CSIRO PUBLISHING

RESEARCH ARTICLE
https://doi.org/10.1071/SH25270

SEXUAL HEALTH

# Changes in sexual behavior among women in studies evaluating the dapivirine vaginal ring for HIV prevention

Kudzai Hlahla[A,*], Moni Neradilek[B], Morgan Garcia[C], Felix Mhlanga[A], Thesla Palanee-Phillips[D,E], Krishnaveni Reddy[D], Nishanta Singh[F], Carolyne A. Akello[G], Samantha Siva[F], Leila E. Mansoor[H], Cindy E. Jacobson[I], Brenda Gati[G] and Jennifer E. Balkus on behalf of the MTN-020/ASPIRE and MTN-025/HOPE Study Teams[J]

For full list of author affiliations and declarations see end of paper

***Correspondence to:**
Kudzai Hlahla
Clinical Trials Research Center, University of Zimbabwe Faculty of Medicine and Health Sciences, Harare, Zimbabwe
Email: khlahla@uz-ctrc.org

**Handling Editor:**
Dan Wu

**Received:** 17 December 2025
**Accepted:** 28 July 2026
**Published:** 20 August 2026

**Cite this:** Hlahla K *et al.* (2026) Changes in sexual behavior among women in studies evaluating the dapivirine vaginal ring for HIV prevention. *Sexual Health* **23**, SH25270. doi:10.1071/SH25270



## ABSTRACT

**Background.** Access to novel HIV prevention technologies often raise concerns of risk compensation. This analysis examined changes in the sexual behaviors of MTN 020/ASPIRE participants, a placebo controlled randomized control trial, who subsequently enrolled in MTN-025/HOPE, an open-label extension using the dapivirine vaginal ring. **Methods.** Both studies enrolled healthy, sexually active, HIV-negative women from Malawi, South Africa, Uganda and Zimbabwe. Longitudinal data on participants' sexual behaviors, specifically sex with a nonprimary partner (past 3 months), and use of male or female condoms at the last vaginal sex act were compared between ASPIRE and HOPE. Conditional and mixed ordinal logistic regression models evaluated associations between study and sexual behaviors at enrollment, and quarterly over the first 12 months. **Results.** Of the 2629 individuals enrolled in ASPIRE, 1456 (55%) participated in HOPE. At enrollment, the proportion of participants who reported sex with a nonprimary partner and condom use at last vaginal sex act did not differ by study. Across all quarterly follow-up visits, sex with a nonprimary partner was more common in HOPE (13.9–18.7%) than ASPIRE (10.7–12.6%); adjusted OR 1.47, 95% CI 1.24–1.75, $P < 0.001$. There was no difference in condom use at the last vaginal act across all quarterly follow-up visits between ASPIRE (36.5–42.7%) and HOPE (43.6–46.7%); adjusted OR 1.05, 95% CI 0.94–1.18. **Conclusion.** More women reported sex with nonprimary partners in HOPE, with little change in condom use over time between the two studies. Understanding behavior changes during PrEP use allows for tailored, holistic reproductive health programming.

**Keywords:** Africa, dapivirine vaginal ring, HIV, risk compensation, sexual behavior, sexual transmitted infection, women.

## Introduction

Despite the decline in the incidence of HIV globally, countries in sub-Saharan Africa continue to bear the brunt of the epidemic, accounting for more than half of all new HIV infections in 2024.[1] In the same year, 37% of new HIV infections were in Southern and Eastern Africa, where 140,000 adolescent girls and young women (AGYW) aged 15–24 years acquired HIV in this region.[1] African AGYW are notably disproportionately affected by the HIV epidemic, as they are three times more likely to acquire HIV than their male counterparts, accounting for 63% of all new infections in the region.[1–3] As such, the successful development of antiretroviral-based HIV prevention methods has been hailed as a critical step in HIV prevention.[2] Pre-exposure prophylaxis (PrEP) in the form of pills containing tenofovir and emtricitabine, injectable cabotegravir and lenacapavir, and the dapivirine vaginal ring (DVR) have been shown to be safe and effective HIV prevention intervention tools.[4–8] However, the introduction of these methods comes with the concern of potential risk compensation from key stakeholders, such as clinicians and policymakers.[9,10]

Defined as an increase in behaviors that may increase the likelihood of transmission of sexually transmitted infections (STI), including HIV, in response to a reduction in the

perceived level of risk or increased sense of protection, risk compensation has been studied in various health-related domains, including sexual health.[10–15] Observational and randomized controlled trials (RCT) exploring risk compensation around HIV prevention methods in various populations have yielded mixed results. Studies involving oral PrEP, topical microbicides and candidate vaccines, mostly among men who have sex with men, have reported an increase in sex with multiple partners, a decrease in condom use and an increase in STI incidence.[16–19] Others showed no evidence of changes in sexual behaviors.[20–24] Studies among heterosexual sero-different couples within the African context have shown similar results, with no evidence of risk compensation in the form of an increase in condomless sex acts or the number of nonprimary partners with the use of oral PrEP.[15,25,26] A study conducted in Uganda to assess risk compensation in African women who had been enrolled in a placebo-controlled RCT using the DVR found a decrease in the number of sexual partners and STI diagnoses in women using the DVR with continued study participation.[27] However, to our knowledge, risk compensation has not been studied in African women who have transitioned from an RCT evaluating the effectiveness of an HIV prevention tool, to a follow-up, open-label extension study (OLE) where participants were aware of the efficacy of the study product.

As new HIV prevention products become available, it is imperative to understand if and how their use impacts sexual behavior and possibly STI incidence among different user groups. Understanding the interaction between PrEP and sexual reproductive health needs will help inform the future design, implementation, and evaluation of effective and holistic HIV prevention and sexual reproductive health programs focused on cisgender women and other at-risk populations. In this analysis, we aimed to examine whether sexual behavior changed over time among women who transitioned from an RCT evaluating the effectiveness of the DVR to a follow-up OLE study where they accessed the DVR and were aware of its levels of efficacy in HIV prevention.

## Methods

### Population

This retrospective analysis compared data from two studies conducted by the Microbicide Trials Network (MTN): MTN-020/ASPIRE and MTN-025/HOPE. The details of both studies have been previously published.[5,28] In brief, ASPIRE was a multisite, double-blind, randomized, placebo-controlled phase III trial that evaluated the safety and effectiveness of the 25-mg DVR versus placebo for HIV prevention [clinical trials #NCT01617096]. Between August 2012 and June 2014, 2629 healthy, sexually active, HIV-negative, nonpregnant women aged 18–45 years were enrolled across 15 clinical research sites in Malawi, South Africa, Uganda, and Zimbabwe. Participants were followed for a median duration of 1.6 years, with the results demonstrating a 27% reduction in HIV incidence compared with that of the placebo group. Following the demonstration of HIV prevention effectiveness, former ASPIRE participants were invited to participate in HOPE [clinical trials # NCT02858037], an OLE study of the DVR. Between July 2016 and October 2018, HOPE enrolled only HIV-negative nonpregnant former ASPIRE participants. Those who enrolled could choose to accept DVR use immediately at enrollment or choose to not use the DVR until they were ready to do so. Participants were followed for a maximum of 13 months. Results from the HOPE study showed a 39% reduction in HIV incidence.[28] This analysis included women who participated in both studies, where they elected to use the DVR, and completed at least one follow-up visit in both ASPIRE and HOPE.

### Study procedures and data collection

In ASPIRE, participants attended monthly follow-up visits. In HOPE, participants attended monthly visits for the first 3 months and then quarterly visits thereafter. At follow-up visits for both studies, participants received HIV risk reduction counseling, HIV testing, pregnancy testing, study product adherence counseling, safety monitoring, provision of study product, provision of free male and female condoms, and STI testing and treatment. Both studies utilized standardized interviewer-administered questionnaires in the participant's preferred language to collect data on participant characteristics, including demographic information, clinical factors and sexual behaviors.

### Statistical analysis

This analysis compared sexual behaviors reported at the enrollment, months 3, 6, 9 and 12, and study exit visits (1 month after returning the DVR to the site and stopping usage) by women who had participated in both ASPIRE and HOPE, attended the visits, and completed questionnaires that included the outcomes of interest. Three self-reported sexual behaviors were assessed in both studies: (i) sex partner other than a primary sex partner in the past 3 months; (ii) percentage of vaginal sex acts in the past 7 days with a male or female condom used; and (iii) use of a male or female condom at the last vaginal sex act. The percentage of sex acts with a condom was calculated by dividing the reported number of vaginal sex acts with a condom in the past 7 days by the reported number of vaginal sex acts in the past 7 days and was subsequently categorized as 0% (no condom use reported), 1–99% (some condom use reported), 100% (always using condoms) or no sex acts. Factors included as potential confounders in the adjusted models were selected *a priori*, and included age, parity, contraception, earning one's own income, alcohol consumption and a change in primary sexual partner during follow up. Unadjusted and adjusted odds ratios to determine the associations between each sexual behavior and the two studies (ASPIRE as the reference) were calculated

using conditional logistic regression for binary outcomes (i and ii) and mixed ordinal logistic regression for ordinal outcomes (iii). *P*-values <0.05 were considered statistically significant and all analyses were conducted using R version 3.5.3 (R Core Team, Vienna, Austria).

## Results

Of the 2629 women enrolled in ASPIRE, 1456 (55.4%) women enrolled in HOPE, completed at least one follow-up visit and were eligible for this analysis. Overall, participant characteristics at enrollment in the respective studies were similar, with relatively minor changes in the number of live births, education level, marital status or partner awareness of DVR use (Table 1). As expected, given that the same cohort was enrolled in both studies, the median age at enrollment in HOPE [31 years (IQR 27–36 years)] was greater than that in ASPIRE [27 years (IQR 23–33 years)]. The most used contraceptive in both studies was intramuscular depot medroxyprogesterone acetate (32.0% in HOPE and 38.8% in ASPIRE).

Regarding sexual behavior at enrollment, the median (IQR) number of vaginal sex acts in the past 3 months was lower when women were enrolled in HOPE [15 (6–36)] vs ASPIRE [20 (8–36)]. At enrollment, the proportion of participants who reported sex with a nonprimary partner in the past 3 months did not differ between HOPE and ASPIRE (18.7% vs 16.9%; adjusted OR 1.19 (95% CI 0.85–1.66). A lower proportion of participants reported condom use at last

**Table 1.** Participant characteristics by study at enrollment.

| | ASPIRE | | | HOPE | | |
|---|---|---|---|---|---|---|
| | *N* | Mean ± s.d. (range) or *n* (%) | Median (IQR) | *N* | Mean ± s.d. (range) or *n* (%) | Median (IQR) |
| Age | 1455 | 28.3 ± 6.4 (18–45) | 27 (23–33) | 1456 | 32.0 ± 6.5 (20–49) | 31 (27–36) |
| Age (years) | 1455 | | | 1456 | | |
| 18–21 | | 236 (16.2%) | | | 9 (0.6%) | |
| 22–26 | | 416 (28.6%) | | | 333 (22.9%) | |
| ≥27 | | 803 (55.2%) | | | 1114 (76.5%) | |
| No. of pregnancies | 1456 | 2.4 ± 1.6 (0–17) | 2 (1–3) | 1456 | 2.6 ± 1.6 (0–16) | 2 (1–3) |
| No. of live births | 1456 | 2.2 ± 1.5 (0–10) | 2 (1–3 | 1456 | 2.4 ± 1.4 (0–10) | 2 (1–3) |
| Secondary school education or higher | 1456 | 1197 (82.2%) | | 1456 | 1196 (82.1%) | |
| Earns own income | 1456 | 665 (45.7%) | | 1456 | 889 (61.1%) | |
| Currently married | 1456 | 676 (46.4%) | | 1456 | 686 (47.1%) | |
| Partner aware of DVR use | 1447 | 952 (65.8%) | | 1396 | 952 (68.2%) | |
| No. of episodes of vaginal intercourse in the past 3 months | 1456 | 27.6 ± 24.8 (0–99) | 20 (8–36) | 1456 | 23.6 ± 22.8 (0–99) | 15 (6–36) |
| Anal sex in the previous 3 months | 1455 | 36 (2.5%) | | 1456 | 12 (0.8%) | |
| Transactional sex in past year (ACASI) | 1447 | 89 (6.2%) | | 1445 | 107 (7.4%) | |
| The primary contraceptive method | 1456 | | | 1456 | | |
| IUD | | 197 (13.5%) | | | 265 (18.2%) | |
| Implant | | 301 (20.7%) | | | 345 (23.7%) | |
| DEPO | | 565 (38.8%) | | | 466 (32.0%) | |
| NET-EN | | 190 (13.0%) | | | 102 (7.0%) | |
| Sterilization | | 61 (4.2%) | | | 72 (4.9%) | |
| Oral | | 142 (9.8%) | | | 206 (14.1%) | |
| Chlamydia | 1456 | 127 (8.7%) | | 1456 | 129 (8.9%) | |
| Gonorrhea | 1456 | 44 (3.0%) | | 1456 | 27 (1.9%) | |
| Trichomonas | 1454 | 97 (6.7%) | | 1456 | 80 (5.5%) | |
| No. of alcohol drinks per week | 1456 | 0.7 ± 2.7 (0–35) | 0 (0–0) | 1456 | 1.1 ± 4.7 (0–99) | 0 (0–0) |
| Any alcohol drinks per week | 1456 | | | 1456 | | |
| None | | 1273 (87.4%) | | | 1178 (80.9%) | |
| Any | | 183 (12.6%) | | | 278 (19.1%) | |

ACASI, audio computer-assisted self-interview; IUD, intrauterine device; DEPO, Depo-Provera; NET-EN, norethisterone enanthate.

vaginal sex act when they were enrolled in HOPE compared with ASPIRE, (HOPE = 43.3% vs ASPIRE = 45.0%; Table 2). The corresponding unadjusted and adjusted odds ratios were 0.91 (95% CI 0.77–1.08) and 0.73 (95% CI 0.58–0.93), respectively (Table 3).

Across all follow-up visits, sex with a nonprimary partner was reported more frequently in HOPE than in ASPIRE (Fig. 1, panel *a*). The adjusted odds ratio (pooling the enrollment and quarterly follow-up visits) also illustrated a greater frequency of sex with a nonprimary partner reported in HOPE than in ASPIRE (OR 1.47, 95% CI 1.24–1.75; Table 3). The frequency of condom use at last vaginal sex reported during enrollment and the quarterly follow-up visits did not differ by study and ranged from 43.6 to 46.2% in HOPE and from

**Table 2.** Sexual behaviors of participants by study visit in ASPIRE (MTN-020) and HOPE (MTN-025).

| Outcome | Group | Category | ASPIRE | | | HOPE | | |
|---|---|---|---|---|---|---|---|---|
| | | | *N* | *n* | % (95% CI) | *N* | *n* | % (95% CI) |
| Nonprimary partner (3 months) | Enrollment | | 1456 | 246 | 16.9 (15.0–18.9) | 1456 | 272 | 18.7 (16.7–20.8) |
| | Q1 | | 1405 | 177 | 12.6 (10.9–14.4) | 1405 | 263 | 18.7 (16.7–20.9) |
| | Q2 | | 1374 | 156 | 11.4 (9.7–13.2) | 1374 | 227 | 16.5 (14.6–18.6) |
| | Q3 | | 1342 | 146 | 10.9 (9.3–12.7) | 1342 | 188 | 14.0 (12.2–16.0) |
| | Q4 | | 1360 | 145 | 10.7 (9.1–12.4) | 1360 | 189 | 13.9 (12.1–15.9) |
| Condom (last vaginal sex) | Enrollment | | 1448 | 652 | 45.0 (42.4–47.6) | 1448 | 627 | 43.3 (40.7–45.9) |
| | Q1 | | 1397 | 596 | 42.7 (40.1–45.3) | 1397 | 645 | 46.2 (43.5–48.8) |
| | Q2 | | 1370 | 572 | 41.8 (39.1–44.4) | 1370 | 624 | 45.5 (42.9–48.2) |
| | Q3 | | 1337 | 546 | 40.8 (38.2–43.5) | 1337 | 583 | 43.6 (40.9–46.3) |
| | Q4 | | 1361 | 529 | 38.9 (36.3–41.5) | 1361 | 600 | 44.1 (41.4–46.8) |
| | Last | | 1451 | 530 | 36.5 (34.0–39.1) | 1451 | 678 | 46.7 (44.1–49.3) |
| Vaginal sex acts with condom (7 days) | Enrollment | Never | 1447 | 451 | 31.2 (28.8–33.6) | 1447 | 551 | 38.1 (35.6–40.6) |
| | | Sometimes | 1447 | 210 | 14.5 (12.7–16.4) | 1447 | 125 | 8.6 (7.2–10.2) |
| | | Always | 1447 | 490 | 33.9 (31.4–36.4) | 1447 | 341 | 23.6 (21.4–25.8) |
| | | No sex | 1447 | 296 | 20.5 (18.4–22.6) | 1447 | 430 | 29.7 (27.4–32.1) |
| | Q1 | Never | 1405 | 473 | 33.7 (31.2–36.2) | 1405 | 516 | 36.7 (34.2–39.3) |
| | | Sometimes | 1405 | 203 | 14.4 (12.7–16.4) | 1405 | 143 | 10.2 (8.6–11.9) |
| | | Always | 1405 | 434 | 30.9 (28.5–33.4) | 1405 | 400 | 28.5 (26.1–30.9) |
| | | No sex | 1405 | 295 | 21.0 (18.9–23.2) | 1405 | 346 | 24.6 (22.4–27.0) |
| | Q2 | Never | 1372 | 470 | 34.3 (31.7–36.8) | 1372 | 536 | 39.1 (36.5–41.7) |
| | | Sometimes | 1372 | 180 | 13.1 (11.4–15.0) | 1372 | 122 | 8.9 (7.4–10.5) |
| | | Always | 1372 | 433 | 31.6 (29.1–34.1) | 1372 | 373 | 27.2 (24.8–29.6) |
| | | No sex | 1372 | 289 | 21.1 (18.9–23.3) | 1372 | 341 | 24.9 (22.6–27.2) |
| | Q3 | Never | 1341 | 455 | 33.9 (31.4–36.5) | 1341 | 543 | 40.5 (37.9–43.2) |
| | | Sometimes | 1341 | 188 | 14.0 (12.2–16.0) | 1341 | 92 | 6.9 (5.6–8.3) |
| | | Always | 1341 | 402 | 30.0 (27.5–32.5) | 1341 | 346 | 25.8 (23.5–28.2) |
| | | No sex | 1341 | 296 | 22.1 (19.9–24.4) | 1341 | 360 | 26.8 (24.5–29.3) |
| | Q4 | Never | 1362 | 473 | 34.7 (32.2–37.3) | 1362 | 542 | 39.8 (37.2–42.5) |
| | | Sometimes | 1362 | 169 | 12.4 (10.7–14.3) | 1362 | 111 | 8.1 (6.8–9.7) |
| | | Always | 1362 | 396 | 29.1 (26.7–31.6) | 1362 | 353 | 25.9 (23.6–28.3) |
| | | No sex | 1362 | 324 | 23.8 (21.5–26.1) | 1362 | 356 | 26.1 (23.8–28.6) |
| | Last | Never | 1454 | 516 | 35.5 (33.0–38.0) | 1454 | 539 | 37.1 (34.6–39.6) |
| | | Sometimes | 1454 | 148 | 10.2 (8.7–11.8) | 1454 | 105 | 7.2 (5.9–8.7) |
| | | Always | 1454 | 412 | 28.3 (26.0–30.7) | 1454 | 410 | 28.2 (25.9–30.6) |
| | | No sex | 1454 | 378 | 26.0 (23.8–28.3) | 1454 | 400 | 27.5 (25.2–29.9) |

*N*, sample size; *n*, count; Q, quarterly visit.

**Table 3.** Associations between study (HOPE compared with ASPIRE) and sexual behaviors at baseline and follow-up visit.

| | Unadjusted | | | | Adjusted[A] | | | |
|---|---|---|---|---|---|---|---|---|
| | *N* | *n* | OR (95% CI) | *P* | *N* | *n* | OR (95% CI) | *P* |
| Outcomes at baseline | | | | | | | | |
| Nonprimary partner (3 months) | 1456 | 2912 | 1.18 (0.95–1.47) | 0.144 | 1456 | 2847 | 1.19 (0.85–1.66) | 0.313 |
| Condom (last vaginal sex) | 1448 | 2896 | 0.91 (0.77–1.08) | 0.286 | 1448 | 2832 | 0.73 (0.58–0.93) | 0.009 |
| Vaginal sex acts with a condom in the past 7 days | 1447 | 2894 | 1.06 (0.92–1.22) | 0.415 | 1447 | 2830 | 1.04 (0.89–1.21) | 0.640 |
| Outcomes across baseline and quarterly follow-up visits | | | | | | | | |
| Nonprimary partner (3 months) | 1456 | 13,874 | 1.67 (1.48–1.89) | <0.001 | 1456 | 13,476 | 1.47 (1.24–1.75) | <0.001 |
| Condom (last vaginal sex) | 1456 | 13,826 | 1.18 (1.08–1.28) | <0.001 | 1456 | 13,428 | 1.05 (0.94–1.18) | 0.405 |
| Vaginal sex acts with condom (7 days) | 1456 | 13,854 | 0.99 (0.93–1.06) | 0.873 | 1456 | 13,455 | 1.04 (0.96–1.13) | 0.306 |

*N*, number of participants; *n*, number of observations.
[A]Adjusted for age (categorical), parity, contraception, earning own income, alcohol consumption and partner change. Odds ratios from conditional logistic regressions for the binary outcomes (sex with a nonprimary partner and condom use) and from mixed ordinal logistic regressions for the ordinal outcome (vaginal sex acts).

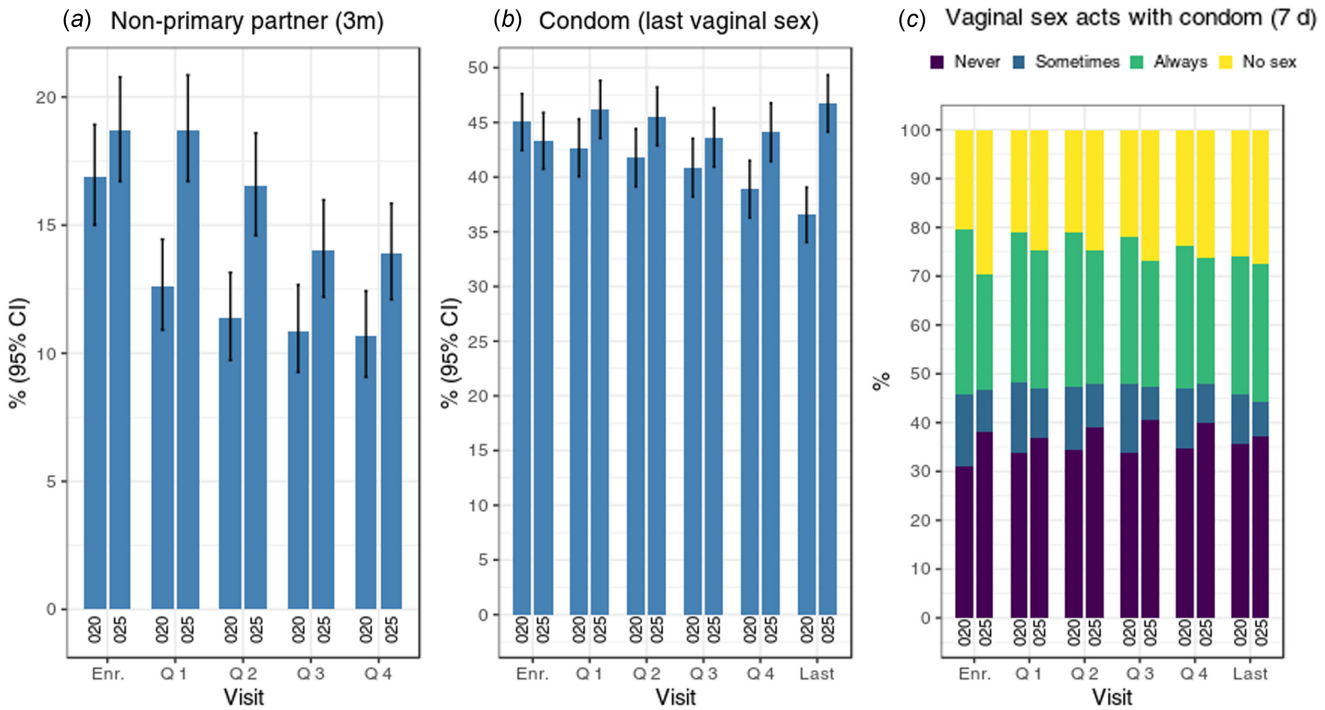


**Fig. 1.** Comparison of the frequency of different sexual behaviors by study visit.

38.9 to 45.0% in ASPIRE (adjusted OR 1.05, 95% CI 0.94–1.18; Tables 2 and 3).

## Discussion

The analysis involved data from women who participated in an HIV prevention trial assessing the effectiveness of the DVR (ASPIRE) and who subsequently transitioned to participate in an OLE study (HOPE), with full knowledge of the effectiveness of the DVR. We found that a greater proportion of women reported sex with a nonprimary partner during the OLE than during the blinded study (ASPIRE). Reported condom use was generally similar across studies during the follow-up period.

Sex with a nonprimary partner was reported more frequently in the HOPE than in the ASPIRE cohort during follow-up visits. This finding contrasts with the findings of studies involving tenofovir and emtricitabine as oral PrEP, in which the prevalence of sex with a nonprimary partner decreased or remained constant over time.[15,16,29] Systematic reviews and meta-analyses evaluating PrEP use among people with a high likelihood of exposure to HIV have shown no

change or an actual decrease in the reported number of sexual partners when comparing data at baseline versus follow-up visits.[25,30] Data from the Partners PrEP trial, in which participants' sexual behavior was analyzed pre- and post-unblinding to determine whether knowledge of PrEP efficacy changed sexual risk behavior, showed a slight increase in sex with an outside additional partner post unblinding, with a statistically significant increase in condomless sex with nonprimary partners.[26]

An increase in the frequency of sex with a nonprimary partner in the HOPE study could be attributed to risk homeostasis theory.[31] When enrolled in HOPE, women might alter their perceived risk compared with when they were in ASPIRE, in light of the known efficacy of the DVR, to a level of acceptable risk they are willing to take, adjusting their behavior accordingly, resulting in increased frequency of sex with a nonprimary partner.[32] Additionally, the increase in reported frequency of sex with a nonprimary partner could reflect reporting bias that is often seen with continued study participation. Under-reporting of sexual behavior that is considered socially undesirable or risky is common for women enrolled in HIV prevention trials.[32] However, prolonged study participation due to transitioning to the open label extension could result in higher reporting rates of sexual behavior as women become more comfortable with the product, procedures such as the CASI and build rapport with study staff, resulting in a decrease in pressure for social desirability.[32] Despite being protected from HIV acquisition by oral PrEP or DVR, as in our case, such adjustments in behavior; for example, increasing the number of sexual partners, could result in increased STI transmission due to the overlapping transmission pathways of HIV and other STIs if other prevention efforts are not undertaken.[16,33] Studies and reports of individuals with a high likelihood of exposure to HIV have shown an association between the use of PrEP and increased STI incidence and recurrence.[34–36] Therefore, the increased incorporation of various PrEP modalities, including the DVR, into national HIV prevention programs and guidelines in Africa warrants continued research into the effect of PrEP use on sexual behavior, such as having multiple partners and any subsequent changes in STI incidence at the individual and community levels.[33]

There was no difference in the frequency of condomless sex acts between HOPE and ASPIRE during the follow-up visits, with results showing an increased frequency of condom use in HOPE compared with ASPIRE only at the last study visit. These results are similar to those of Fonner *et al.* (2016), who, in their meta-analysis, found no difference in condom use when comparing the sexual behavior of participants in the PrEP arm with those in the placebo arm; moreover, neither did the analysis find a difference in condom use between PrEP trials and non-PrEP trials.[30] In addition, the authors found that in some trials, there was a slight increase in condom use with continued trial participation, findings that echo those presented in this current study. We attribute such results to increased personal risk perception, which has been associated with protective behavioral change, including increased use of condoms.[37,38] Studies in South Africa, Mozambique and Zimbabwe have shown that people who have increased risk perception, as is possible among those enrolled in ASPIRE and HOPE, are more likely to use condoms.[37,39,40] Various factors influence risk perception, including being in a long-term relationship compared with having casual partners, a partner's behavior and having socioeconomic dynamics within the sexual relationship.[41] A longitudinal study conducted in Manicaland, Zimbabwe, showed that increased risk perception in women was associated with increased use of condoms, which was attributed to the possibility of marrying a partner living with HIV and the suspicion that their partner had other partner(s).[37] This highlights the need to incorporate assessment of risk and risk perception in HIV risk reduction counseling and PrEP initiation, as well as further research on the economic and social drivers that may affect PrEP uptake, continued use, and associated changes in sexual behavior.

The continued and increased condom use observed in HOPE could also be due to the comprehensive risk reduction package that women received in both trials, which included risk reduction counseling and HIV testing. Risk reduction counseling and HIV testing result in increased self-efficacy, which has been associated with the adoption of HIV prevention tools and services, such as increased condom use, as seen in a trial conducted among women in Mozambique.[27,40] A meta-analysis conducted using data from seven developing countries showed evidence of a moderate and significant increase in protected sex after voluntary counseling and testing.[42] Marcus *et al.* (2013) highlighted that regular counseling and testing in conjunction with the use of HIV prevention tools may increase PrEP users' self-efficacy, allowing for contemplation and management of risk, resulting in sexual practices that reduce HIV exposure.[22] Although debates do exist around the effectiveness of counseling targeted at behavioral change, a consensus has been reached around the importance of providing education and information that allows an individual to understand one's health, risk, and available services to reduce HIV and STI acquisition.[43] As such, it is essential to ensure continued and concurrent access to condoms, HIV testing, and supportive counseling services for women while incorporating PrEP and other HIV prevention products, such as the DVR, into the current basket of HIV prevention tools. This approach will equip women with choices, and empower them to consider their individual context and experiences, which may influence their personal risk perception, sexual reproductive health needs, and eventual uptake and sustained use of current and upcoming PrEP products. As highlighted by Warren *et al.* (2018), '... HIV falls within a much larger and complex hierarchy of concerns extending beyond a disease and entering into deeply personal realms ...'.[41]

Our study has various limitations. First, due to the nature of the study, we were unable to establish a causal relationship

between study participation and sexual behavior, and explanations for changes in sexual behavior were not explored during qualitative study procedures. Second, only 55% of women enrolled in ASPIRE were enrolled in HOPE. Such attrition could have been due to participant aging, change in risk perception and profiles, and change in partner status or seroconversions between the end of ASPIRE (June 2015) and the beginning of HOPE (Aug 2016). The change in the composition of the population may introduce selection bias, with observed changes in sexual behavior being due to differences in the cohorts and not contextual differences between trials. As such, our results are not generalizable to the general population of sexually active women in the sub-Saharan African region. In addition, sexual behavior data were self-reported and subject to social desirability bias and the white coat effect. Although cross-validation with STI incidence in each study could indicate a correlation between changes in sexual behavior and STI incidence, this was not possible in our analysis.

## Conclusion

We found moderate evidence of risk compensation, as indicated by an increase in sex with a nonprimary partner, although without a significant change in self-reported condom use, during the HOPE study, where women were aware of the efficacy of the DVR. Understanding if and how sexual behaviors change with the use of PrEP products, such as the DVR, is important for the development of integrated PrEP and STI programs tailored to the needs of women in sub-Saharan Africa. There is a need for continued efforts to provide a patient-centered, comprehensive risk reduction package, including condom promotion, health education and counseling, and HIV testing, in addition to various PrEP products, thereby giving women choices and empowering them regarding their sexual reproductive health.

## Supplementary material

Supplementary material can be accessed from the article page online.

## References


1 UNAIDS. UNAIDS Global AIDS Update 2025-AIDS, Crisis and the Power to Transform. UNAIDS: Geneva; 2025. Available at https://www.unaids.org/en/UNAIDS-global-AIDS-update-2025
2 UNAIDS. Fact Sheet- World AIDS Day 2021. UNAIDS; 2021. pp. 1–6.
3 HIV/AIDS JUNP on, Joint United Nations Programme on HIV/AIDS (UNAIDS). In Danger- UNAIDS Global AIDS Update 2022. Joint United Nations Programme on HIV/AIDS. UNAIDS; 2022. Available at https://www.unaids.org/en/resources/documents/2022/in-danger-global-aids-update
4 WHO. WHO Implementation Tool for Pre-Exposure Prophylaxis (PrEP) of HIV Infection. WHO; 2018.
5 Baeten JM, Palanee-Phillips T, Brown ER, Schwartz K, Soto-Torres LE, Govender V, *et al.* Use of a Vaginal Ring Containing Dapivirine for HIV-1 Prevention in Women. *N Engl J Med* 2016; 375(22): 2121–32. doi:10.1056/nejmoa1506110
6 Nel A, van Niekerk N, Van Baelen B, Malherbe M, Mans W, Carter A, *et al.* Safety, adherence, and HIV-1 seroconversion among women using the dapivirine vaginal ring (DREAM): an open-label, extension study. *Lancet HIV* 2021; 8(2): e77–86. doi:10.1016/S2352-3018(20)30300-3
7 WHO. WHO recommends long-acting cabotegravir for HIV prevention. WHO; 2022. Available at https://www.who.int/news/item/28-07-2022-who-recommends-long-acting-cabotegravir-for-hiv-prevention [accessed 2023 Feb 15]
8 Landovitz RJ, Donnell D, Clement ME, Hanscom B, Cottle L, Coelho L, *et al.* Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women. *N Engl J Med* 2021; 385(7): 595–608. doi:10.1056/nejmoa2101016
9 Jansen MPM, Tromp N, Baltussen R. PrEP: Why we are waiting. *Lancet HIV* 2016; 3(1): e11–2. doi:10.1016/S2352-3018(15)00250-7
10 Marcus JL, Katz KA, Krakower DS, Calabrese SK, Adminis D. Risk Compensation and Clinical Decision Making-The case of HIV PREP. *N Engl J Med* 2019; 380(6): 510–2.
11 Levym DT, Miller T. Review: Risk Compensation Literature—The Theory and Evidence. *J Crash Prev Inj Control* 2000; 2(1): 75–86. doi:10.1080/10286580008902554
12 Prasad V, Jena AB. The Peltzman effect and compensatory markers in medicine. *Healthcare (Basel)* 2014; 2(3): 170–2. doi:10.1016/j.hjdsi.2014.05.002
13 Secura GM, Adams T, Buckel CM, Zhao Q, Peipert JF. Change in Sexual Behavior With Provision of No-Cost Contraception. *NIH Public Access-Obstet Gynecol* 2014; 123(4): 771–6. doi:10.1097/AOG.0000000000000184.Change
14 Nyirenda HT, Mukanga B, Choka N, Jegede AI, Mulenga D, Nyirenda HBC, *et al.* Sexual behaviour and risk compensation among single women of reproductive age using hormonal contraception in Zambia. *Eur J Contracept Reprod Health Care* 2021; 26(3): 255–60. doi:10.1080/13625187.2021.1874335
15 Ortblad KF, Stalter RM, Bukusi EA, Ngure K, Mujugura A, Celum C, *et al.* No Evidence of Sexual Risk Compensation Following PrEP Initiation Among Heterosexual HIV Serodiscordant Couples in Kenya and Uganda. *AIDS Behav* 2020; 24(5): 1365–75. doi:10.1007/s10461-019-02720-4
16 Kumar S, Haderxhanaj LT, Spicknall IH. Reviewing PrEP's Effect on STI Incidence Among Men Who Have sex with Men—Balancing Increased STI Screening and Potential Behavioral Sexual Risk Compensation. *AIDS Behav* 2021; 25(6): 1810. doi:10.1007/S10461-020-03110-X
17 Hoornenborg E, Coyer L, Achterbergh RCA, Matser A, Schim van der Loeff MF, Boyd A, *et al.* Sexual behaviour and incidence of HIV and sexually transmitted infections among men who have sex with men using daily and event-driven pre-exposure prophylaxis in AMPrEP: 2 year results from a demonstration study. *Lancet HIV* 2019; 6(7): e447–55. doi:10.1016/S2352-3018(19)30136-5
18 Montaño MA, Dombrowski JC, Dasgupta S, Golden MR, Duerr A, Manhart LE, *et al.* Changes in Sexual Behavior and STI Diagnoses Among MSM Initiating PrEP in a Clinic Setting. *AIDS Behav* 2019; 23(2): 548–55. doi:10.1007/S10461-018-2252-9/METRICS
19 Ramchandani MS, Golden MR. Confronting Rising STIs in the Era of PrEP and Treatment as Prevention. *Curr HIV/AIDS Rep* 2019; 16(3): 244–56. doi:10.1007/S11904-019-00446-5/METRICS
20 Blumenthal J, Haubrich R. Risk compensation in PrEP: An old debate emerges yet again. *Virtual Mentor* 2014; 16(11): 909–15. doi:10.1001/virtualmentor.2014.16.11.stas1-1411.Risk
21 Shi CF, Li M, Dushoff J. Evidence that promotion of male circumcision did not lead to sexual risk compensation in prioritized Sub-Saharan countries. *PLoS One* 2017; 12(4): 1–12. doi:10.1371/journal.pone.0175928
22 Marcus JL, Glidden DV, Mayer KH, Liu AY, Buchbinder SP, Amico KR, *et al.* No Evidence of sexual risk compensation in the iPrEx trial of daily oral HIV preexposure prophylaxis. *PLoS One* 2013; 8(12): e81997. doi:10.1371/journal.pone.0081997
23 Sagaon-Teyssier L, Suzan-Monti M, Demoulin B, Capitant C, Lorente N, Préau M, *et al.* Uptake of PrEP and condom and sexual risk behavior among MSM during the ANRS IPERGAY trial. *AIDS Care*

*Psychol Socio-Med Asp AIDS/HIV* 2016; 28: 48–55. doi:10.1080/09540121.2016.1146653
24 Hojilla JC, Koester AK, Cohen ES, Buchbinder S, Ladzekpo D, Matheson T, Liu YA. Sexual Behavior, Risk Compensation and HIV Prevention Strategies Among Participants in a San Francisco PrEP Demonstartion Project: A Qualitative Analysis of Counseling Notes. *AIDS Behav* 2017; 176(3): 139–48. doi:10.1007/s10461-015-1055-5.Sexual
25 Murchu E, Marshall L, Teljeur C, Harrington P, Hayes C, Moran P, *et al.* Oral pre-exposure prophylaxis (PrEP) to prevent HIV: a systematic review and meta-analysis of clinical effectiveness, safety, adherence and risk compensation in all populations. *BMJ Open* 2022; 12(5): e048478. doi:10.1136/bmjopen-2020-048478
26 Mugwanya KK, Donnell D, Celum C, Thomas KK, Ndase P, Mugo N, *et al.* Sexual behaviour of heterosexual men and women receiving antiretroviral pre-exposure prophylaxis for HIV prevention: A longitudinal analysis. *Lancet Infect Dis* 2013; 13(12): 1021–8. doi:10.1016/S1473-3099(13)70226-3
27 Kusemererwa S, Abaasa A, Kabarambi A, Onyango M, Mugisha JO. Assessment of risk compensation following use of the dapivirine vaginal ring in southwestern Uganda. *Sex Transm Infect* 2022; 98(1): 32–7. doi:10.1136/sextrans-2020-054718
28 Baeten JM, Palanee-Phillips T, Mgodi NM, Mayo AJ, Szydlo DW, Ramjee G, *et al.* Safety, uptake, and use of a dapivirine vaginal ring for HIV-1 prevention in African women (HOPE): an open-label, extension study. *Lancet HIV* 2021; 8(2): e87–95. doi:10.1016/S2352-3018(20)30304-0
29 Van Damme L, Corneli A, Ahmed K, Agot K, Lombaard J, Kapiga S, *et al.* Preexposure Prophylaxis for HIV Infection among African Women. *N Engl J Med* 2012; 367(5): 411–22. doi:10.1056/nejmoa1202614
30 Fonner VA, Dalglish SL, Kennedy CE, Baggaley R, O'Reilly KR, Koechlin FM, *et al.* Effectiveness and safety of oral HIV preexposure prophylaxis for all populations. *AIDS* 2016; 30(12): 1973–83. doi:10.1097/QAD.0000000000001145
31 Wilde GJS. Risk homeostasis theory: An overview. *Inj Prev* 1998; 4(2): 89–91. doi:10.1136/ip.4.2.89
32 Glynn JR, Kayuni N, Banda E, Parrott F, Floyd S, Francis-Chizororo M, *et al.* Assessing the validity of sexual behaviour reports in a whole population survey in rural Malawi. *PLoS One* 2011; 6(7): e22840. doi:10.1371/journal.pone.0022840
33 Quaife M, MacGregor L, Ong JJ, Gafos M, Torres-Rueda S, Grant H, *et al.* Risk compensation and STI incidence in PrEP programmes. *Lancet HIV* 2020; 7(4): e222–3. doi:10.1016/S2352-3018(19)30333-9
34 Traeger MW, Cornelisse VJ, Asselin J, Price B, Roth NJ, Willcox J, *et al.* Association of HIV Preexposure Prophylaxis With Incidence of Sexually Transmitted Infections Among Individuals at High Risk of HIV Infection. *JAMA* 2019; 321(14): 1380–90. doi:10.1001/JAMA.2019.2947
35 Rojas Castro D, Delabre RM, Molina JM. Give PrEP a chance: moving on from the "risk compensation" concept. *J Int AIDS Soc* 2019; 22(S6): 50–6. doi:10.1002/jia2.25351
36 WHO. Prevention and Control of Sexually Transmitted Infections (STIs) in the Era of Oral Pre-Exposure Prophylaxis (PrEP) for HIV: Technical Brief; 2019. Available at https://apps.who.int/iris/bitstream/handle/10665/325908/WHO-CDS-HIV-19.9-eng.pdf?ua=1
37 Schaefer R, Thomas R, Maswera R, Kadzura N, Nyamukapa C, Gregson S. Relationships between changes in HIV risk perception and condom use in East Zimbabwe 2003-2013: Population-based longitudinal analyses. *BMC Public Health* 2020; 20(1): 1–14. doi:10.1186/s12889-020-08815-1
38 Cassell MM, Halperin DT, Shelton JD, Stanton D. Risk compensation: The Achilles' heel of innovations in HIV prevention? *BMJ* 2006; 332(7541): 605. doi:10.1136/bmj.332.7541.605
39 Maharaj P, Cleland J. Risk Perception and Condom Use Among Married or Cohabiting Couples in KwaZulu-Natal, South Africa. *Int Fam Plan Perspect* 2005; 31: 24–9. doi:10.1363/ifpp.31.24.05
40 Prata N, Morris L, Mazive E, Vahidnia F, Stehr M. Relationship between HIV risk perception and condom use: Evidence from a population-based survey in Mozambique. *Int Fam Plan Perspect* 2006; 32(4): 192–200. doi:10.1363/3219206
41 Warren EA, Paterson P, Schulz WS, Lees S, Eakle R, Stadler J, *et al.* Risk perception and the influence on uptake and use of biomedical prevention interventions for HIV in sub-Saharan Africa: A systematic literature review. *PLoS One* 2018; 13(6): 1–181. doi:10.1371/journal.pone.0198680
42 Denison JA, O'Reilly KR, Schmid GP, Kennedy CE, Sweat MD. HIV Voluntary Counseling and Testing and Behavioral Risk Reduction in HIV Voluntary Counseling and Testing and Behavioral Risk Reduction in Developing Countries : A Meta-analysis, 1990–2005. *AIDS Behav* 2008; 12: 363–73. doi:10.1007/s10461-007-9349-x
43 WHO. Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations. WHO Guidelines. WHO; 2022. p. 184.
44 Ring DV, Medicines EU, Union E. Vaginal ring to reduce the risk of HIV infection for women in non-EU countries with high disease burden. EMA; 2020. pp. 3–5.

**Ethical approval and consent to participate.** Ethical approvals for the parent protocols were obtained from ethics review committees from all the participating sites (Supplementary Table S1).[28,44] All participants provided written informed consent in English or in their local language of choice. Participants were offered a signed copy of the informed consent form for their records. If the copy was declined, it was retained at the study sites for access at the participant's discretion.

**Data availability.** The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Conflicts of interest.** The authors declare that they have no conflicts of interest.

**Declaration of funding.** The MTN-020 and MTN-025 studies were designed and implemented by the MTN funded by the National Institute of Allergy and Infectious Diseases through individual grants (UM1AI068633, UM1AI068615 and UM1AI106707), with co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the US National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

**Acknowledgements.** The authors thank all the participants in the study.

**Author contributions.** KH conceptualized and is the lead investigator and author of this publication. MN analyzed the data. TPP was the protocol co-chair. FM, KR, NS, CAA, SS and LEM were site investigators, and MG, CEJ, BG and JB contributed to the coordination of the study and critical revisions of the manuscript. All authors read and approved the final manuscript.

**Author affiliations**

[A]Clinical Trials Research Center, University of Zimbabwe Faculty of Medicine and Health Sciences, Harare, Zimbabwe. Email: fmhlanga@uz-ctrc.org

[B]Statistical Center for HIV/AIDS Research and Prevention (SCHARP), Fred Hutchinson Cancer Center, Seattle, WA, USA. Email: bneradil@scharp.org

[C]FHI 360, Durham, NC, USA. Email morgan.d.garcia@gmail.com

[D]Wits RHI, University of the Witwatersrand, Faculty of Health Sciences, Johannesburg, South Africa. Email: TPalanee@wrhi.ac.za; Kreddy@wrhi.ac.za

[E]University of Washington, Department of Epidemiology, School of Public Health, Seattle, WA, USA.

[F]South African Medical Research Council, HIV and other Infectious Diseases Research Unit (HIDRU), Johannesburg, South Africa. Email: Nishanta.Singh@mrc.ac.za; Samantha.Siva@mrc.ac.za

[G]Makerere University - Johns Hopkins University (MU-JHU) Research Collaboration CRS, Kampala, Uganda. Email: cakello@fhi360.org; bgati@mujhu.org

[H]Center for the AIDS Programme of Research in South Africa (CAPRISA), University of KwaZulu-Natal, Durban, South Africa. Email: Leila.Mansoor@caprisa.org

[I]Microbicides Trials Network MTN 020 and MTN 025 Protocol Team, Pittsburgh, PA, USA. Email: CJacobson@fhi360.org

[J]University of Washington, Departments of Epidemiology and Global Health, School of Public Health, Seattle, WA, USA. Email: jbalkus@uw.edu