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Acceptability of the dapivirine vaginal ring for HIV-1 prevention among women reporting engagement in transactional sex

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ABSTRACT

We assessed if acceptability of the dapivirine vaginal ring for HIV prevention differed among the subgroup of women who reported engaging in transactional sex prior to enrollment in MTN-020/ASPIRE (phase III trial in Malawi, South Africa, Uganda, and Zimbabwe, 2012-2015; $n = 2629$). Transactional sex was defined as receipt of money, goods, gifts, drugs, or shelter in exchange for sex in the past year. Dimensions of acceptability included: ease of use and physical sensation in situ, impacts on sex, partner's opinion, and likelihood of future use. We used Poisson regression models with robust standard errors to compare risk of acceptability challenges by baseline history of transactional sex. At product discontinuation, women exchanging sex found the ring comfortable (90%), easy to insert (92%) and nearly all (96%) were likely to use the ring in the future. Women who had exchanged sex were more likely to report feeling the ring during sex (ARR 1.43, 95% CI: 1.09, 1.89; $p = 0.01$) and slightly more likely to mind wearing the ring during menses (ARR 1.22, 95% CI: 1.01, 1,46; $p = 0.04$) and during sex (ARR 1.22, 95% CI: 1.02, 1.45; $p = 0.03$). Messaging and counseling should include enhanced support for use during sex and menses to support optimal use.

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HIV prevention; acceptability; vaginal ring; sub-saharan Africa; transactional sex; women

Introduction

In eastern and southern Africa, women who exchange sex for money or material goods have a high incidence of HIV and are 13 times more likely to become infected with HIV than adults in the general population (UNAIDS, 2018a). They also often face additional barriers to accessing HIV prevention services including stigma and discrimination (Hensen et al., 2021). Mathematical modeling suggests that the unmet HIV prevention and treatment needs of women who sell sex will have an outsized contribution to HIV transmissions over the next decade, becoming increasingly important drivers in both concentrated and generalized epidemics (Mishra et al., 2016). "Transactional sex" is a term that has emerged to describe exchange practices beyond formal sex work, where women may describe their sex partners as lovers or boyfriends instead of as clients, but an implicit assumption exists within the relationship that sex will be exchanged for material benefit or status. Relationship power dynamics, along with social and economic aspects of gender inequality, are thought to explain the increased risk of HIV among women who practice transactional sex in sub-Saharan Africa (Wamoyi et al., 2016). Given their heightened risk of HIV acquisition, addressing the needs of women who engage in transactional sex is a critical component toward achieving the UNAIDS 95-95-95 goals for ending the global HIV epidemic, including by providing access to novel biomedical prevention technologies as they become available.

The monthly dapivirine vaginal ring (i.e., the ring) is a monthly topical HIV prevention option that will provide women with much needed choice for preventing HIV acquisition. The ring has been found to be well-

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tolerated and acceptable to women and can reduce HIV risk by 27% (95% confidence interval [CI], 1–46%; Baeten et al., 2016; Brown et al., 2020; Montgomery et al., 2017; Nel et al., 2016). In 2020, the ring received a positive opinion from the European Medicines Agency, and the World Health Organization issued a recommendation for the product in November 2020 ('IPM's dapivirine ring for women's HIV prevention receives WHO prequalification', 2020). In July 2021, the WHO released updated consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring that included a recommendation for the ring as an additional prevention choice for women at substantial risk of HIV infection. The ring was approved for use by the Medicines Control Authority of Zimbabwe in July 2021 with regulatory reviews in other African countries underway (Gwarisa, 2021).

To assist in informing rollout given the imminent introduction of the ring, we assessed whether attitudes about the ring differed among women who had engaged in transactional sex, as they are at higher risk for acquiring HIV and could benefit from ring access. While trials for the ring did not specifically target recruitment of women who engage in transactional sex, the MTN-020/ASPIRE trial (conducted in Malawi, South Africa, Uganda, and Zimbabwe) asked participants about their recent history of exchanging sex for goods, money, or other services. Our objective was to describe the acceptability of the ring among women who engaged in transactional sex and to evaluate if ring acceptability differed among those who had or had not engaged in transactional sex.

Materials and methods

Study design and procedures

The MTN-020/ASPIRE phase III randomized, double-blind, placebo-controlled clinical trial (NCT01617096) enrolled healthy women aged 18–45 across 15 sites in Malawi (2 sites), South Africa (9 sites), Uganda (1 site), and Zimbabwe (3 sites). Details of the trial design, recruitment, and results have been previously published (Baeten et al., 2016). In summary, women were randomized in a 1:1 ratio to use either a monthly silicone elastomer vaginal matrix ring containing 25 mg of dapivirine or a placebo ring. Participants were followed monthly for at least one year (maximum 33 months) between August 2012 and June 2015. At each monthly visit, participants received HIV-1 serologic and pregnancy testing and safety monitoring. In addition, participants were counseled on how to insert and remove the ring, instructed to keep the ring inserted for the entire month and were provided individualized adherence counseling based on their ring use experiences. Audio computer-assisted self-interviews (ACASIs) at baseline, the Month-3 visit, and at the Product Use End visit (PUEV, the penultimate study visit when study product dispensing was permanently discontinued) collected behavioral and acceptability data. All participants provided written informed consent; all procedures were approved by local IRBs.

Measures

We assessed if participants had engaged in transactional sex on the baseline self-administered ACASI using the following question: 'in the past year, did you receive money, material goods, gifts, drugs, or shelter in exchange for vaginal or anal sex?' Transactional sex was dichotomized (yes/no) defined by an affirmative response.

Acceptability measures included in the ACASI were informed by the components of acceptability outlined by Mensch et al., 2012. Dimensions of acceptability included: ease of use and physical sensation in situ, impact on sex, partner's opinion, and likelihood of future use if a similar vaginal ring that provided some protection against HIV became available. During each ACASI, participants were asked to reflect on their experiences using the ring in the prior 3 months. At PUEV, additional questions captured perceptions of the ring based on participants' entire experience. A list of acceptability question text with response options are outlined in full in Mayo et al., 2021.

Analysis

Characteristics of the subsample of participants who reported engaging in transactional sex were summarized using descriptive statistics (e.g., frequencies, means). A Chi-square test was used to compare proportions of participants reporting exchanging sex by country. We used Poisson regression with robust standard errors (binary outcomes) or linear regression (continuous outcomes) models adjusting for country to compare characteristics of those who did and did not report engagement in transactional sex. Acceptability measures were summarized by study visit. To test for associations between recent history of transactional sex and acceptability, measures of acceptability were dichotomized. We used Poisson regression models with robust standard errors to compare risk of acceptability challenges by baseline history of engaging in transactional sex, controlling for country, study arm, and months of follow-up.

Results

Among the 2629 women enrolled, 2614 (99%) completed the baseline ACASI; 162 (6%) reported engaging in transactional sex in the year prior to enrollment. Table 1 describes the baseline characteristics of this subgroup of participants. The median age was 26 years (interquartile range [IQR] 22–30; max 43 years). Nearly all reported having a primary sex partner (97%), and 28% said that they had multiple sex partners in the past 3 months. Compared to those who did not report engaging in transactional sex, women who exchanged sex were more likely to have tested positive for an STI at screening (adjusted relative risk [ARR] 1.38, 95% CI 1.06, 1.80; $p = 0.02$), to report multiple sex partners in the past 3 months (ARR 1.36, 95% CI: 1.05, 1.77; $p = 0.02$), and to report excessive alcohol use (ARR 1.78, 95% CI: 1.19, 2.62; $p = 0.004$) at enrollment. More participants in Uganda (15%) said they had recently exchanged sex for money/goods compared to those in other countries (3–6%, $p < 0.001$). There was no difference in follow-up time between those who did and did not engage in transactional sex (median 21, IQR 14–30 months). A similar proportion of women with a history of transactional sex seroconverted during the study (5.6%, $n = 9$) compared to those who did not report engaging in transactional sex (6.5%, $n = 159$).

Of the 162 women with a baseline history of transactional sex, 156 (96%) completed at least one follow-up ACASI; 153 of 156 (98%) reported using the ring during at least one three-month period prior to an ACASI and responded to questions of acceptability. A summary of acceptability measures collected at the Month-3 visit and at the PUEV is presented in Table 2. At both visits, most women who reported engaging in transactional sex indicated that the ring was "usually comfortable" ($n = 121$, 85%; $n = 106$, 90%), that they were unaware of the ring in situ during normal activities ($n = 106$, 75%; $n = 90$, 76%), and that they found removal ($n = 111$, 82%; $n = 84$, 85%) and insertion ($n = 118$, 83%; $n = 109$, 92%) easy. At the PUEV, more than a third minded wearing the ring during sex (37%) or during menses (39%) and felt it during sex most or some of the time (34%). Nearly all (96%) reported being likely

Table 1. Baseline characteristics of participants in the MTN-020/ASPIRE Trial (Aug 2012–Jun 2015), by report of engaging in transactional sex[a] in the year prior to enrollment.

	Engaged in transactional sex[a]					
	Yes		No		Total	
	N	(%)	*N*	(%)	*N*	(%)
Total	162	(100)	2452	(100)	2614[e]	(100)
Sociodemographic characteristics						
Age, years – *mean median (IQR)*	26.5, 26	(22–30)	27.2, 26	(22–31)	27.2, 26	(22–31)
Younger, aged 18–21	32	(20)	488	(20)	520	(20)
Secondary education completed	56	(35)	1136	(46)	1192	(46)
Earns income	90	(56)	1090	(44)	1180	(45)
Has primary sex partner	157	(97)	2405	(98)	2562	(98)
Married	52	(32)	1020	(42)	1072	(41)
Parous	148	(91)	2244	(92)	2392	(92)
Risk behavior & history						
Excessive alcohol use[b]	26	(16)	156	(6)	182	(7)
Multiple sex partners in past 3 months	46	(28)	390	(16)	436	(17)
Condomless sex[c]	66	(41)	1050	(43)	1116	(43)
Positive for sexually transmitted infection[d]	45	(28)	475	(19)	520	(20)
Contraceptive method and vaginal practices						
Current contraceptive method						
Injectable	91	(56)	1347	(55)	1438	(55)
Implant	33	(20)	468	(19)	501	(19)
Copper intrauterine device (IUD)	16	(10)	308	(13)	324	(12)
Oral contraceptive	21	(13)	266	(11)	287	(11)
Sterilization	1	(1)	77	(3)	78	(3)
Menstruation in past 3 months	118	(73)	1903	(78)	2021	(77)
Vaginal practices: tissue/toilet paper/cloth inside the vagina prior 3 months	56	(35)	543	(23)	599	(23)
Enrollment location						
Malawi	16	(10)	256	(10)	272	(10)
South Africa	87	(54)	1325	(54)	1412	(54)
Uganda	38	(24)	214	(9)	252	(10)
Zimbabwe	21	(13)	657	(27)	678	(26)

[a]Received money, goods, gifts, drugs, or shelter in exchange for sex in past year.
[b]Defined by 7 or more alcoholic drinks per week or drinking alcohol 2 or more times per week.
[c]Last vaginal sex act without use of a male or female condom.
[d]Positive for Chlamydia, Gonorrhea, and/or Trichomoniasis prior to enrollment.
[e]2629 women were enrolled but 15 did not complete the baseline ACASI and therefore are missing data on recent history of transactional sex.

Table 2. Dapivirine vaginal ring acceptability among those who reported engaging in transactional sex prior to enrollment ($n = 162$), collected via ACASI at Month-3 and Product Use End Visit (PUEV).

	Month-3		PUEV	
	N	(%)	*N*	(%)
Total completed visit	155		148	
Total completed ACASI	152		131[b]	
Total who used ring in past 3 months[a]	142	(93)	118	(90)
Use attributes: Ease and comfort of use				
Difficulty with insertion at last insertion				
Not difficult at all	118	(83)	109	(92)
Very/somewhat difficult	23	(16)	8	(7)
Never inserted ring in past 3 months	1	(1)	1	(1)
Difficulty with removal at last removal				
Not difficult at all	111	(78)	84	(71)
Very/somewhat difficult	20	(14)	19	(16)
Never took out ring in past 3 months	11	(8)	15	(13)
Use attributes: Physical sensation in situ				
In past 3 months, comfort with wearing ring every day				
Usually comfortable	121	(85)	106	(90)
Sometimes/usually uncomfortable	21	(15)	12	(10)
In past 3 months, frequency of awareness during normal daily activities				
Never	106	(75)	90	(76)
Most/some of the time	36	(25)	28	(24)
Effects on sex				
In past 3 months, frequency felt ring during sex				
Never	90	(63)	75	(64)
Most/some of the time	49	(35)	39	(33)
Did not have sex in past 3 months	3	(2)	4	(3)
In past 3 months, any partners felt ring during sex				
No	83	(58)	67	(57)
Yes	33	(23)	23	(19)
Don't know	23	(16)	24	(20)
Did not have sex in past 3 months	3	(2)	4	(3)
Overall impressions of the ring (PUEV only, N = 131)				
Minded wearing ring during menses				
No	Na		71	(54)
Yes	Na		44	(34)
Did not have menses during the study	Na		14	(11)
Did not wear ring during menses	Na		2	(2)
Ring's effect on sexual pleasure				
Increases sexual pleasure	Na		52	(40)
Does not change pleasure	Na		74	(57)
Decreases sexual pleasure	Na		5	(4)
Minded wearing ring during sex				
No	Na		82	(63)
Yes	Na		48	(37)
Ring acceptable to primary partner				
Yes	Na		88	(67)
No	Na		21	(16)
Don't know	Na		22	(17)
Likelihood of future use				
Very likely	Na		87	(66)
Likely	Na		39	(30)
Unlikely	Na		0	(0)
Very unlikely	Na		5	(4)

[a]Participants may have been on a product hold for pregnancy, adverse experience, or another reason.
[b]148 (91%) completed the PUEV ACASI, but because of electronic transmission errors, ACASI responses are missing for $n = 17$.
Na: Not applicable; question was not asked.

to use the ring in the future, with two-thirds (66%) saying that they were "very likely" to wear a ring in the future. When asked about the ring's effect on sexual pleasure, 40% reported it increased pleasure, 57% reported that it did not change pleasure and, 4% said it decreased pleasure, although reasons behind these responses were not captured.

At the PUEV, women who had exchanged sex were more likely to report feeling the ring during sex (adjusted predicted percentage [PP] 33% versus 23%; ARR 1.43, 95% CI: 1.09, 1.89; $p = 0.01$) and slightly more likely to mind wearing the ring during menses (PP 22% vs 18%; ARR 1.22, 95% CI: 1.01, 1,46; $p = 0.04$) and during sex (PP 22% vs 18%; ARR 1.22, 95% CI: 1.02, 1.45; $p = 0.03$) compared to women who had not reported exchanging sex prior to enrollment (Figure 1). They were also more likely to report having multiple sex partners in the 3 months prior to the

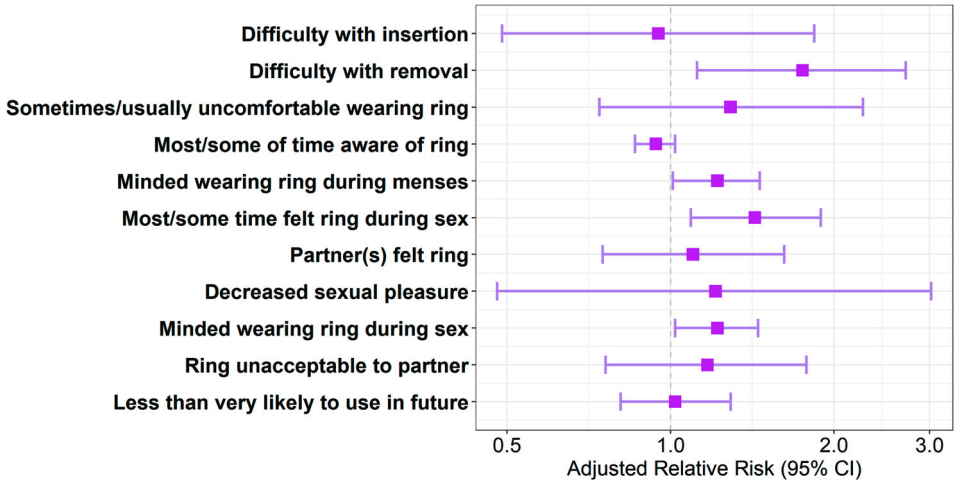


Figure 1. Comparing acceptability challenges reported at PUEV among women who reported engaging in transactional sex in year prior to enrollment to those who had not. Each model adjusted for country, treatment arm, and months of follow-up ($N = 2219$).

PUEV (PP 16% versus 10%; ARR 1.64, 95% CI: 1.18, 2.30; $p = 0.004$) and had more vaginal sex acts in the past week (mean 4.1 times versus 2.4 times; adjusted mean difference = 1.8, 95% CI: 0.99, 2.60; $p < 0.001$). They were as likely to have reported any anal sex in the past 3 months (9%, ARR 1.08, 95% CI: 0.62, 1.88; $p = 0.78$). Women who said they had exchanged sex were not more likely to report that their partner(s) had felt the ring during sex (ARR 1.10, 95% CI 0.75, 1.62), and they were not significantly more likely to note that their partner found the ring unacceptable (ARR 1.17, 95% CI 0.76, 1.78). Though difficulty with ring removal was reported by few women who had engaged in transactional sex ($n = 19$), they were more likely to note difficulty at last removal (PP 18% vs 10%; ARR 1.75, 95% CI: 1.12, 2.71; $p = 0.01$). Despite some differences in acceptability, women who had engaged in transactional sex were equally as willing to use the ring in the future ("very likely" ARR 0.98; 95% CI: 0.87, 1.11; $p = 0.78$).

Discussion

Overall, acceptability of the monthly dapivirine vaginal ring for HIV prevention was high among women who reported transactional sex in the year prior to enrollment, with these women perceiving the ring to be easy to use, comfortable and most reporting an interest in using the ring in the future when it is available for HIV prevention. Ring acceptability did not differ by reported engagement in transactional sex and findings are similar to prior research showing acceptability of the ring to prevent HIV among a larger population of healthy, HIV uninfected women and to prevent pregnancy (Griffin et al., 2019; Montgomery et al., 2017). Further, women who reported transactional sex were more vulnerable to HIV than women who did not report transactional sex; they had more STIs, were more likely to have multiple partners and more vaginal sex acts in the past week. Given their greater risk of HIV as well as the high acceptability of the ring, women who engage in transactional sex are an important population to be offered the ring when it becomes available. Since the ring only protects against infection from vaginal sex, other prevention methods such as oral pre-exposure prophylaxis should be encouraged for anyone engaging in anal sex. The availability of multiple PrEP products allows women to find the one that best fits their needs and preferences, and the ring provides women with a long-acting, user-controlled, immediately reversible option.

In terms of challenges with the ring, women exchanging sex prior to enrollment were more likely to note difficulty at last removal than those who did not report exchanging sex. These findings suggest the need for an added emphasis on counseling and training on proper insertion/removal of the ring in this population as part of adherence related support and education during roll-out. Additionally, women who had exchanged sex were more likely to report feeling the ring during sex and slightly more likely to mind wearing the ring during menses and during sex. Messaging and discussion of the effect and noticeability of the ring during sex and menses may be an important when counseling on use of the vaginal ring versus other HIV prevention options. Although vaginal rings can be noticed during sex, a recent systematic review indicated that generally sex partners don't mind having sex with a ring in situ, even if they feel it (Ridgeway et al., 2022).

Data in our study are from a randomized phase III trial, and there may be some social desirability bias in answers about ring preferences or acceptability whereby users may respond in a more favorable manner. Acceptability of the ring was assessed independent of its efficacy. As the availability of PrEP products continues to increase, the acceptability of the ring may change in context of choice among highly effective products. Nonetheless, a vaginal ring as a PrEP delivery mechanism was found to be a highly acceptable. Additionally, we measured self-reported transactional sex and were unable to differentiate acceptability by transactional sex versus women engaged in formal sex work. Sexual exchange occurs along a spectrum, and the motivations underlying formal sex work versus transactional sex may vary, leading to differences in perceived HIV risk and differences in preferences for HIV prevention products (Kilburn et al., 2018; UNAIDS, 2018b; Wamoyi et al., 2016). Women who engage in transactional sex may be less likely to access HIV and other health services, and may therefore be a population in particular need of targeted services (Hensen et al., 2019). Differing recruitment strategies across sites resulted in over representation of women exchanging sex from Uganda; however, modeling results adjusted for country to adjust for geographic and cultural differences. Lastly, detailed information from casual partners was not collected and partners are known to have an important influence on product use (Mayo et al., 2021; Montgomery et al., 2017; Roberts et al., 2020).

This study provides evidence showing high acceptability of the dapivirine vaginal ring to prevent HIV among women who engaged in transactional sex. Challenges using the ring among this population were related to use during sex and menses. Messaging and counseling should emphasize how to use the ring during sex and menses to encourage persistent use. And, more broadly, as the choice of PrEP products continues to increase, counseling should focus on helping women select an HIV prevention method that will be most acceptable for them.

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