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Research Article

Assessing the Use of Progesterone Vaginal Ring among Women in Sub-Saharan Africa: Results of an Acceptability Study in Kenya

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Abstract

Introduction: The postpartum period is characterized by a limited choice of family planning methods especially in sub-Saharan Africa. Addition of a novel contraceptive ring designed for lactating mothers will be suitable for countries in sub-Saharan Africa where women breastfeed for long durations and there is a high unmet need for contraception during the postpartum period. Previous studies have demonstrated that contraceptive vaginal rings are well accepted in culturally varied settings including Latin America. However, the extent to which contraceptive vaginal rings are acceptable in the sub-Saharan African context including Kenya is unknown.

Objective: Assess factors influencing the acceptability of the progesterone vaginal ring among clients, their spouses, providers and community members.

Methodology: The study used both prospective and cross-sectional designs. Under prospective design, participants were enrolled and followed up over a period of 6 months or up to discontinuation of use of the ring. The cross-sectional design involved interviews with women who were counseled on the ring but did not choose it. Recruitment period was from November 2013 to February 2014. Follow-up period was up to August 2014 that marked the last follow-up for clients who were recruited in February of that year. Data collection was undertaken at baseline, during follow-up and at endline and involved interviews with providers on completion of case record forms as well as their knowledge and practice on PVR; quantitative interviews with PVR users who were enrolled for prospective follow-up; and in-depth interviews with additional women who were enrolled in the study on their experiences in using the ring. Quantitative data were entered in EpiData and exported to Stata for cleaning and analysis. Qualitative interviews were audiotaped, translated into English where necessary and transcribed in Word.

Results: About 77% of women who enrolled for the quantitative interviews were aged between 20 and 29 years. Seventy-one percent of women desired to space the next pregnancy by at least four years, 37% of them were new family planning users, and 95% chose the ring as the preferred method. The most common reasons for choosing the ring as the preferred method were that it is user-controlled (49%) and had fewer side effects (46%). There were remarkable changes in participants' perceptions about the ring between baseline and follow-up. For instance, half of the participants (50%) felt that the ring was too big at baseline while at follow-up, the majority of them (93%) reported that the size of the ring was just fine. Similarly, the proportion of participants that felt that the color of the ring was just fine increased from 78% at baseline to 93% at follow-up. In addition, the proportion that felt that the texture of the ring was just fine increased from 53% at baseline to 86% at endline. All participants reported that they were shown how to insert the ring while 73% reported that providers showed them how to remove the ring. Eighty percent of participants

interviewed upon follow-up reported that they were satisfied with the ring. The proportion that reported satisfaction with the ring was nearly twice as high among those who completed the two ring cycles (100%) than among those who terminated use (57%). The proportion of providers who stated that they would dispense the ring to lactating unmarried women with no contraindications rose from 9% at baseline to 87% at endline.

Conclusion: The progesterone contraceptive vaginal ring was acceptable to most clients and key stakeholders.

Keywords: *Progesterone contraceptive vaginal ring; breast-feeding; family planning*

Introduction

The progesterone vaginal ring (PVR) is used to extend the contraceptive effectiveness of lactational amenorrhea among breastfeeding women. The ring is inserted in the vagina 6 - 9 weeks postpartum for continuous use for up to three months and replaced with a new one if breastfeeding is continued and extended contraception is desired. The PVR is effective as long as the user is breastfeeding at least four times a day. Women can use these rings successively for up to one year. PVR functions by diffusing a continuous flow of natural progesterone through the vaginal walls-approximately 10 mg per day-which then enters the bloodstream and regulates the woman's fertility by suppressing ovulation. Progesterone also thickens the cervical mucus thereby inhibiting sperm penetration into the uterus. Clinical trials have shown that PVR is an effective and safe contraceptive method [1,2]. The method was first registered in Chile and Peru in 1998 and has since been expanded to other Latin American countries including Bolivia, Ecuador, Guatemala, and the Dominican Republic [3].

Previous studies have demonstrated that vaginal rings are well accepted in settings as culturally varied as in Latin America, Australia, Singapore, Egypt and the United States [3]. However, the extent to which PVR is acceptable in the sub-Saharan African context is unknown, especially since vaginal rings are a new technology in this setting and use of any vaginal product including tampons is low. An understanding of the acceptability of the ring is important for informing the introduction of the method in the region. Women in Sub-Saharan Africa breastfeed for long durations and also have a high unmet need for contraception, especially during the postpartum period [4,5]. Since the use of the PVR is predicated upon women breastfeeding at least four times a day, it provides an opportunity to promote breastfeeding while ensuring contraceptive protection, thereby benefiting both mothers and their babies.

Estimates from the Kenya Demographic and Health Surveys (KDHS) show that the contraceptive prevalence rate more than doubled from 27% in 1989 to 58% in 2014 [6,7]. Over the same period, the use of modern methods increased almost three-fold from 18% in 1989 to 53% in 2014 and unmet need for contraception declined by almost half from 35% in 1993 to 18% in 2014. In spite of these improvements, estimates from the 2008 - 2009 KDHS showed that only 25% of postpartum women were using a family planning (FP) method compared to the national contraceptive prevalence rate (CPR) of 46% at that time [8,9]. Studies that have demonstrated that short birth spacing has negative effects on infant and child survival given that the assertion is not based on our findings.

The postpartum period is characterized by a limited choice of FP methods that include lactational amenorrhea method (LAM), IUCD, sterilization, progestin-only pills, injectables, implants and condoms. However, not all these methods are available at all points of care or are preferred by users. The Kenya Ministry of Health (MOH) therefore recognizes the need for FP information and services during the postpartum period as an integral component of maternal and neonatal care services [10]. However, programs to strengthen FP service provision during the postpartum period have been implemented on a pilot basis in selected districts with limited financial contribution by local institutions to ensure sustainability [11,12].

Regarding breastfeeding practices, estimates from the 2008 - 2009 KDHS showed that nearly all children under five years (97%) had been breastfed. Mothers initiated breastfeeding within one hour of birth for 58% and within one day of birth for 86% of the children ever breastfed. The median duration for any breastfeeding was 21 months while the median duration for exclusive breastfeeding (EBF) was

less than one month. Ninety-three percent of children under the age of six months were breastfed 6 or more times within 24-hour period while 32% of children under the age of six months are exclusively breastfed. In September 2012, parliament passed a law aimed at promoting EBF for the first 6 months and continuous breastfeeding after the introduction of other foods up to a period of 24 months [13]. The law was, however, criticized for seeking to regulate the marketing, promotion, distribution and sale of breast milk substitutes rather than promote EBF. The government has also formulated several policies aimed at protecting, promoting and supporting optimal infant feeding practices [14]. Since the PVR amplifies the contraceptive effect of breastfeeding, it has the potential to support breastfeeding initiatives while also expanding contraceptive choice.

In order to understand the extent of acceptability of the method in sub-Saharan Africa, we conducted acceptability studies in Kenya, Nigeria and Senegal. This paper presents findings from the study in Kenya. The specific objective of the study was to assess the factors influencing the acceptability of the method among clients, their spouses, providers, community members and women who were counseled on but did not choose the method.

Methods

The study used both prospective and cross-sectional designs. The prospective component involved enrolling and following up participants over a period of 6 months (2 ring cycles) or up to discontinuation of use of the ring. The cross-sectional component, on the other hand, involved interviews with women who were counseled on the ring but did not choose it. The study was conducted in 6 public health facilities (two health centers and 4 hospitals) in three counties in Kenya (Nairobi, Kiambu and Murang'a Counties). The sites were selected based on onsite availability of postpartum family planning (FP) services, a caseload of women seeking FP before 9 weeks postpartum and ability to meet global Good Clinical Practice (GCP) guidelines.

Study Procedures

Ethical clearance for the study was granted by the Institutional Review Board (IRB) of the Population Council and the Ethics and Research Committee (ERC) of Kenyatta National Hospital/University of Nairobi (Protocol number P625/11/2012). A total of 35 service providers from the six selected sites and 4 health managers were trained on the PVR including its mechanism of action, service provision including the client counseling process, and study procedures such as enrollment, completion and maintenance of study documentation, and good clinical practice. Six research assistants (RAs) with social science backgrounds were also trained to conduct interviews with clients after they had received the PVR from the study providers and during follow-up. RAs were also trained in research ethics and were stationed at the facilities throughout the duration of the study.

Recruitment of participants into the study started in November 2013 following the training of providers and RAs and there was follow-up of clients up to August 2014 when the required sample was realized. A total of 60 women who chose PVR after contraceptive counseling were enrolled in the study and followed up for six months or up to discontinuation of use. An additional 58 women aged 18 - 35 years who were counseled on the PVR but did not choose the method were interviewed after their counseling session to understand the reasons guiding their choices. The recruitment process entailed the providers counseling postpartum clients seeking FP services on all available methods including PVR so that all clients had a choice of methods. A client who chose the ring during counseling was directed to the RA who obtained written informed consent before a provider could dispense the method following a medical examination and counseling on PVR.

Data Collection and management

Data collection involved quantitative interviews with PVR users who were enrolled into the study these women were interviewed immediately after receiving the PVR (at baseline) and at most twice subsequently. Baseline interviews captured information on background characteristics, reproductive history, contraceptive use, perceptions about the quality of care received during the counseling as well as perceptions about the PVR. Follow-up interviews captured information on status of ring use, ease of use, experiences of ring expulsion, sexual activity during ring use, and level of satisfaction with the ring.

Exit interviews with PVR users at baseline and endline were conducted using personal digital assistants (PDAs). The data were then downloaded into computers at the Population Council office in Nairobi. Data from quantitative interviews with service providers and case record forms were entered in EpiData. Quantitative interviews with PVR users and non-users were conducted using PDAs and exported straight away to Stata for cleaning and analysis.

Results

Demographic characteristics of study participants

More than three-quarters of the women who were enrolled for the quantitative interviews (77%) were aged between 20 and 29 years (Table 1). More than two-thirds (70%) of the women were from urban or peri-urban areas, 60% had secondary and above level of education while nearly all of them (98%) were either married or living with a man. Half of the women (50%) were not working although partners of 98% of them were engaged in some work with the majority (75%) of the partners being engaged in non-professional jobs such as manual/casual work and business/farming (Table 1).

Variable	(n)	Percent
Age		
18 - 19	4	6.7
20 - 24	31	51.7
25 - 29	15	25.0
30 - 35	10	16.7
Place of residence		
Urban	18	30.0
Peri-Urban	22	36.7
Rural	20	33.3
Education		
Primary or lower	24	40.0
Secondary	26	43.3
College/university	10	16.7
Marital status		
Never married	1	1.7
Married	58	96.7
Cohabiting	1	1.7
Respondent's occupation		
Not working	30	50.0
Non- professional	26	43.3
Professional	4	6.7
Partner's occupation		
Not working	4	6.7
Non- professional	45	75.0
Professional	11	18.3
Total	60	100.0

Table 1: *Demographic characteristics of study participants.*
Data source: Baseline dataset

Reproductive and family planning history

Nearly half of the women (47%) who were enrolled in the study had given birth to one child and almost a similar proportion (48%) had one living child (Table 2). The majority (63%) reported that the pregnancy for the current child was intended and most of the women

(71%) desired to space the next pregnancy by at least four years. The majority (89%) reported discussing pregnancy spacing with their partners. In addition, 37% of the women were new family planning users (Table 2). The results of further analysis showed that the proportion of new users was higher among younger (below 25 years of age) than older (25 years and above) women (49% and 20% respectively).

Variable	(n)	Percent
Children ever born		
1	28	46.7
2	20	33.7
3 or more	12	20.0
Number of living children		
1	29	48.3
2	19	31.7
3 or more	12	20.0
Pregnancy was intended		
Yes	38	63.3
No	22	36.7
Preferred spacing of next birth		
2 - 3 years	14	28.6
4 - 5 years	23	46.9
6 years or more	12	24.5
Discussed pregnancy spacing with partner		
Yes	50	89.3
No	6	10.7
Prior use of a method		
Ever used	38	63.3
Never used	22	36.7

Table 2: *Reproductive history and family planning use.*
Data source: Baseline dataset (N = 60)

Method choice among PVR users and non-users

Ninety-five percent of the women chose the ring as the preferred method while 5% chose it because their preferred method (progestin-only pills) was not available at the time of the visit. The most common reasons for choosing the ring as the preferred method were that it is user-controlled (49%), perception that it did not have many side effects (46%), perception that it was safe for breastfeeding (18%), perceived ease, comfort and convenience associated with the method (14%), and the desire to try a new method (14%; Figure 1).

Among women who were counseled on the ring but did not choose it and who agreed to be interviewed upon exit, the majority (47%) chose injectables, 34% chose progestin-only pills, 12% chose implants, 3% chose male condoms, 2% chose intra-uterine contraceptive device (IUCD) and another 2% opted to use lactational amenorrhea method (LAM).

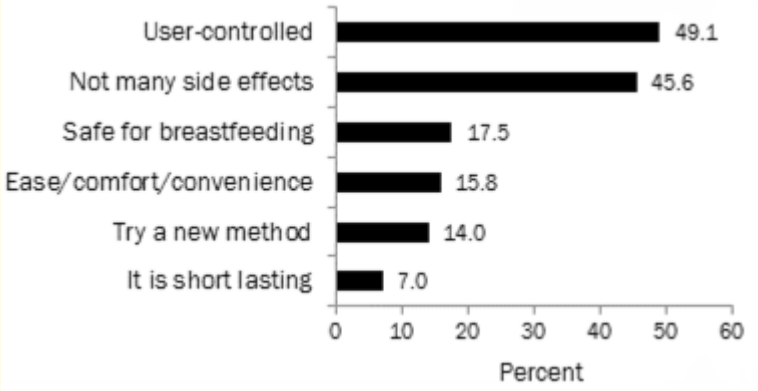

Figure 1: *Reasons for PVR Choice*

Note: Question allowed for multiple responses; Data source: Baseline dataset (N = 57)

Reasons for choosing other methods

The most commonly cited reason for choice of a particular method was that they had known it from before (39%; Figure 2). Just under 35% cited other reasons including few or no side effects, convenience of use including secret use without partner's knowledge, preference for long-term methods, and the desire to try another method. About 14% and 12% cited use of the method by someone else they knew as well as ease of use of the other methods compared to PVR respectively.

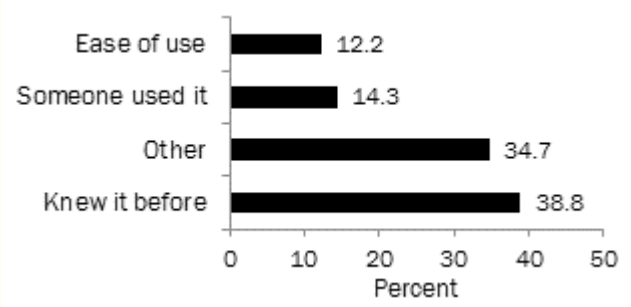

Figure 2: *Reasons for Choosing Other Methods.*

Impressions about the ring

There were remarkable changes in participants' perceptions about the ring between baseline and follow-up. For instance, half of the participants (50%) felt that the ring was too big at baseline while at follow-up, the majority of the women who were interviewed (93%) reported that the size of the ring was just fine (Table 3). Similarly, the proportion of participants that felt that the color of the ring was just fine increased from 78% at baseline to 93% at follow-up. In addition, the proportion that felt that the texture of the ring was just fine increased from 53% at baseline to 86% at endline (Table 3).

Indicator	Baseline, % (N = 60)	Follow-up, % (N = 42)
Impressions about size		
Too small	1.7	0.0
Too big	50.0	7.1
Just fine	48.3	92.9
Impressions about color		
Too bright	21.7	7.1
Just fine	78.3	92.9
Impressions about texture		
Too soft	23.3	11.9
Too hard	23.3	2.4
Just fine	53.3	85.7

Figure 3: *Impressions about the ring.*
Data source: Baseline and follow-up datasets

Perceived quality of care

Interviews with participants upon exit during recruitment showed that 85% of the respondents reported that providers had counseled them about breastfeeding requirements when using the ring (Table 4). Nearly all participants (97%) reported that providers counseled them on how to remove the ring while all participants were given opportunity to ask questions. More than three-quarters (77%) of the participants were encouraged to insert the ring themselves. All participants reported that they were shown how to insert the ring while 73% reported that providers showed them how to remove the ring (Table 4). However, some providers reported that a few clients were reluctant to touch their private parts and expected the providers to insert the ring for them just like they do with other methods requiring insertion like IUCD and implants.

Domain	Item	Response	(n)	Percent
Counseling on the PVR method	Provider conveyed minimum breastfeeding requirement	Yes	51	85.0
	Provider conveyed when to remove PVR	Yes	58	96.7
	Provider allowed respondent to ask questions	Yes	60	100.0
	Provider encouraged respondent to insert PVR	Yes	46	76.7
Counseling on PVR use	Provider showed how to insert PVR	Yes	60	100.0
	Provider showed how to remove PVR	Yes	44	73.3

Figure 4: *Perceived quality of care.*
Data source: Baseline dataset

Satisfaction with the use of the ring

Majority of participants who were interviewed upon follow-up reported that they were satisfied with the ring. The proportion that reported satisfaction with the ring was nearly twice as high among those who completed the two ring cycles (100%) than among those who terminated use (57%). Table 5 presents the distribution of participants who expressed satisfaction and dissatisfaction with the ring by experiences of using the method. A similar proportion of satisfied and dissatisfied participants found it easy inserting the ring (76% and 75% respectively). However, a higher proportion of dissatisfied participants compared to their satisfied counterparts found it easy to

remove the ring (75% and 54% respectively) and to re-insert the ring (100% and 54% respectively). None of the satisfied and dissatisfied clients reported experiencing side effects, which could imply that participants who terminated use because of side effects were not interviewed at follow-up.

Domain	Item	Response	Satisfied	Not Satisfied	p-value: Fisher's Exact Test
Ease of use	Ease of inserting PVR Ease of removing PVR Ease of re-inserting PVR	Easy/Very easy Easy/Very easy Easy/Very easy	75.7% 51.4% 54.1%	75.0% 75.0% 100.0%	0.82 0.30 0.08
Side effects	Reported	No	100.0%	100.0%	--
Expulsion	PVR fell out on its own	No	86.1%	66.7%	0.40
Sexual intercourse	Feel PVR during sex	No	88.6%	50.0%	0.00
	Partner feels PVR during sex Change in frequency of sex Change in sexual pleasure	No No change Increase	62.9% 62.9% 34.3%	25.0% 75.0% 25.0%	0.29 0.18 1.00
Will use in future	Interested	Yes	91.8%	50.0%	0.00
Partner/Family would support use	Reported	Yes	86.5%	0.0%	0.00
Will recommend	Reported	Yes	91.9%	50.0%	0.03
Already recommended	Reported	Yes	73.0%	50.0%	0.04
Willingness to Pay	Interested	Yes	76.5%	0.0%	0.07

Figure 5: *Responses by satisfaction related to PVR use.*
Source: Follow up datasheet

The results in Table 5 further show that a higher proportion of satisfied than dissatisfied participants did not experience expulsions (86% and 67% respectively), did not feel the ring during sexual intercourse (89% and 50% respectively), did not report partners feeling the ring during sexual intercourse (63% and 25%), and indicated that their sexual pleasure increased during the time they were using the ring (34% and 25% respectively). In addition, a higher proportion of satisfied than dissatisfied participants reported that they would use the ring in future (92% and 50% respectively), their partners and family members would support them in using the ring in future (87% versus none respectively), they would recommend the use of the ring to friends and family members (92% and 50% respectively), they had already recommended the ring to family members or friends (73% and 50% respectively), and that they would be willing to pay for the method (77% and none respectively; Table 5).

Providers' impressions

Interviews with providers showed notable changes in their perceptions about the ring between baseline and endline. At endline, all providers reported that the ring was safe for postpartum women and for the baby and that they would recommend it to family members or friends (Table 6). By contrast, slightly more than half of the providers (57%) felt that the ring was safe for postpartum women and the baby at baseline while less than 10% indicated that they would recommend it to family members or friends. Similarly, less than 10% indicated that they would dispense PVR to unmarried women with no contraindications and a similar proportion would not require husband's consent before dispensing PVR. Nearly all providers (97%) at endline indicated that women in their locality would like the ring compared to just about half at baseline. A similar proportion of providers (97%) reported at endline that they would prescribe the ring to lactating women after the study ends.

Domain	Baseline (N = 35)	Endline (N = 30)
PVR is safe for postpartum women	57.1%	100.0%
PVR is safe for baby	57.1%	100.0%
PVR does not increase risk of vaginal/pelvic infections	37.1%	56.7%
Lactating women in the locality would like PVR	54.3%	96.7%
Community health workers should be allowed to dispense PVR	17.1%	66.7%
PVR does not affect sexual pleasure	51.4%	83.3%
PVR does not interfere with sexual intercourse	57.1%	93.3%
Would recommend PVR to family members/friends	8.6%	100.0%
Would dispense PVR to unmarried women with no contraindications	8.6%	86.7%
Would not require husband's consent before dispensing PVR	8.6%	83.3%
Did not receive any complaints from clients regarding PVR use	--	53.3%
Did not receive any complaints from spouses/partners regarding PVR use	--	93.3%
Would prescribe PVR to lactating women after the study ends	--	96.7%

Figure 6: *Providers' responses by satisfaction related to PVR use.*
Data source: Provider interviews at baseline and endline

The results in Table 6 further show that there were notable changes between baseline and endline in the proportion of providers that reported that community health workers should be allowed to dispense the ring (from 17% to 67%), the ring does not affect sexual pleasure (from 51% to 83%), the ring does not interfere with sexual intercourse (from 57% to 93%), they would dispense the ring to lactating unmarried women with no contraindications (from 9% to 87%), and that they would not require husband's consent before dispensing the ring (from 9% to 83%). In addition, most of the providers (93%) reported at endline that they did not receive any complaints from husbands/partners of study participants regarding the use of the ring while about half (53%) reported that they did not receive any complaints from users. The smallest increase was in the proportion of providers that felt that the ring does not increase the risk of vaginal or pelvic infections (from 37% at baseline to 57% at endline; Table 6).

Discussion

The specific objective of the study was to assess the factors influencing the acceptability of the PVR method among clients, providers, and women who were counseled on but did not choose the method. The main finding of the study is that the ring was acceptable to most users, their partners and providers. Majority of participants who completed the two ring cycles indicated that they would use it in future, their partners or family members would support future use, they would recommend or had already recommended the ring to their friends or family members, and that they were willing to pay for the method.

These findings are similar to what other researchers have observed and documented in other studies. For instance, Ramarao and her colleagues [15] found that a contraceptive method such as PVR provides a safe and effective solution for both breastfeeding and contraceptive needs. Since its efficacy relies on at least four breastfeeding episodes per day, it offers contraceptive protection while promoting breastfeeding at the same time, and hence addresses the needs of mothers and their babies. From a programmatic perspective, further analysis of the various patterns of postpartum contraception noted earlier showed that women who had used either maternal or child health services were found to be likely using contraception.

Speizer and colleagues [16] found that the association between health care utilization and postpartum contraception varies from context to context. From a service delivery and program perspective, there is evidence to suggest that integrated MCH and FP services could offer women and their babies with multiple services when they are in contact with the health system.

However, the study had certain limitations, key among them being:

- **Small sample size:** The target sample size of 58 clients for follow-up was small. However, the sample size was powered to detect significant differences for the three countries combined (Kenya, Nigeria and Senegal) with 58 clients targeted in each country.

- **Loss to follow-up:** Given that the study involved prospective follow-up of clients, it was affected by loss to follow-up mostly occasioned by participants moving out of the study area or giving incorrect contact information. However, the rate of loss to follow-up (17%) was within the recommended minimum of between 20% and 30% for cohort studies [17,18].

- **Discontinuation of use:** Discontinuation was mainly due to experiences of ring expulsion followed by side effects and non-adherence to study procedures. Ring expulsion and non-adherence to use procedures were found to be the second most common reasons for termination of ring use in other studies. The rate of discontinuation of ring use in the study (40%) was also comparable to or lower than that of other methods in the country. For instance, estimates from 2008-2009 KDHS show that the rate of discontinuation was 29% for injectables, 43% for pills, 59% for condoms, and 36% for all methods.

These findings have a number of implications on FP programming and service delivery. First, the ring is likely to expand contraceptive choices during the postpartum period. This is borne out of the realization that the choice of the ring was largely based on perceived fewer side effects by lactating mothers. Secondly, the ring is likely to sustain or contribute to increased contraceptive prevalence rate. A significant proportion of respondents cited the fact that the ring can be inserted and removed by users themselves. As such expanding its usage would not require skilled healthcare personnel or technical equipment, hence the Ministry of Health is likely to meet its contraceptive prevalence coverage by promoting utilization of the ring especially among women in the postpartum period. Similarly, unlike other clinical FP methods, creating awareness and education around utilization of the ring could competently be carried out by non-skilled health workers such as community health volunteers.

This creates the potential for grassroots dissemination and increasing utilization of PVR at the community level [19]. Three, the ring is likely to bridge users to long-term methods, especially those involving insertion. This is because users who completed two ring cycles were observed to be more likely to switch to implants and IUCD compared to those who terminated use. Switching to long-term methods was also consistent with the finding that most users desired to space the next pregnancy by at least 4 years.

Significant changes were noted between baseline and follow up with respect to the impressions created by clients about the ring on factors such as size, colour and texture. The changes offer vital lessons for future scaling up efforts of the PVR contraception technology. One of the most important lessons is that with use, familiarity grows and so does the proportion of clients who feel comfortable using the ring.

Given that majority of women found the method acceptable, it is proposed that future studies should focus on documenting experiences that women will have as well as the logistics pipeline including procurement, storage and distribution when the method is scaled-up nationally.

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Author Contributions

All authors made substantial contributions to the paper in terms of conception, design, writing, and review. All authors approved the final paper and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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