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## CONTRACEPTIVE PREFERENCE AMONG WOMEN AT RISK OF HIV ACQUISITION IN A PREPARATORY SCREENING STUDY FOR A PHASE III MICROBICIDE TRIAL IN SOUTH WESTERN UGANDA

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### Abstract

Contraceptive preferences of women at risk for HIV acquisition are not well documented. We report on contraceptive choices among women residing in small townships in southwestern Uganda. This was part of preparatory efforts for recruitment into the Ring Study, a phase 3 microbicide trial, between July 2013 and October 2014. Clinicians provided contraceptives per a woman's choice. HIV testing and screening for other sexually transmitted infections were done at first contact and at screening for the trial. Contraceptive choice was summarized by demographics and regression analysis to show factors associated with use of the injectable method. Of 6725 women contacted, 489 were prescreened. Of these 489 women, most (306, 63%) were already using contraception. Injectables were most preferred (58.7%), followed by implants (23.9%). Women living with a regular sexual partner preferred the injectable method (61.0%,  $P=.06$ ), compared with other methods. Women at risk for HIV infection are willing to initiate use of modern contraceptives, which may reduce study dropout during intervention trials due to unintended pregnancy.

### Keywords

contraceptives; contraceptive preference; women at high-risk; Uganda

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Author contribution:

SK, AA, MO, AN designed the study and AA did the analysis. GA contributed to the writing and editing of the manuscript. SK and MO directed the work. All authors contributed to the interpretation of the results and critically commented and provided revisions to the manuscript.

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## INTRODUCTION

Annually, women in sub-Saharan Africa experience more than 14 million unintended pregnancies due to improper use of short-acting contraceptives.[1] Approximately 775,000 women in Uganda have unintended pregnancies every year due to low uptake of contraception.[2] Although there has been an increase in the use of modern contraceptives, there is still an unmet need for contraception in many developing countries. In Uganda, unmet need for contraception, both traditional and modern, remains high at 28% despite a decline from 34% in 2011.[3] Women at high risk for acquiring HIV face a high burden of sexually transmitted infections (STI) and unintended pregnancies, with little access to sexual and reproductive health services.[4] An increase in access to and use of effective modern contraceptives is needed among this key population in order to improve their reproductive health.[5]

HIV intervention studies target women at high risk for HIV for enrollment in clinical trials. The use of modern contraceptives has become a key inclusion criterion for enrollment.[6,7] Modern contraceptives are recommended because the effect of trial-investigational products on embryos or fetuses is unknown.[8] Furthermore, the recent UNAIDS guidelines issued a call for comprehensive and sustainable HIV prevention programs emphasizing reliable and affordable access to health-related services, including contraceptives.[9] In order to adequately plan for contraception needs during trial participation, there is an urgent need to assess contraceptive preference among women at risk for HIV, especially in high-risk settings.[10] Promotion and provision of contraception prior to trial onset may also create a pool of women at high risk who can be enrolled in trials. Consistent contraception use may limit trial dropout due to unintended pregnancies.[8] A few studies among this population demonstrated low levels of contraceptive use resulting in unintended pregnancy and abortion.[11,12] Studies have mostly focused on the influence of community factors and female education in contraceptive use[13,14], and most have been conducted among women who fully participated in prevention trials[8,15–17]. Other studies related to contraception among women at high risk have investigated the association of family planning methods with HIV incidence[18–20], and have not necessarily focused on broader participant characteristics, other than sex-worker status, that influence contraceptive use and the incidence of pregnancy.

We report findings on contraceptive choice and the association with participant characteristics in a cohort of women at risk for HIV who resided in small townships in southwestern Uganda before enrollment in a multicenter, phase 3 microbicide trial. The trial (also known as the Ring Study) is part of collaborative work between the Medical Research Council / Uganda Virus Research Institute (MRC/UVRI), Uganda Research Unit on AIDS, and International Partnership for Microbicides (IPM) that evaluated the safety and efficacy of a dapivirine vaginal ring among healthy, HIV-negative women who were at high risk. The trial recruitment and follow-up procedures have been reported elsewhere.[21]

## METHODS

### Study setting and population

This study was conducted in preparation for a multicenter, phase 3 microbicide trial (the Ring Study) that evaluated the safety and efficacy of a dapivirine vaginal ring among HIV-uninfected women in Uganda. The microbicide trial recruited healthy, HIV-uninfected women between the ages of 18 and 45 years who were using modern contraception: either depot medroxyprogesterone acetate (DMPA) for at least 6 months or other methods, such as combined oral contraceptives (COC), implants, intrauterine contraceptive devices (IUCD), or surgical sterilization, for at least 3 months prior to screening for the trial.

To identify women at high risk for HIV, we approached those who were residing in 37 small townships in the 3 neighboring districts of Masaka, Kalungu, and Lyantonde along the Trans-African Highway in Uganda between July 2013 and October 2014. The districts are about 120 kilometers from Kampala, the capital of Uganda. Women working in bars, hotels, restaurants, small shops, hair salons, and other small-scale businesses were prescreened for the study via a door-to-door approach. Trained counselors supported by local community mobilizers offered HIV counseling and testing. During the counseling sessions, information about age and current contraceptive use was collected. Reasons for not using contraception were not collected. Those who were found to be HIV positive at this stage were referred to antiretroviral therapy providers for treatment and care. Women who tested HIV negative and were using modern contraception, or were willing to initiate a method, were invited to the research center for HIV risk assessment and a study screening.

At the research-center screening visit, women using contraception were assessed by trained nurses about the duration of use. Contraceptive use was promoted and provided to those who were not using any method but were willing to initiate one of their choosing. Acceptable contraceptive methods included COC, injectable DMPA, implant (etonogestrel-Implanon® or levonogestrel-Jadelle®), IUCD (Copper T-380A), and surgical sterilization. Condoms were provided but were not considered an acceptable contraceptive method for enrollment in the Ring Study. Sources of contraceptives included the research center and referral to a provider in the community—the nearby Marie Stopes Clinic—for implants, IUCDs, and surgical sterilization. HIV risk was assessed via face-to-face interview using a standardized questionnaire. High risk for HIV acquisition was defined by the presence of any 2 of the following in the past 3 months: (1) history of STI, (2) self-reported unprotected sex with multiple sex partners or a new partner, and (3) frequent use of recreational drugs (eg, marijuana, alcohol). During the assessment, those who were diagnosed with an STI were offered treatment using the Uganda national STI syndromic management guidelines.[22] After this screening visit, women were given appointments to return when recruitment into the microbicide trial began. At the recruitment visit, they were evaluated for contraception compliance (at least 6 months for DMPA and at least 3 months for the other methods), a requirement for the Ring Study.

## Laboratory testing

Serial HIV-antibody rapid tests were done using Alere Determine™ HIV-1/2 (Alere Medical Co Ltd, Matsuhidai, Matsudo-shi, Chiba, Japan), followed by OraQuick-ADVANCE® Rapid HIV-1/2 Test (OraQuick-OraSure Technologies Inc, Pennsylvania, USA) to confirm a positive Determine result, with Uni-Gold™ HIV (Trinity Biotech, Ireland) as the tiebreaker. The tests were run by a laboratory technician. A participant was considered to be HIV positive if 2 antibody rapid tests showed positive results.

Additionally, cervico-vaginal samples were taken and tested for *T. vaginalis* (OSOM® Trichomonas Test, Sekisui Diagnostics LLC, USA) and *C. trachomatis* / *N. gonorrhoeae* (Cobas® Amplicor CT/NG PCR test, Roche Diagnostic Systems, Branchburg, New Jersey, USA), and blood samples were taken for syphilis testing using rapid plasma reagin (RPR) (Wampole® Impact RPR Test Kit, Alere™, Pennsylvania, USA). A positive RPR was confirmed using the *Treponema pallidum* particle agglutination assay (TPPA) (Serodia TP.PA, Fujirebio Inc, Pennsylvania, USA). A participant was reported to have syphilis if both the RPR and TPPA results were positive. Treatment was provided to those who tested positive for any STI according to the Centers for Disease Control and Prevention (CDC) STD treatment guidelines for 2010.[23]

## Statistical methods

Data on demographic characteristics, sexual behaviors, contraceptive use or agreement to initiate contraception, dates of first and subsequent contacts, and STI test results including HIV status were recorded in Microsoft Excel 2016. Data were exported to STATA version 14 (StataCorp, College Station, Texas, USA) for statistical analysis. All participants who completed at least 2 visits by the time of enrollment in the microbicide trial were included in this analysis. Participant characteristics were summarized using frequencies and percentages and stratified by contraceptive choice. The proportion of women who indicated a preference for DMPA was used as the referent method in this analysis because most of the participants preferred this method. We used log-binomial regression models to estimate unadjusted and adjusted prevalence proportion ratios (PPR) and 95% confidence intervals (CI) of factors associated with use of DMPA. When the proportion of a primary outcome is greater than 10%, odds ratios can give biased estimates of proportion ratios, so this led to the choice of log-binomial regression instead of logistic regression.[24] Only factors for which the association attained a statistical significance at the 15% level[25] using a likelihood ratio test (LRT) in a univariate analysis were considered for the multivariable model. Only participant age was included *a priori*. In the final multivariable model, factors were removed using a backward elimination algorithm if removing them did not make the fit of the model significantly worse at the 5% level in an LRT.

In a secondary investigation, HIV incidence was determined between the initial participant contact date and the later visit date to the research center. Overall HIV incidence was computed as the number who were HIV positive divided by the total person-years at risk. Person-years at risk were calculated as the sum of time from the first date of contact to the date of last HIV-uninfected result date, or to the estimated date of HIV infection, for each participant. Date of HIV infection was estimated as the midpoint of the interval between the

last HIV-uninfected result date and the first HIV-infected result date. We did not investigate factors associated with HIV incidence because our study was not empowered to test these associations.

### **Ethical considerations**

The study protocol was approved by the UVRI Research Ethics Committee and the Uganda National Council of Science and Technology (UNCST). Written informed consent was obtained from women who were willing to be screened. Those who tested HIV positive were referred to an antiretroviral therapy provider of their choice for care and treatment.

## **RESULTS**

### **Study screening profile**

Overall, 6725 women were prescreened between July 2013 and October 2014 (Figure 1). Of these, 780 (12%) were excluded due to HIV infection. Of the 5456 who were HIV uninfected, 325 were excluded based on age (52 women were younger than 18 years, and 273 were older than 45 years). Only 8% (489) were already using modern contraception, or were willing to initiate contraception, and attended the study screening to be assessed for HIV risk. This screening visit typically occurred within 8 months (interquartile range: 5–9 months) of the prescreening visit. Of those using contraception or willing to initiate a method, 34% (164) were excluded from the study mainly because of low risk for HIV or refusal to participate due to lack of interest or partner challenges. Of the remaining 325 women who returned for a second visit to confirm contraceptive uptake, 322 were invited into the Ring Study.

### **Baseline characteristics and contraception choices**

Table 1 shows the distribution of study participants' characteristics and contraceptive choices. About half (45%) were aged 25 to 34 years, 53% had attained primary education, 43% were married, and most (83%) had a main partner. Approximately 39% of the women were bar or hotel/restaurant attendants, 27% owned a small-scale business, 16% were unemployed and 11% worked in a hair salon. The majority of women had had an STI (80%), had had unprotected sex (85%), or had a new partner (78%), and most had used alcohol or recreational drugs (61%). More than half of the women (181, 56%) tested positive for at least 1 STI. Approximately two-thirds (322 of 489, 66%) of the women screened and invited into the Ring Study, were already using or willing to initiate a method of contraception (Figure 1). The main method used by these women was injectable DMPA (59%), followed by implant (24%) and COC (12%). Of the 489 women screened, 183 who were not using any method chose options in very similar proportion to their counterparts who were already using contraception: DMPA, 106 women (58%); implant, 40 (22%); COC, 33 (18%); and IUCD, 4 (2%). Nine women seroconverted in 206.6 person-years, for an overall HIV incidence of 4.4 per 100 person-years (95% CI, 2.3–8.4).

### **Choice of DMPA and associated factors**

The choice of DMPA did not differ significantly by participant characteristic, except for whether or not a woman had a main sexual partner. Of those who had a main sexual partner,

61% preferred DMPA, compared with 47% for those who did not ( $P=.06$ ) (Table 2). In the adjusted log-binomial regression models, having a main sexual partner remained of borderline statistical significance (adjusted prevalence proportion ratio [aPPR] = 0.77, 95% CI, 0.57–1.04).

## DISCUSSION

In this study, we observed that contraception use was high among women who were residing in the small townships in this region and at high risk for HIV infection (63%), compared with the general population (35%).<sup>[3]</sup> We observed a higher preference for injectable progesterone contraceptive method (ie, DMPA), followed by implant and COC. This was similar among women who were already using contraceptives at the time of screening and among women who agreed to initiate contraceptives for the Ring Study; it also conforms to findings from the Uganda Demographic and Health Survey.<sup>[3]</sup> Preference for DMPA may be due to its free availability in the region and the perception that it is convenient and easy to use.<sup>[26]</sup> Although other modern contraceptive methods are commonly used in certain regions in eastern and southern Africa, injectables are very popular, representing 40% of contraceptive use.<sup>[27]</sup> However, concerns have been raised about an increased risk for HIV acquisition with the use of hormonal contraceptives, though this has not been consistent across studies and may be related to methodological limitations rather than to actual increased risk.<sup>[28,29]</sup> Based on a review of the current literature and convening of experts on the topic, the World Health Organization has recommended that hormonal contraceptive use (including progesterone-only injectables such as DMPA) among women at high risk for HIV be combined with condom use and other risk reduction strategies.<sup>[30]</sup> As DMPA was the most prevalent contraceptive used by our study population, following these guidelines carefully will be important in future studies.

We also found that had a main sexual partner was associated with a woman's contraceptive preference, as those who had a main partner preferred DMPA, compared with other methods. This could be because DMPA offers privacy and is easy and convenient to use.<sup>[31]</sup> A study in Nigeria found that DMPA was the most-preferred method because women did not want to reveal to their partners that they were using contraceptives.<sup>[32]</sup> DMPA also might be preferred because the privacy it allows may help minimize disagreements between partners.<sup>[33]</sup>

### Study limitations

This was a preparatory study for screening participants for a microbicide trial. The selection of women during the first contact visit was a convenience sample from areas thought to be associated with higher-risk behavior, and many did not come to the study clinic for further screening. Therefore, the contraceptive use among women in this study needs to be interpreted with caution and may not represent use among the general population. As a preparatory study, no data were collected on the side effects of contraceptives. It was also not possible to determine whether women switched from 1 method to another, and pregnancy rates could not be estimated because these data were collected once and only HIV status was reassessed prior to screening for the main study. We did not investigate the

reason(s) for a contraceptive preference. Furthermore, we did not investigate the reasons for refusing to initiate contraceptive use even when the methods were freely provided. This information would have been useful to contraceptive providers in the community. Uptake of DMPA could have been high because it was offered on-site and immediately; women had to go off-site for other methods.

## CONCLUSION

Women at risk for HIV acquisition in this community are willing to initiate modern contraceptives, with a high preference for the injectable contraceptive DMPA. Use of modern contraceptives may reduce intervention trial discontinuation due to pregnancy. Further studies using qualitative methods are needed to better understand why this key population prefers the injectable method.

## Compliance with Ethical Standards

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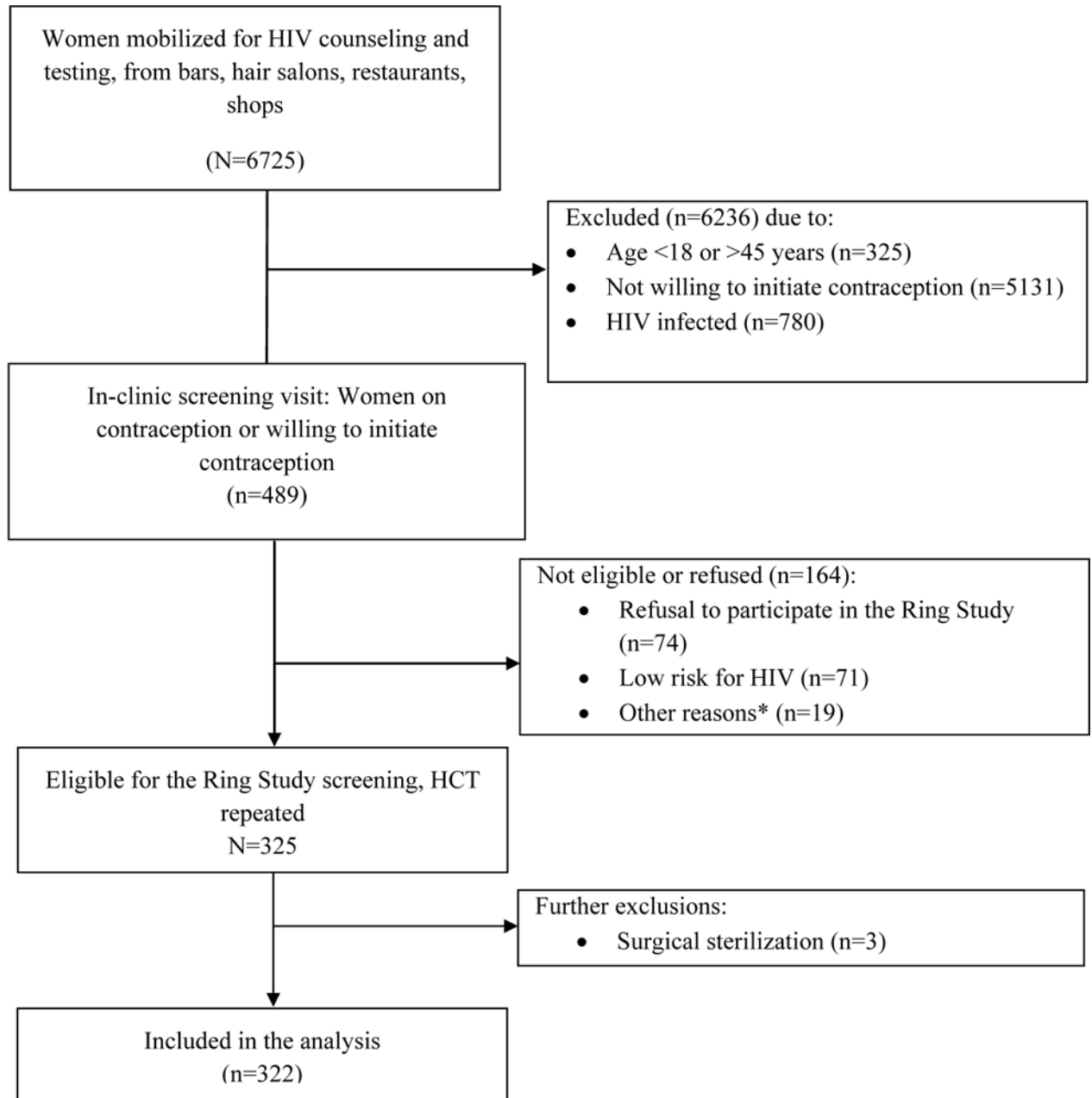
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\*Other reasons: partner not interested, pregnancy, breastfeeding.

**Figure 1:** Study profile of women screened for contraception use and HIV risk in preparation for microbicide trial in southwestern Uganda (July 2013-October 2014).

**Table 1:**

Baseline characteristics and contraception choices among 322 women screened for a phase 3 microbicide trial in southwestern Uganda (July 2013 to October 2014).

Variable	n(%)	DMPA* n(%)	Implant** n(%)	IUCD*** n(%)	COC**** n(%)
Overall	322 (100)	189 (58.7)	77 (23.9)	16 (5.0)	40 (12.4)
<i>Age (years)</i>					
18–24	117 (36.3)	69 (58.9)	29 (24.8)	5 (4.3)	14 (12.0)
25–34	145 (45.0)	86 (59.3)	36 (24.8)	6 (4.2)	17 (11.7)
35–44	60 (18.6)	34 (56.7)	12 (20.0)	5 (8.3)	9 (15.0)
<i>Education</i>					
None	116 (36.0)	65 (56.0)	28 (24.2)	5 (4.3)	18 (15.5)
Primary	172 (53.4)	102 (59.3)	43 (25.0)	10(5.8)	17 (9.9)
Secondary	34 (10.6)	22 (64.7)	6 (17.7)	1 (2.9)	5 (14.7)
<i>Marital status</i>					
Married	137 (42.6)	84 (61.3)	29 (21.2)	6 (4.4)	18 (13.1)
Single	143 (44.4)	79 (55.2)	39 (27.3)	6 (4.2)	19 (13.3)
Divorced/separated/widowed					
<i>Occupation</i>					
Bar/hotel	125 (38.8)	72 (57.6)	29 (23.2)	6 (4.8)	18 (14.4)
Small-scale business	87 (27.0)	48 (55.2)	23 (26.4)	5 (5.8)	11 (12.6)
Salon/shop	35 (10.9)	22 (62.9)	9 (25.7)	0 (0.0)	4 (11.4)
Unemployed	52 (16.2)	32 (61.5)	11 (21.2)	3 (5.8)	6 (11.5)
Other	23 (7.1)	15 (65.2)	5 (21.7)	2 (8.7)	2 (8.7)
<i>Source of contraceptives</i>					
Self/other clinics	206 (64.0)	122 (59.2)			
Study site	116 (36.0)	67 (57.8)	22 (19.0)	2 (1.7)	25 (21.5)
<i>Currently has a main partner</i>					
Yes	267 (82.9)	163 (61.0)	61 (22.9)	11 (4.1)	32 (12.0)
No	55 (17.1)	26 (47.3)	16 (29.1)	5 (9.1)	8 (14.5)
<i>Has an STI</i>					
No	141 (43.8)	80 (56.7)	32 (22.7)	8 (5.7)	21 (14.9)
Yes	181 (56.2)	109 (60.2)	45 (24.9)	8 (4.4)	19 (10.5)
<i>HIV status</i>					
Positive	9(2.8)	4(44.5)	3(33.3)	2(22.2)	0(0.0)
Negative	313(97.2)	185 (59.1)	74 (23.6)	14 (4.5)	40 (12.8)
<i>Has unprotected sex</i>					
Yes	275 (85.4)	163 (59.3)	65 (23.6)	13 (4.7)	34 (12.4)
No	47 (14.6)	26 (55.3)	12 (25.5)	3 (6.4)	6 (12.8)
<i>Has a new partner</i>					
Yes	251 (78.0)	149 (59.4)	58 (23.1)	13 (5.2)	31 (12.3)
No	71 (22.0)	40 (56.3)	19 (26.8)	3 (4.2)	9 (12.7)

Variable	n(%)	DMPA* n(%)	Implant** n(%)	IUCD*** n(%)	COC**** n(%)
<i>Alcohol/drug use</i>					
Yes	195 (60.6)	112 (57.4)	48 (24.6)	11 (5.7)	24 (12.3)
No	127 (39.4)	77 (60.6)	29 (22.8)	5 (4.0)	16 (12.6)

\* DMPA = depot medroxyprogesterone acetate.

\*\* Implanon® and Jadelle®.

\*\*\* IUCD = intrauterine contraceptive devices.

\*\*\*\* COC = combined oral contraceptives.

**Table 2:**

Choice of DMPA and associated factors among 322 women screened for a phase 3 microbicide trial in southwestern Uganda (July 2013 to October 2014), proportions and log-binomial regression models.

Variable	DMPA* n (%)	Other** n (%)	Unadjusted PPR 95% CI	LRT P value	Adjusted PPR 95% CI
Overall	189(58.7)	133(41.3)	-	-	
<i>Age (years)</i>					
18–24	69 (59.0)	48 (41.0)	1.0	.938	1.0
25–34	86 (59.3)	59 (40.7)	1.01 (0.82–1.23)		1.00 (0.82–1.22)
35–44	34 (56.7)	26 (43.3)	0.96 (0.74–1.26)		0.96 (0.74–1.25)
<i>Education</i>					
None	65 (56.0)	51 (44.0)	1.0	.645	
Primary	102(59.3)	70 (40.7)	1.06 (0.86–1.30)		
Secondary	22 (64.7)	12 (35.3)	1.15 (0.86–1.55)		
<i>Marital status</i>					
Married	84 (61.3)	53 (38.7)	1.0	.531	
Single	79 (55.2)	64 (44.8)	0.90 (0.74–1.10)		
Divorced/separated/widowed	26 (61.9)	16 (38.1)	1.01 (0.77–1.33)		
<i>Occupation</i>					
Bar/hotel	72 (57.6)	53 (42.4)	1.0	.854	
Small-scale business	48 (55.2)	39 (44.8)	0.96 (0.75–1.22)		
Salon/shop	22 (62.9)	13 (37.1)	1.09 (0.81–1.47)		
Unemployed	32 (61.5)	20 (38.5)	1.07 (0.82–1.39)		
Other	15 (65.2)	8 (34.8)	1.13 (0.81–1.58)		
<i>Source of contraceptives</i>					
Self/other clinics	122 (59.2)	84 (40.8)	1.0	.798	
Study site	67 (57.8)	49 (42.2)	0.98 (0.80–1.18)		
<i>Currently has a main partner</i>					
Yes	163 (61.0)	104 (39.0)	1.0	.061	1.0
No	26 (47.3)	29 (52.7)	0.77 (0.58–1.04)		0.77 (0.57–1.04)
<i>Has an STI</i>					
No	80 (56.7)	61 (43.3)	1.0	.529	
Yes	109 (60.2)	72 (39.8)	1.06 (0.88–1.28)		
<i>Has unprotected sex</i>					
Yes	163 (59.3)	112 (40.7)	1.0	.612	
No	26 (55.3)	21 (44.7)	0.93 (0.71–1.23)		
<i>Has a new partner</i>					
Yes	149 (59.4)	102 (40.6)	1.0	.648	
No	40 (56.3)	31 (43.7)	0.95 (0.75–1.19)		
<i>Alcohol/drug use</i>					
Yes	112 (57.4)	83 (42.6)	1.0	.569	
No	77 (60.6)	50 (39.4)	1.06 (0.88–1.27)		

\* DMPA = depot medroxyprogesterone acetate.

\*\* Other = implants, intrauterine contraceptive devices, combined oral contraceptives.

PPR = prevalence proportion ratio. CI = confidence interval. LRT = log rank test.

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