiscordant couples (where one partner was HIV infected and the other was not), suggested that consistent use of condoms may reduce the risk of transmission by 60–96% [15]. A European study of HIV-serodiscordant couples showed that among 123 partners who used condoms consistently none became infected, whereas 10% of those who did not use condoms or only used them inconsistently became infected [16]. Similarly, in Lusaka, Zambia, the HIV seroconversion rate was almost five times lower among consistent condom users, compared to irregular users [17]. On average, these studies show that the HIV infection rate in HIV discordant partners was less than 1% with consistent condom use, compared with 10–14.5% among inconsistent and non-users. However, these studies were based on small sample sizes and restricted to HIV-discordant couples who knew their HIV status.

Several studies suggest that irregular use of condoms provides no protection against transmission of HIV and STD [18–21]. Moreover, inconsistent condom use has been shown to increase HIV infection rates among female Zairian sex workers [22] and married monogamous women in India [23]. A randomized behavioral modification trial in high-risk individuals performed in the USA showed that although consistent condom use increased significantly in the intervention group compared to the control group, no difference was found in STD reinfection rates [24]. Also, a study in Bangkok found that despite the '100% condom program', HIV infection rates among female sex workers are increasing [25].

Most studies on condom effectiveness have been conducted among high-risk populations, such as serodiscordant couples, sex workers, and STD clinic attendees, who were aware of their higher risk status, and consequently were more likely to be motivated to use condoms consistently [15–17,21,22,26]. However, among general populations, in which individuals may not be aware of their risk status, motivation to use condoms may be lower or present only with high-risk sexual encounters. The effectiveness of consistent or irregular condom use on HIV and STD transmission is unknown at a general population level, particularly in rural Africa.

The assessment of the effectiveness of condom use for HIV and STD prevention is complicated by the fact that individuals with higher risk behaviors (e.g., those having multiple sex partners and sex outside of regular relationships) are more likely to use condoms, but also are more likely to contract STD and HIV because of their behaviors [27]. Because of this potential confounding between risk behavior and condom use, estimation of the true effectiveness of condoms is difficult.

We examined the effectiveness of condoms for HIV and STD prevention in a rural sub-Saharan African population. We examined HIV incidence rates and prevalence rates for syphilis, *Trichomonas*, bacterial vaginosis, gonorrhea and Chlamydia infection among consistent or irregular condom users, and non-users, controlling for socio-demographic and high-risk behavioral factors.

Methods

Study setting

This study uses data from a community randomized trial of STD control for HIV prevention in rural Rakai district, south-western Uganda. In adults aged 15–59 years, the prevalence of infections at enrollment were: HIV, 16%; syphilis, 10%; *Trichomonas*, 24%; bacterial vaginosis, 50%; and in persons less than 30 years of age: gonorrhea, 1.5%; Chlamydia, 3.1% [28,29]. Briefly, 56 communities on secondary roads were grouped into 10 clusters which were allocated randomly to intervention and control arms. The intervention arm received STD mass treatment and the control arm received vitamin/iron-folate/antihelminthic mass treatment. All other program activities such as health education, condom promotion, provision of free condoms, and HIV testing counseling were identical in both arms. Follow-up surveys were conducted at intervals of 10 months between 1994 and 1998.

Eligible persons gave written informed consent which explained study objectives, methods including randomization, masking of study assignment, and expected risks and benefits of participation. No cash incentives were provided. The trial was approved by the AIDS Research Subcommittee of the Uganda National

Council for Science and Technology, the Columbia University Institutional Review Board, the Johns Hopkins Committee on Human Research, and the National Institutes of Health Office for Protection from Research Risk.

Reports of condom use were available from 17 264 participants interviewed over three study survey rounds. To improve reliability and reduce reporting bias, condom use information was obtained by a series of questions regarding use for contraception, HIV/STD prevention, or both reasons, as well as current and past use. In addition, a sexual networks module ascertained condom use specific to individual partners and responses were cross-validated with the earlier responses regarding use with all partners. Although the project provided the same prevention education, counseling, STD and free general health care, and promotion of condom use in the two randomization arms, in statistical analysis the strata of randomization was taken into consideration to control for possible unobserved heterogeneity between the two groups.

Biological sample collection

Biological samples were collected in the home, immediately following the interview. Venous blood was collected for HIV-1 and syphilis testing. Sera were assayed for HIV-1 using two enzyme immunoassay tests (Vironostika HIV-1: Organon Teknika, Charlottesville, NC and Cambridge Biotech, Wooster, MA, USA), with Western blot (HIV-1 Western Blot, BioMerieux Vitek, St Louis, MO, USA) confirmation of enzyme immunoassay discordant results and of HIV seroconverters. Syphilis screening used the non-treponemal toluidine red unheated serum test or fluorescent treponemal antibody absorption.

Subjects provided 10 ml of first catch urine which was assayed for *Neisseria gonorrhoeae* and *C. trachomatis* by ligase chain reaction (LCX Probe System, Abbott Laboratories, Abbott Park, IL, USA); because of high cost these assays were conducted on a random sample of subjects aged 15–29 years. Urinary HIV testing was conducted for subjects who declined to provide a blood sample or whose blood draw was insufficient. Specimens positive on urine EIA were confirmed by Western blot. Approximately 10% of HIV results in both arms were based on urine assay. Compliance with urine provision was 95%.

Women were asked to provide two self-administered vaginal swabs during the home visit. One swab was used for *T. vaginalis* culture (InPouch TV: BioMed Diagnostics, San Jose, CA, USA) and a second swab was used for diagnosis of bacterial vaginosis using quantitative, morphologic scoring of Gram-stained slides. Compliance with self-collected vaginal swabs was 96%.

Description of the variables

The use of condoms was categorized into three groups: consistent use, irregular use, and non-use, based on responses to the question 'How often do you use condoms with this partner', with three possible responses: never, sometimes/inconsistent, and always. The response 'always' was defined as 'consistent' condom use. For the baseline survey round, the information on condom use was derived from the sexual network data that included questions on condom use with each partner (consistently, irregularly, or never) during a 1 year period prior to survey date. For the follow-up surveys, the condom information was derived from the questions on use with each partner, and pertains to the 10 month inter-survey periods. Those respondents who reported never having sex were excluded, because no question was asked about their condom usage. Covariates consisted of demographic variables (age, sex, education, mobility, marital status), and behavioral variables (sex out side of marriage/partnership, and multiple sex partners). In addition, we also used randomized study arm as a controlling variable.

To test the efficacy of condoms we use two dependent variables: HIV incidence and STD prevalence, as dichotomous outcomes. The HIV incidence rate was estimated from the number of HIV seroconverters per 100 person-years (py) of observation with the assumption that infection occurred at the mid-point of the interval of seroconversion. The analysis was based on 7100 participants who provided repeat blood for HIV testing, tested HIV seronegative at study enrollment and reported sexual exposure (i.e., those defined as the at-risk population for condom usage and HIV acquisition). STD prevalence was measured for syphilis, *Trichomonas*, bacterial vaginosis, gonorrhea and Chlamydia infection at each study round.

We tested for the null hypothesis that HIV incidence and STD prevalence did not differ significantly according to condom use status, controlling for the background characteristics, high-risk behavioral variables and randomized study arms.

Statistical analysis

Poisson regression models were used to estimate the log of expected (mean) value of HIV incidence counts over a period of consistent, irregular or no condom use. Rate ratios (RR) were estimated from the observed to expected counts. Because the data were collected from a community based trial, there may be correlation within clusters (clustering effect) and the estimated variances are expected to be greater than those from independent samples of equal size. Ignoring this overdispersion may affect tests of statistical inference [30]. We used marginal Poisson regression models to estimate 'robust' variance (Huber–White informa-

tion-sandwich estimate of the variance–covariance matrix), that take into account the correlations within clusters. The 95% confidence intervals (CI) were estimated from the robust variances.

To test the effect of condom use on STD prevalence, the differentials in STD rates were examined by logistic regression models [31] in which the adjusted odd ratios (OR) of STD presence was modeled from the logit of probability conditioned by condom use, controlling for other covariates. The logistic regression models were fitted separately for syphilis, gonorrhea and Chlamydia in both sexes and for trichomoniasis and bacterial vaginosis in women. We fitted separate models for each survey round and present pooled estimates from three study rounds. To control intra-class correlation due to repeated observations on the same individuals, we fitted the marginal logistic model using generalized estimating equations [32]. The robust standard error estimates were used to compute 95% CI. The population attributable fraction (PAF) of condom use was estimated from the prevalence of use and the adjusted RR of HIV incidence or of STD prevalence [33]. This estimates the reduction of infection attributable to condom use in the population.

Table 1. Characteristics of the study population at baseline survey (n = 17 264).

Variable	n (%)
Age (years)	
15–24	7121 (41.3)
25–34	5183 (30.0)
35–44	2654 (15.4)
⩾ 45	2306 (13.4)
Sex	
Male	7728 (44.8)
Female	9536 (55.2)
Education	
None	1972 (11.4)
Primary	11 061 (64.1)
Secondary or higher	4231 (24.5)
Marital status	
Never married	3655 (21.2)
Currently married	11 100 (64.3)
Divorced/separated/widowed	2509 (14.5)
Number of sex partners during last year	
1	14 213 (82.3)
2	2087 (12.1)
⩾ 3	964 (5.6)
Sex outside marriage/consensual union	
Yes	4018 (23.3)
No	13 246 (76.7)
Mobility (travel outside of Rakai)	
Yes	12 453 (72.1)
No	4811 (27.9)
Randomized block	
Treatment arm	8890 (51.5)
Control arm	8374 (49.5)

Results

Table 1 shows the characteristics of the respondents. The mean age of the study participants was 29.6 years (± 11.1) and 71.3% of the respondents were aged less than 35 years. Almost 90% had received some formal education. There were slightly more female than male respondents. About two-thirds of the respondents were currently married. Twenty-three percent reported having sex outside a marital or consensual partnership, and 17.7% reported more than one sexual partner in the past year.

Condom use was low in the population (Table 2). At baseline, 11% reported current condom use and 25% had ever used condoms. Twenty-one percent reported use in the past year, but only 4.4% reported using condoms consistently. Male respondents were more likely to report condom use than females; ever-use of condoms was reported by 36.4% of males and 16.1% of females, and current use by 16.6% of males and 5.8% of females ($P < 0.001$). However, consistent condom use with all sex partners was uncommon (6.0% in males and 3.2% in females). Condoms were used more frequently by the younger and better educated participants. Condom use was much higher with those reporting multiple partners, sex outside of marriage, and by the unmarried respondents. The treatment arm showed somewhat higher condom use than the control arm. Among those reporting condom use, the main reasons for use were both STD prevention and contraception (61.8%), STD prevention alone (30.9%) and contraception alone (7.3%).

HIV incidence rates by condom use and other controlling variables are shown in Table 3. HIV incidence rates were 1.9 and 1.4 per 100 py in ever-users and never-users, respectively, with a crude incidence rate ratio of 1.32 (95% CI, 0.92–1.87). HIV incidence for consistent condom users (0.97 per 100 py) was much lower than that of non-users (1.69 per 100 py), and was less than half the incidence rate of irregular condom users (2.14 per 100 py). Incidence did not vary significantly by sex or age, but was higher for divorced, separated and widowed subjects, and those reporting multiple partners and sex outside marriage.

Table 4 shows the results of the Poisson multivariate regression for HIV incidence. In Model I, including only condom use, irregular condom use was associated with increased HIV risk, and consistent use was associated with decreased the risk of seroconversion, but these differences were not statistically significant. Model II adjusted for demographic variables and study arm, but this did not affect the estimates for condom usage. In Model III the introduction of behavioral risk factors showed that after adjustment for behaviors, consistent condom use significantly reduced the risk of HIV incidence (RR, 0.37; 95% CI, 0.15–0.88), but

Table 2. Differentials in condom use by demographic and behavioral variables and sexually transmitted disease symptoms at baseline survey, Rakai (χ^2 tests show $P < 0.001$ for all cross tabulations).

			Consistency of use over past year[a]	
Variable	Ever used (%)[b]	Current use (%)[b]	Used consistently (%)[b]	Used irregularly (%)[b]
All	24.7	10.6	4.4	16.5
Age (years)				
15–24	34.0	15.0	7.9	21.8
25–34	27.3	11.0	2.9	18.3
35–44	14.4	5.9	1.5	9.9
⩾ 45	5.6	1.7	0.4	3.4
Sex				
Male	36.4	16.6	6.0	23.1
Female	16.1	5.8	3.2	11.2
Education				
None	7.2	2.5	1.5	4.6
Primary	20.8	8.0	3.0	13.6
Secondary or higher	45.1	21.2	9.5	29.5
Marital status				
Never married	47.6	25.4	16.3	28.6
Currently married	19.7	6.3	0.7	13.7
Divorced/separated/widowed	17.0	7.2	2.2	12.7
Sex outside marriage/ consensual union				
Yes	52.7	34.7	13.2	34.6
No	16.8	3.3	1.8	11.0
Number of sex partners during last year				
1	17.9	6.8	4.4	10.0
2	50.8	23.5	4.9	39.5
⩾ 3	69.1	39.3	3.8	62.1
Randomized block				
Treatment arm	27.7	12.5	4.8	18.3
Control arm	22.5	8.7	4.0	14.6

[a]Condom use during last one year with all the partners. [b]Row percentages (all, n = 17 264).

incidence risk was unaffected by irregular use (RR, 0.96; 95% CI, 0.53–1.74). Currently married persons were at reduced risk, and previously married persons and those reporting multiple partners had an increased risk of HIV acquisition. We fitted a parsimonious model (data not shown) with covariates found to be significant in Model III (marital status, multiple partners and condom usage), and the effects remained essentially the same (irregular condom use: RR, 0.97; 95% CI, 0.53–1.81; consistent condom use: RR, 0.38; 95% CI, 0.16–0.89). We also tested for interaction of condom use with the high-risk behavioral factors (multiple partnership and sex outside of marriage/consensual union), but found no statistically significant interactions.

Condom effectiveness against STD/RTI

Table 5 shows the association between condom use and prevalence of STDs. Multivariate logistic regression with robust variance estimates showed that the prevalence of syphilis (OR, 0.71; 95% CI, 0.53–0.94) and of gonorrhea/Chlamydia (OR, 0.50; 95% CI, 0.25–0.97) were significantly lower among the consistent condom users. In women, consistent condom use was associated with reduced bacterial vaginosis prevalence which was significant in unadjusted analysis. Consistent condom use was not associated with *Trichomonas* prevalence. Irregular condom use was associated with an increased risk of bacterial vaginosis and *Trichomonas* which was of borderline significance, and irregular condom use was associated with a significantly higher risk of gonorrhea/Chlamydia (OR, 1.44; 95% CI, 1.06–1.99).

The lack of efficacy of consistent condom use for the prevention of bacterial vaginosis and *Trichomonas* probably reflect the fact that these vaginal infections are chronic or recurrent conditions, whereas cervical infections with gonorrhea or Chlamydia are more likely to reflect recent infections. The effects of consistent condom use in the recent past are likely to be more apparent for recent infections than for chronic prior infections.

PAF of HIV and STD by condom use

We estimated the PAF of HIV acquisition associated with condom use at population level. The estimated PAF for consistent condom use was −4.5% (95% CI,

Table 3. HIV incidence rates by the selected variables.

Variable	HIV cases per 100 person years (n = 7100)	Incidence rate (95% CI)	Crude incidence rate ratios (95% CI)
Condom use			
Non-use	141/8331	1.69 (1.44–2.00)	1.00
Irregular use	21/983	2.14 (1.39–3.28)	1.26 (0.80–2.00)
Consistent use	4/414	0.97 (0.36–2.57)	0.57 (0.21–1.54)
Age (years)			
15–24	63/3729	1.69 (1.32–2.16)	1.00
25–34	53/2973	1.78 (1.36–2.33)	1.05 (0.73–1.52)
35–44	29/1732	1.67 (1.16–2.40)	0.99 (0.64–1.54)
⩾ 45	21/1294	1.62 (1.06–2.49)	0.96 (0.58–1.57)
Sex			
Male	76/4411	1.72 (1.38–2.16)	1.02 (0.75–1.38)
Female	90/5317	1.69 (1.38–2.08)	1.00
Education			
None	14/1047	1.34 (0.79–2.26)	1.00
Primary	112/6475	1.73 (1.44–2.08)	1.29 (0.74–2.25)
Secondary or higher	40/2206	1.81 (1.33–2.47)	1.36 (0.74–2.49)
Marital status			
Never married	21/972	2.16 (1.41–3.31)	1.00
Currently married	124/8099	1.53 (1.28–1.83)	0.71 (0.45–1.13)
Divorced/separated/widowed	21/657	3.20 (2.08–4.90)	1.48 (0.81–2.70)
Multiple sex partners			
Yes (⩾ 2)	29/1221	2.38 (1.65–3.42)	1.48 (0.99–2.20)
No	137/8507	1.61 (1.36–1.90)	1.00
Sex outside marriage/consensual union			
Yes	52/2415	2.15 (1.64–2.83)	1.38 (0.99–1.92)
No	114/7312	1.56 (1.30–1.87)	1.00
Mobility (travel outside of Rakai)			
Yes	142/8257	1.72 (1.46–2.03)	1.05 (0.68–1.63)
No	24/1471	1.63 (1.09–2.43)	1.00
Randomized block			
Treatment arm	88/5001	1.76 (1.43–2.17)	1.07 (0.79–1.45)
Control arm	78/4727	1.65 (1.32–2.06)	1.00

CI, Confidence interval.

−8.3 to 0.0). The PAF of syphilis and gonorrhea/Chlamydia were −1.23% (95% CI, −2.67 to 0.2) and −2.97% (95% CI, −5.76 to −0.25), respectively, for consistent condom use. The negative sign indicates a protective effect of consistent condom use.

Discussion

Although the condom is considered to be effective against HIV and STD transmission its use-efficacy in a general population has not previously been determined in rural sub-Saharan Africa. Several urban studies in sub-Saharan Africa found that condom use was not associated with a reduction in STD rates or HIV incidence [19,34]. Assessing the effectiveness of condoms in reducing HIV infection and other STDs at the general population level is difficult because condom use is generally more common with irregular sexual partners and with high-risk sexual encounters, which are also risk factors for STD and HIV acquisition. Another problem is that most investigations have not assessed the consistency of condom use. This study provides empirical evidence that consistent condom use significantly reduces HIV incidence, and the prevalence of syphilis and gonorrhea/Chlamydia, but that irregular condom use provides no protection.

Ascertaining the validity of self-reported condom use is crucial for evaluation of condom effectiveness. It is of concern that potential bias may occur with condom use reporting because responses may reflect social desirability and, particularly in areas where condoms are heavily promoted, people may be motivated to report their use to conform with the perceived expectations of the researcher [35–37]. Although condom promotion was a major HIV/STD prevention component of health education services, the promotion of condom use was not the primary focus of the Rakai trial. It is, however, possible that over-reporting of condom use, particularly consistent use, may have occurred. Over-reporting of consistent condom use is likely to underestimate its effectiveness.

The HIV incidence rate was 1.0 per 100 py for the

Table 4. Incidence rate ratios (IRR) for HIV estimated from Poisson regression models.

Covariates	Model I IRR (95% CI)[a]	Model II IRR (95% CI)	Model III IRR (95% CI)
Condom use			
None	1.0	1.0	1.0
Irregularly	1.26 (0.76–2.11)	1.21 (0.72–2.04)	0.96 (0.53–1.74)
Consistently	0.57 (0.26–1.27)	0.55 (0.22–1.36)	0.37 (0.15–0.88)
Age (years)			
15–24		1.00	1.00
25–34		1.04 (0.70–1.54)	1.10 (0.73–1.67)
35–44		0.99 (0.67–1.48)	0.99 (0.63–1.54)
⩾ 45		0.98 (0.68–1.43)	1.01 (0.68–1.51)
Sex			
Female		1.0	1.0
Male		0.99 (0.73–1.34)	0.92 (0.68–1.23)
Education (in years)		1.12 (0.90–1.39)	1.13 (0.91–1.40)
Mobility			
Never traveled outside		1.0	1.0
Traveled outside of Rakai		1.02 (0.75–1.38)	1.00 (0.74–1.34)
Treatment arm			
Control		1.0	1.0
Treatment		1.05 (0.81–1.37)	1.03 (0.80–1.33)
Marital status			
Never married			1.0
Currently married			0.55 (0.28–1.05)
Divorced/separated/widowed			1.32 (0.82–2.15)
Multiple sex partners			
No			1.0
Yes (⩾ 2)			1.63 (0.99–2.68)
Sex outside marriage/consensual union			
No			1.0
Yes			0.90 (0.44–1.81)

[a]95% Confidence intervals (CI) are based on robust variances, adjusted for correlation at cluster level.

consistent condom users. This is comparable to the estimate of 0.9 per 100 py for consistent condom users in a meta-analysis of 25 published studies of serodiscordant heterosexual couples [15]. Despite the differences in the study populations (seroserodiscordant couples versus a general population), a similar low HIV incidence rate among the consistent condom users might suggest that consistent use provides a similar level of protection, irrespective of HIV exposure risks in the population under study. However, the prevalence of consistent condom use in the population was 4.4%, and the population attributable fraction of the reduction in HIV incidence associated with consistent condom was only −4.5% and of borderline statistical significance. Thus, it is critical that programs promoting condoms stress the need for consistency of use in order to reduce HIV and STD.

Inconsistent condom use was not protective against HIV and STDs, and significantly increased the risks of infections such as gonorrhea and Chlamydia (Table 5). Inconsistent condom use may actually be an 'enabling' process allowing individuals to persist in high-risk behaviors with a false sense of security. Many evaluations of condom promotion only consider 'ever-use' or 'current use' of condoms to measure the effectiveness of prevention programs [26,38]. This is clearly inadequate and potentially misleading because most condom use is inconsistent. Thus, it is inappropriate to attribute changes in HIV or STD prevalence to condom use unless consistency of that use is ascertained.

In summary, consistent condom use is significantly protective for HIV, syphilis and gonorrhea/Chlamydia, and such use must be promoted to prevent these infections. However, inconsistent condom use is not protective against HIV, and may be associated with increased gonorrhea and Chamydia infection. It is critical that programs discourage irregular use of condoms and emphasize consistency of use. In the study population condoms were available free of charge and distributed by the community health workers and clinic facilities. In populations where HIV prevalence is very high, it is imperative that program and policy adopt such a free distribution program and promotion of consistent condom use without delay.

Acknowledgements

The authors thank S. K. Sempalla (Director, Uganda Virus Research Institute) for his support.

Table 5. Odds ratios (OR) for risk of the sexually transmitted disease (STD) by condom use status estimated from cross-sectional repeated observations by generalized estimating equations models: Rakai, Uganda.

		Baseline	
STD/condom use status	n (%)[a]	Crude OR (95% CI)[b]	Adjusted OR (95% CI)[c]
Syphilis			
Never used	25 699 (8.6)	1.0	1.0
Used irregularly	3865 (5.8)	0.80 (0.71–0.91)	1.06 (0.92–1.22)
Used consistently	1373 (3.2)	0.46 (0.35–0.60)	0.71 (0.53–0.94)
Bacterial vaginosis			
Never used	15 408 (52.1)	1.0	1.0
Used irregularly	1328 (53.2)	1.06 (0.94–1.18)	1.11 (0.99–1.25)
Used consistently	521 (47.4)	0.83 (0.69–0.99)	0.89 (0.74–1.07)
Trichomonas			
Never used	13 795 (17.9)	1.0	1.0
Used irregularly	1308 (20.8)	1.21 (1.06–1.39)	1.15 (0.99–1.33)
Used consistently	462 (18.8)	1.02 (0.80–1.29)	0.93 (0.73–1.19)
Gonorrhea or Chlamydia			
Never used	7310 (3.3)	1.0	1.0
Used irregularly	1155 (6.2)	1.90 (1.44–2.50)	1.44 (1.06–1.99)
Used consistently	421 (2.4)	0.70 (0.36–1.35)	0.50 (0.25–0.97)

[a]Number of observations during the study period: round 1 to round 3 (repeated observations). [b]95% Confidence intervals (CI) are based on robust variance. [c]Adjusted for age, education, marital status, multiple sex partners, sex outside marriage/consensual union, and gender where appropriate.

Sponsorship: Supported by grants RO1 AI34826 and RO1 AI3426S from the National Institute of Allergy and Infectious Diseases; grant 5P30HD06826 from the National Institute of Child Health and Development; grant 5D43TW00010 from the Fogarty Foundation; the US National Institutes of Health; the Word Bank STI Project, Uganda; the Glaxo Wellcome Foundation, and the Winkler Foundation.

References

1. UNAIDS. *Report on the Global HIV/AIDS Epidemic.* Geneva: UNAIDS; 2000.
2. World Health Organization. *Management of Patients with Sexually Transmitted Diseases.* Technical Report Series No 810. Geneva: WHO; 1991.
3. Panel on Data and Research Priorities for Arresting AIDS in Sub-Saharan Africa. *Preventing and Mitigating AIDS in Sub-Saharan Africa: Research and Data Priorities for the Social and Behavioral Sciences.* Edited by Cohen B, Trussell J. Washington, DC: National Research Council, National Research Council, National Academy Press; 1996.
4. Carey RF, Herman WA, Retta SM, Rinaldi JE, Herman BA, Athey TW. **Effectiveness of latex condoms as a barrier to human immunodeficiency virus-sized particles under conditions of simulated use.** *Sex Transm Dis* 1992, **19**:230–234.
5. Rietmeijer CA, Krebs JW, Feorino PM, Judson FN. **Condoms as physical and chemical barriers against human immunodeficiency virus.** *JAMA* 1988, **259**:1851–1853.
6. Centers for Disease Contol and Prevention. **Perspectives in disease prevention and health promotion condoms for prevention of sexually transmitted diseases.** *MMWR* 1988, **37**: 133–137.
7. Van de Perre P, Jacobs D, Sprecher-Goldberger S. **The latex condom, an efficient barrier against sexual transmission of AIDS-related viruses.** *AIDS* 1987, **1**:49–52.
8. Conant MA, Spicer DW, Smith CD. **Herpes simplex virus transmission: condom studies.** *Sex Transm Dis* 1984, **11**:94–95.
9. d'Oro LC, Parazzini F, Naldi L, La Vecchia C. **Barrier methods of contraception, spermicides, and sexually transmitted diseases: a review.** *Genitourin Med* 1994, **70**:410–417.
10. Pinkerton SD, Abramson PR. **Occasional condom use and HIV risk reduction.** *J Acquir Immune Defic Syndr Hum Retrovirol* 1996, **13**:456–460.
11. Hanenberg RS, Rojanapithayakorn W, Kunasol P, Sokal DC. **Impact of Thailand's HIV-control programme as indicated by the decline of sexually transmitted diseases.** *Lancet* 1994, **344**: 243–245.
12. Rojanapithayakorn W, Hanenberg R. **The 100% condom program in Thailand.** *AIDS* 1996, **10**:1–7.
13. Nelson KE, Celentano DD, Eiumtrakol S, *et al* . **Changes in sexual behavior and a decline in HIV infection among young men in Thailand.** *N Engl Med* 1996, **335**:297–303.
14. Celentano DD, Nelson KE, Lyles CM, *et al.* **Decreasing incidence of HIV and sexually transmitted diseases in young Thai men: evidence for success of the HIV/AIDS control and prevention program.** *AIDS* 1998, **12**:F29–F36.
15. Davis KR, Weller SC. **The effectiveness of condoms in reducing heterosexual transmission of HIV.** *Fam Plann Perspect* 1999, **31**:272–279.
16. De Vincenzi, I. **A longitudinal study of human immunodeficiency virus transmission by heterosexual partners.** *N Engl J Med* 1994, **331**:341–346.
17. Hira SK, Feldblum PJ, Kamanga J, *et al.* **Condom and nanoxynol-9 use and the incidence of HIV infection in serodiscordant couples in Zambia.** *Int J STD AIDS* 1997, **8**:243–250.
18. Deschmps MM, Pape JW, Hafner A, *et al.* **Heterosexual transmission of HIV in Haiti.** *Ann Int Med* 1996, **125**:324–330.
19. Taha TE, Canner JK, Chiphangwi JD, *et al.* **Reported condom use is not associated with incidence of sexually transmitted diseases in Malawi.** *AIDS* 1996, **10**:207–212.
20. Saracco A, Mussico M, Nicolosi A, *et al.* **Man-to-woman sexual transmission of HIV: Longitudinal study of 343 steady partners of infected man.** *J Aquir Immune Defic Syndr* 1993, **6**: 497–502.
21. Darrow WW. **Condom use and use-effectiveness in high-risk populations.** *Sex Transm Dis* 1989, **16**:157–160.
22. Laga M, Alary M, Nzila N, *et al.* **Condom promotion, sexually**

transmitted diseases treatment, and declining incidence of HIV-1 infection in female Zairian sex workers. *Lancet* 1994, **344**:246–248.
23. Gangakhedkar, RR, Bentley ME, Divekar A, *et al.* **Spread of HIV infection in married monogamous women in India.** *JAMA* 1997, **278**:2090–2092.
24. The National Institute of Mental Health (NIMH) Multisite HIV Prevention Trial Group. **The National Institute Mental Health (NIMH) Multisite HIV Prevention Trial: reducing HIV sexual risk behavior.** *Science* 1998, **280**:1889–1894.
25. Kilmarx PH, Palanuvej T, Limpakarnjanarat K, Chitvarakorn A, St Louis ME, Mastro TD. **Seroprevalence of HIV among female sex workers in Bangkok: evidence of ongoing infection risk after the '100% condom program' was implemented.** *J Acquir Immune Defic Syndr Hum Retrovirol* 1999, **21**:313–316.
26. Weller SC. **A meta-analysis of condom effectiveness in reducing sexually transmitted HIV.** *Soc Sci Med* 1993, **36**:1935–1944.
27. Evans BA, Bond RA, MackRae KD. **Sexual relationships, risk behavior, and condom use in the spread of sexually transmitted infections to heterosexual men.** *Genitourin Med* 1997, **73**: 368–372.
28. Wawer MJ, Gray RH, Sewankambo NK, *et al.* **A randomized, community trial of intensive sexually transmitted disease control for AIDS prevention, Rakai, Uganda.** *AIDS* 1998, **12**: 1211–1225.
29. Wawer MJ, Sewankambo NK, Serwadda D, *et al.* **Control of sexually transmitted diseases for AIDS prevention in Uganda: a randomised community trial. Rakai Project Study Group.** *Lancet* 1999, **353**:525–535.
30. McCullagh P, Nelder JA. *Generalized Linear Models (The Monographs on Statistics and Applied Probability, Vol 37).* New York: John Wiley; 1990.
31. Hosmer DW, Lameshow S. *Applied Logistic Regression (Wiley Series in Probability and Statistics: Texts and References Section)* New York: John Wiley; 1989.
32. Liang KY and Zeger SL. **Longitudinal data analysis using generalized linear models.** *Biometrika* 1986, **73**:13–22.
33. Gray RH, Wawer MJ, Sewankambo NK, *et al.* **Relative risks and population attributable fraction of incident HIV associated with symptoms of sexually transmitted diseases and treatable symptomatic sexually transmitted diseases in Rakai District, Uganda.** *AIDS* 1999, **13**:2113–2123.
34. Weir SS, Roddy RE, Zekeng L, Ryan KA. **Association between condom use and HIV infection: A randomised study of self reported condom use measures.** *J Epidemiol Community Health* 1999, **53**:417–422.
35. Zenilman JM, Weisman CS, Rompalo AM, *et al.* **Condom use to prevent incident STDs: the validity of self-reported condom use.** *Sex Transm Dis* 1995, **22**:15–21.
36. Crossby, R. **Condom use as a dependent variable: Measurement issues relevant to HIV prevention programs.** *AIDS Educ Prevent* 1998, **10**:548–557.
37. Goodrich J, Wellings K, McVey D. **Using condom data to assess the impact of HIV/AIDS prevention interventions.** *Health Educ Res* 1998, **13**:267–274.
38. Warner DL, Hatcher RA**. A meta-analysis of condom effectiveness in reducing sexually transmitted HIV.** *Soc Sci Med* 1994, **38**:1169–1170.