



## Original research article

# Contraceptive method switching among women living in sub-Saharan Africa participating in an HIV-1 prevention trial: a prospective cohort study



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## ABSTRACT

**Objective:** Long-acting reversible contraceptive (LARC) method uptake has been low within the context of HIV prevention trials. Within a multinational study (MTN-020/ASPIRE), the Contraceptive Action Team improved LARC accessibility and uptake. In this secondary analysis, we determined the rate of contraceptive method continuation among the women enrolled.

**Study design:** ASPIRE was a randomized, double-blinded, placebo-controlled phase III safety and effectiveness study of the Dapivirine Vaginal Ring for HIV-1 prevention. Between 2012 and 2014, sexually active women aged 18–45 from Malawi, South Africa, Uganda and Zimbabwe were enrolled. All participants were required to use contraception for enrollment to the study and could choose between all highly effective contraceptive methods available in their respective countries. Women were seen monthly and could change methods at any time. Continuation rates from study enrollment to 6 and 12 months were determined.

**Results:** The overall contraceptive method continuation rate was 77% (1972/2551) at 6 months and 66% (1694/2551) at 12 months. The 6- and 12-month continuation rates were highest for implantable contraceptives (89%, 82%) followed by copper intrauterine device (83%, 77%). Rates of continuation for injectable contraceptives depot medroxyprogesterone acetate (80%, 69%) and norethisterone enanthate (71%, 54%) were higher than for oral contraceptives, which were continued at 47% at 6 months and 35% at 12 months. The continuation rates of all methods did not differ by users with and without previous contraceptive experience.

**Conclusions:** LARC methods have the highest rates of continuation at 12 months and should be routinely offered in the context of HIV prevention trials in sub-Saharan Africa.

**Implications:** Intrauterine devices and contraceptive implant continuation was high at 12 months among women participating in an HIV prevention trial in sub-Saharan Africa and LARCs and should be routinely offered.

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## 1. Introduction

Enrollment into HIV prevention studies evaluating safety and efficacy of biomedical interventions not yet evaluated in pregnancy often requires female participants to use effective methods of contraception. Previous HIV prevention studies reported high uptake (>90%) of

short-acting reversible contraceptive (SARC) methods, including progestin-only injectables (norethisterone enanthate [NET-EN] or depot medroxyprogesterone acetate [DMPA]) and oral contraceptive pills (OCPs) [1–5]. However, SARC methods have lower contraceptive efficacy and are less cost-effective than long-acting reversible contraceptive (LARC) methods, such as the intrauterine device (IUD) or progestin-containing subdermal implants [6]. Several studies suggest a possible association between DMPA and increased risk of HIV acquisition [7], and a clinical trial is under way evaluating HIV incidence

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among women randomized to DMPA, copper IUD or levonorgestrel-containing implants ([Clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02550067) NCT02550067). In response to this concern, the World Health Organization called for diversification of the contraceptive mix available to women at risk of HIV acquisition, including women participating in HIV prevention studies [8]. The Microbicide Trials Network (MTN) created the Contraception Action Team to assist ASPIRE study sites in provision of all contraceptive methods, including LARC methods. LARC uptake increased through contraceptive counseling and immediate access to at least four contraceptive options [9].

Ensuring access to LARC methods is a critical first step in contraceptive mix diversification. However, continuation is the key factor for the effectiveness of any contraceptive method. Data are limited on contraceptive method continuation and switching in resource-constrained settings. Most of the existing data on contraceptive continuation in resource-constrained settings come from country-level Demographic and Health Surveys and are limited by the retrospective nature of survey data. Nonetheless, they demonstrate high rates of LARC continuation, especially compared to SARC methods [10,11]. Similar results have been reported in the United States in the prospective CHOICE study, which showed that 12-month continuation rates for LARC methods versus SARC methods were 87% and 57%, respectively [12]. The primary objective of this analysis was to determine the continuation of LARC versus SARC methods at 6 months and 12 months for women participating in the ASPIRE trial.

## 2. Materials and methods

This is a secondary analysis of data regarding the contraceptive method continuation among the women participating in the ASPIRE trial, a randomized, double-blind, placebo-controlled phase III safety and effectiveness study of the Dapivirine Vaginal Ring for HIV-1 prevention ([Clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01617096) NCT01617096). Detailed methods and results for the trial have been published [13]. Briefly, between August 2012 and June 2014, 2629 healthy, sexually active, HIV-1-uninfected women aged 18–45 years from Malawi, South Africa, Uganda and Zimbabwe were enrolled and were randomly assigned in equal proportions to receive either the Dapivirine Vaginal Ring or matching placebo ring. Participants provided written informed consent, and applicable local and national ethical and regulatory authorities approved the study protocol. Women who were pregnant or intending to become pregnant were not eligible for enrollment, and use of a highly effective contraceptive method was a trial inclusion criterion, specifically use of injectables (DMPA or NET-EN), OCPs, implants, IUDs and tubal ligation. This secondary analysis is a prospective cohort study of the contraceptive use among the ASPIRE participants. The primary objective was to describe the contraceptive continuation rates among the women enrolled in the ASPIRE study and the factors associated with contraceptive method switching. All participants were included in the analysis except those that had undergone tubal ligation and thus did not require reversible contraception.

At enrollment and monthly follow-up visits, standardized face-to-face interviews were conducted to collect data on the contraceptive method used since the participant's last visit. Contraceptive counseling was provided at every visit. Effective contraceptive methods, including IUDs and implants, were provided on-site, and women were permitted to change contraceptive methods during follow-up. Despite ongoing contraceptive counseling, participants were also permitted to stop contraception altogether and continue the study. Participant study charts were retrospectively reviewed to determine if the participant was using a contraceptive method prior to screening for ASPIRE and the reasons for initiating or switching a contraceptive method during study participation using a standardized data abstraction form. Enrollment method use was compared between participants who had previously used a modern method of contraception (injectables, OCPs, IUDs or implants) or “established users” and compared to participants

who had not previously used a modern method of contraceptive method or “new users.” Over the course of ASPIRE, contraceptive method switching was determined by chart review.

Contraceptive continuation was determined overall and by each method at 6 months and 12 months. Contraceptive method switching was described by method between both screening and enrollment and over the follow-up period. Only the first contraceptive method switch after enrollment was described in this analysis. Reasons for contraceptive method switching were tabulated from the most common reason to the least. Participant demographics and characteristics were compared between women that continued their contraceptive method or switched by  $\chi^2$  adjusted by country. Analyses were performed using SAS© software (SAS institute, Cary, NC, USA).

## 3. Results

### 3.1. Participant characteristics

Of the 2692 participants who enrolled in the ASPIRE study, 78 were excluded from the analysis because they had a previous tubal ligation and did not require reversible contraception (Fig. 1). Participants who had tubal ligation ( $n=78$ ) were older and had higher parity than women using reversible contraception. Women who chose LARC methods tended to be older than women using SARC (Table 1). The most common contraceptive method used by women when they were screened for the study was DMPA ( $n=792$ ; 31%) followed by OCPs ( $n=465$ ; 18%) (Supplemental Table). Over 90% of participants using DMPA, NET-EN, implants and IUDs at screening reported using that method at the enrollment visit. In contrast, only 20% ( $n=95$ ) of participants using OCPs at the screening visit continued to use OCPs at enrollment, with 56% ( $n=260$ ) switching to a LARC method and 25% ( $n=115$ ) switching to DMPA. Of participants not using any contraceptive method prior to ASPIRE participation ( $n=746$ ), 29% ( $n=217$ ) chose DMPA, 26% ( $n=191$ ) chose NET-EN, 25% ( $n=186$ ) chose OCPs, 7% ( $n=52$ ) chose implants, and 13% ( $n=100$ ) chose IUDs. A higher proportion of new contraceptive users chose to use NET-EN, OCPs and IUDs at enrollment than established contraceptive users (Fig. 2).

### 3.2. Contraceptive method continuation

Overall, contraceptive method continuation was 77% at 6 months and 66% at 12 months in the study population. Contraceptive continuation was higher for LARC methods at 6 months (87%) and remained high at 12 months (80%) compared to SARC methods at 6 months (73%) and

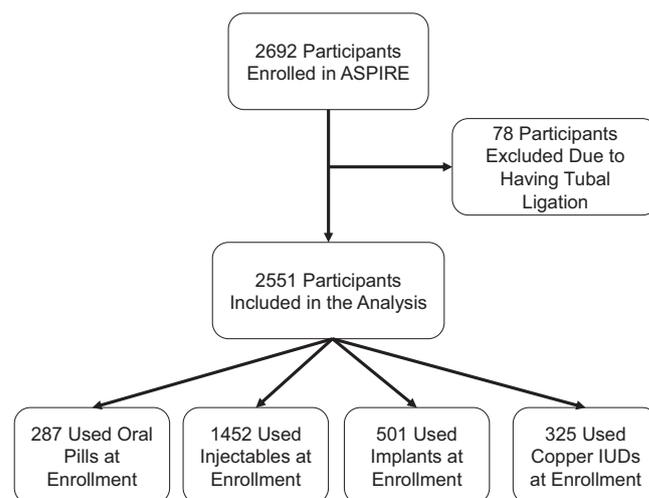
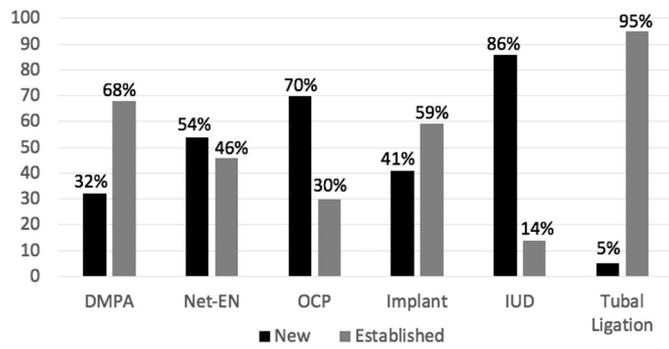


Fig. 1. Flow diagram of participants. \* Fourteen women were using more than one contraceptive method at enrollment and therefore were counted for both methods.



**Fig. 2.** Percent of new users vs. established users by contraception method at enrollment.\*  
\*New contraceptive users were participants who were not using contraception prior to screening, and established contraceptive users used contraception (OCPs, injectables, implants or IUD) prior to screening for ASPIRE.

12 months (60%). For the SARC methods, contraceptive continuation at 12 months was highest for DMPA (69%), followed by NET-EN (54%), and lowest for OCPs (35%) (Table 2).

Among those 788 participants who chose a SARC method at enrollment, 442 (56%) switched to a LARC method (60% DMPA, 58% NET-EN, 43% of OCP users) (Table 3). OCP users were more likely than DMPA or NET-EN users to discontinue contraceptive use altogether (15% vs. 5% or 6%, respectively). The most common reason given for SARC users to switch was interest in a “forgettable option,” such as an IUD or an implant (Table 4). A higher proportion of DMPA and NET-EN users switched methods due to bleeding side effects than OCP users. Weight gain was more frequently cited as the reason to switch from DMPA when compared with NET-EN and OCPs. Pregnancy and difficulty with adherence were reported more commonly as the reason for switch from OCPs when compared with NET-EN and DMPA. Participants who were less than 25 years of age ( $p=.048$ ; 48% <25 years vs. 37% ≥25 years of age discontinued) and those with higher educational achievement ( $p=.003$ ; 47% for secondary education complete or higher vs. 40% for incomplete secondary education vs. 32% for primary education or less discontinued) were more likely to discontinue DMPA. There were no participant characteristics associated with discontinuation of the other SARC methods.

**Table 1**  
Participant characteristics at enrollment by method of contraception used at enrollment

	Contraceptive method <sup>a</sup>						Total
	DMPA	NET-EN	OCP	Implant	IUD	Tubal ligation	
Participants (number)	1071	381	287	501	325	78	2629
Age, years (median, IQR)	26 (22–30)	24 (21–28)	25 (21–31)	28 (24–32)	28 (24–33)	36 (33–39)	26 (22–31)
Currently married	377 (35)	20 (5)	53 (18)	400 (80)	185 (57)	47 (60)	1074 (41)
Education							
No schooling or primary only	166 (15)	9 (2)	22 (8)	119 (24)	62 (19)	29 (37)	404 (15)
Some secondary education or more	905 (85)	372 (97)	265 (92)	382 (76)	263 (81)	49 (63)	2225 (85)
Participant earns own income	527 (49)	106 (28)	116 (40)	244 (49)	157 (48)	44 (56)	1186 (45)
Prior live births (median, IQR)	2 (1–3)	1 (1–2)	1 (1–2)	3 (2–3)	2 (1–3)	4 (3–4)	2 (1–3)
Prior pregnancies (median, IQR)	2 (1–2)	1 (0–2)	1 (0–2)	2 (2–3)	2 (1–3)	4 (3–4)	2 (1–3)
Condom use at last vaginal sex act	613 (57)	258 (68)	196 (68)	236 (47)	181 (56)	35 (45)	1508 (57)
More than 1 sex partner in the past 3 months	175 (16)	58 (15)	58 (20)	67 (13)	72 (22)	12 (15)	439 (17)
Travel time to the clinic							
<30 min	258 (24)	141 (37)	82 (29)	71 (14)	75 (23)	10 (13)	632 (24)
30–60 min	522 (49)	192 (50)	163 (57)	263 (53)	158 (49)	40 (51)	1331 (51)
1–2 h	259 (24)	47 (12)	41 (14)	152 (30)	81 (25)	22 (28)	600 (23)
>2 h	32 (3)	1 (<1)	1 (<1)	15 (3)	11 (3)	6 (8)	66 (3)
Country							
Malawi	115 (11)	0 (0)	6 (2)	120 (24)	6 (2)	25 (32)	272 (10)
South Africa	665 (62)	381 (100)	241 (84)	21 (4)	79 (24)	43 (55)	1426 (54)
Uganda	112 (10)	0 (0)	14 (5)	49 (10)	71 (22)	7 (9)	253 (10)
Zimbabwe	179 (17)	0 (0)	26 (9)	311 (62)	169 (52)	3 (4)	678 (26)

<sup>a</sup> Participants could report using more than one contraceptive method (14 participants were using more than one method).

**Table 2**  
Contraception continuation at 6 and 12 months<sup>a</sup>

Method	Enrollment	6 Months	12 Months
OCPs	287	135 (47)	100 (35)
NET-EN	381	269 (71)	206 (54)
DMPA	1071	857 (80)	734 (69)
Implant	501	447 (89)	411 (82)
IUD	325	271 (83)	250 (77)
Any method <sup>b</sup>	2565	1972 (77)	1694 (66)

<sup>a</sup> Number of participants using each contraceptive method at enrollment, 6 months and 12 months (percentage of each continuing at 6 months and 12 months). Participants could report more than one method of contraception (14 participants reported more than one method at enrollment).

<sup>b</sup> Any method includes only those using a reversible contraceptive method and excludes participants who had a tubal ligation.

#### 4. Discussion

Effective contraception at enrollment was required for all participants in an HIV prevention study of 2551 women (excluding those with previous tubal ligation) from South Africa, Zimbabwe, Malawi and Uganda. Even though only 14% of women were using LARCs at the time of screening, uptake of LARCs over the study increased during study participation. Women who chose LARCs had an 80% continuation rate after a year, while only 60% of women who chose SARCs continued to use the same method at 12 months. Of the participants who discontinued SARC methods during follow-up, the majority (56%) chose to switch to a LARC method. This multinational HIV prevention study was the first to routinely offer LARC methods and demonstrates that women living in sub-Saharan Africa find LARC methods highly acceptable since 80% continued their chosen method for a year. This analysis demonstrates that women using injectable contraceptives will switch to LARC methods if provided.

Our findings are consistent with retrospective survey studies from other resource-constrained settings located in the African continent. The 12-month continuation rate in Senegal from 2010 to 2015 was 93.7% for implants, 81.6% for IUDs, 67.3% for injectables and 62.0% for OCPs [10]. In an analysis of IUD uptake and continuation in 14 resource-constrained settings, none of which were in sub-Saharan Africa, the 12-month median probability of IUD continuation was 91.1% [11]. The findings from our study are also similar to those reported in the United States from the contraceptive CHOICE study [14]. The

**Table 3**  
First contraceptive method switch after enrollment among DMPA, NET-EN and OCP users<sup>a</sup>

Enrollment method	Method after switch							Total
	DMPA	NET-EN	OCPs	Implant	IUD	TL	None	
DMPA	–	53 (13)	91 (22)	124 (29)	131 (31)	3 (<1)	21 (5)	423
NET-EN	21 (10)	–	51 (25)	64 (32)	53 (26)	1 (<1)	13 (6)	203
OCPs	32 (20)	34 (21)	–	24 (15)	46 (28)	2 (1)	24 (15)	162

<sup>a</sup> Number of participants (Percentage of total participants who switched contraceptive methods).

CHOICE study enrolled 9256 women living in St. Louis, MO, and women were provided access to all contraceptive methods at no cost with standardized contraceptive counseling. The overall LARC continuation rate was 87% and 80% and the SARC continuation rate was 57% and 60% at 12 months in the CHOICE and ASPIRE studies, respectively. The continuation rate at 12 months was 85% and 77% for copper IUDs and 83% and 82% for contraceptive implants in the CHOICE and ASPIRE studies, respectively. In contrast, the continuation rates for the SARC methods were more divergent between the two studies. The continuation rate at 12 months was 69% and 58% for DMPA and 35% and 59% for OCPs in the ASPIRE and CHOICE studies, respectively. These differences could be due to alternative methods available or due to the differences in trial design. Participants in the CHOICE study had access to the levonorgestrel-containing IUD, which has the noncontraceptive benefit of reducing menstrual bleeding oftentimes causing amenorrhea. Participants in the ASPIRE study who desired reduced menstrual bleeding may have been counseled to select DMPA.

In a previous HIV prevention study (MTN-003/VOICE) which also included women living in sub-Saharan Africa, a pregnancy rate of 42.7 and 23.7 per 100 person-years was reported among new and established users of oral contraceptives, respectively [15]. It is possible that a subset of women who initially chose OCPs at enrollment in our study had the intention of becoming pregnant, as contraception was required for enrollment in the study. This hypothesis is supported by the low OCP continuation rate and the high rate of women reporting pregnancy as the reason for discontinuing OCPs.

This study has several limitations and strengths. First, this study is smaller than other studies of contraceptive method continuation in sub-Saharan Africa that have previously used country-level data from Demographic and Health Surveys [10,11]. This limitation is mitigated by several strengths, including the multinational, prospective design and the monthly follow-ups with the opportunity for women to change contraceptive methods free of charge. A second limitation of our study is

that the contraceptive provision was implemented within the context of the HIV prevention trial, and not all LARC methods were available at every site at the time of participant enrollment. Thus, some contraceptive method switching was likely related to increased contraceptive choice at the sites over time and might not be generalizable to other settings. Additionally, we do not have information on the duration of method use at the time of study screening or enrollment, which is related to contraceptive continuation. Regardless, the results are reassuring that if women in resource-constrained settings are given easy access to LARC methods of contraception and provided with comprehensive counseling about expected side effects, then the continuation rates will be high.

Overall, our study found that the continuation rate for LARC methods is higher than for SARC methods. Our findings in this study of women from Sub-Saharan Africa are strikingly consistent with the continuation of LARCs in a conceptually similar study of women in the United States (the contraceptive CHOICE study). Regardless of differences in culture and setting, women who chose the use LARC methods of contraception will have high rates of continuation. Given this high rate of continuation, contraceptive policymakers consider making LARC methods readily available for women living in sub-Saharan Africa interested in preventing pregnancy which will reduce system and family planning provider burden in the long run.

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.contraception.2019.06.006>.

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## Potential conflicts of interests

Catherine Chappell is receiving research funding Gilead Sciences and Merck though Magee-Womens Research Institute, and Catherine Chappell has served as a consultant for Gilead Sciences. Sharon Hillier

**Table 4**  
Reasons for switching from DMPA, NET-EN and OCPs after enrollment<sup>a</sup>

	DMPA (n=423)		NET-EN (n=203)		OCP (n=162)	
	n	%	n	%	n	%
Interested in "forgettable option"	170	40	85	42	54	33
Bothered by bleeding side effects	67	16	34	17	2	1
Amenorrhea	8	2	3	1	0	0
Bothered by pain	5	1	6	3	0	0
Wanted a break from hormones	34	8	3	1	3	2
Weight gain	26	6	3	1	0	0
Expressed interest getting pregnant	9	2	4	2	2	1
Pregnancy	3	<1	1	<1	19	12
Partner objection or family suggestion	4	<1	0	0	2	1
Difficulty with adherence	7	2	7	3	56	35
Contraceptive choice not initially available	17	4	10	5	3	2
Other reason given <sup>b</sup>	13	3	10	5	12	7
No reason given	90	21	48	24	19	12

<sup>a</sup> Participant could give more than one reason for contraceptive switch.

<sup>b</sup> Other common reasons for switching included worried about association between DMPA and HIV, no longer sexually active, wanted permanent method and increased appetite.

has served as a consultant for Merck. Jennifer Balkus received honoraria from Lupin and was a scientific advisor to uBiome. The other authors have no conflicts of interest to disclose.

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