2015

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report

PROGESTERONE VAGINAL RING: RESULTS OF A THREE-COUNTRY ACCEPTABILITY STUDY

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DECEMBER 2015

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New York, NY 10017
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Suggested citation: RamaRao, Saumya, Heather Clark, Deepa Rajamani, Salisu Ishaku, Babacar Mané, Francis Obare, Harriet Birungi, Nafissatou Diop, Wilson Liambila, Fatou Bintou Mbow, Chi-Chi Undie, Godwin Unumeri, and John Townsend. 2015. “Progesterone Vaginal Ring: Results of a Three-Country Acceptability Study.” New York: Population Council.

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Acknowledgments

We would like to thank the women, their partners, and the providers who participated in the study described in this report for their time and thoughtful insights. Collaboration with the Ministries of Health in Kenya, Nigeria, and Senegal was integral to the completion of this study. We also thank all of the health centers and research assistants involved. Special acknowledgment goes to Marlena Plagianos for her assistance with data analysis. We are grateful to colleagues Anrudh Jain, Ruth Merkatz, Martha Brady, Barbara Mensch, and Barbara Friedland for their helpful insights and suggestions over the course of the study. We acknowledge the Bill and Melinda Gates Foundation for its generous support.

List of Acronyms

ART	Antiretroviral Therapy
BMGF	Bill and Melinda Gates Foundation
CNERS	Comité National d'Ethique pour la Recherche en Santé
CRF	Case report form
FGD	Focus Group Discussion
FP	Family Planning
GCP	Good Clinical Practice
HIV	Human Immunodeficiency Virus
IAMRAT	Institute for Advanced Medical Research and Training
IDI	In-depth Interview
IRB	Institutional Review Board
IUD	Intrauterine Contraceptive Device
MCH	Maternal and Child Health
MEC	Medical Eligibility Criteria for Contraceptive Use
MNCH	Maternal, Newborn, and Child Health
MOH	Ministry of Health
MPT	Multipurpose Prevention Technology
NAFDAC	National Agency for Food and Drug Administration and Control
PPB	Pharmacy and Poisons Board
PPFP	Postpartum Family Planning
PVR	Progesterone Vaginal Ring
URHI	Urban Reproductive Health Initiative
WHO	World Health Organization

Executive Summary

The progesterone vaginal ring (PVR) is a contraceptive designed specifically for use by breastfeeding women in the first year postpartum. The PVR is inserted in the vagina 30–90 days postpartum for continuous use for up to 3 months and replaced with a new ring if breastfeeding is continued and extended contraception is desired. Women can use four rings successively for up to one year. The progesterone vaginal ring functions by diffusing a continuous flow of progesterone through the vaginal walls—approximately 10 mg per day—which then enters the bloodstream and regulates the woman's fertility by suppressing ovulation. Clinical trials have proven the PVR to be a safe and effective contraceptive; furthermore, it is currently registered in eight countries in Latin America. The PVR has also been included in the 2015 WHO Essential Medicines List and the Medical Eligibility Criteria guidance.

Global and national policies have refocused attention on postpartum family planning (PPFP) as an important intervention to ensure healthy outcomes for women and infants. In this policy context, underused technologies such as the PVR have the potential to contribute to national and global goals, especially in settings where breastfeeding is prevalent and unmet need for spacing is high.

The Population Council conducted a multicountry acceptability study of the PVR in Kenya, Nigeria, and Senegal with funding from the Bill and Melinda Gates Foundation (BMGF). The acceptability study was part of a series of activities that assessed the feasibility of and preparation for eventual introduction of the PVR in these markets. This report summarizes the results of the acceptability study from the three countries. Data were collected from 191 users of the PVR who had sought family planning services at 1 of 15 public-sector service-delivery points, their husbands (11), health care providers (141), and three focus groups with community members to evaluate factors influencing acceptability of the PVR. Data were also collected from 178 women who chose a method other than the PVR, to provide additional and contrasting insights into how users view new contraceptives.

Key findings from the acceptability study are as follows:

- The aggregated sample across the three countries reflected a young demographic, with over two-thirds of study participants being under the age of 29. More than half of the women (51 percent) had never used contraceptives before. These results imply the potential for the PVR to appeal to a younger demographic and to attract new users to adopt contraceptives. Attraction of new users will contribute to the FP2020 goal of adding 120 million additional contraceptive users.
- Unique features of the PVR that drove users' choice were that it can be user-initiated/controlled (35%), is short-acting (10%), and can be used while breastfeeding without detrimental effects (6%). Four percent of users reported the novelty of a new technology.
- Upon using the PVR, women reported high rates of satisfaction: 89% reported overall satisfaction with the method after 3 months of use, which increased to 98% at 6 months. More than 70% of the women found the PVR easy to insert, remove, and reinsert. Furthermore, these proportions rose the longer the women used it.
- Perceptions of the ring's size, texture, and color did not emerge as important factors; perceptions of all these physical aspects became more positive from the time the ring was first seen to the time it was used.

- The great majority of women did not report any ring expulsions, although 5% of the women did. Half the women reported that they had felt the ring slip occasionally; however, with provider guidance and their own experience they learned to reinsert or reposition the ring so they did not feel it slipping.
- The PVR had no detrimental effects on intercourse; four-fifths of PVR users did not feel the ring during intercourse, although one-fifth reported feeling it occasionally or all the time. Even more noteworthy is that the presence of the ring did not alter either the frequency of sex or sexual pleasure.
- In terms of continuation of the PVR, 64% of participating women used one PVR for the entire cycle of 3 months and 55% used two PVRs for the entire cycle of 6 months. Of the women who had completed one ring cycle, 86% went on to complete the second ring cycle. Those women who discontinued did so early, within the first month of use; others discontinued because of lack of adherence to study protocol, including not returning for scheduled follow-up visits at the health centers, and because they breastfed less than required as they weaned their babies.
- Most husbands of the participating women were supportive of the use of the PVR. A few women reported that their husbands objected to their using the ring and these women terminated participation in the study. In terms of feeling the ring during sex, 68% of women reported that their husbands did not feel it, although the remainder reported that their husbands did feel it. In-depth interviews with a few men indicate that most men did not feel the ring during sex and did not object to its presence during sex. These results of sexual-partner responses are in line with those reported by other studies.
- Family planning providers are interested and engaged in learning about a new contraceptive to include in the choice of methods they offer. Study providers were able to manage side-effects, such as spotting, that some women reported. Their attitudes as to which type of user could use the method changed as their experience with the PVR increased. The study providers were able to counsel women well and provide accurate information on the ring, suggesting that the curriculum and the modality of training were successful.
- Focus group discussions with community members in the three countries indicate that there is support for breastfeeding and spacing births for the health of mothers and babies. There is support for the PVR in those communities where family planning is an accepted norm, and less so in those where the concept of family planning is still an issue of debate.
- Across the 15 study centers, 24 adverse events were recorded over the course of the study and they were managed as per the standard of care in each of the study facilities. These adverse events are similar to those recorded in other studies of the PVR. One serious adverse event was recorded and deemed to be unrelated to the PVR; it was reported to the appropriate health authorities as per study protocol.

In summary, the PVR is an acceptable method of contraception in Kenya, Nigeria, and Senegal, and we can extrapolate that the method will be just as acceptable in other developing countries. Users, their husbands, and their providers find the PVR acceptable for breastfeeding women. There is widespread community support for the product, and it is feasible to integrate into existing health systems.

A few lessons emerged from the experience that will be useful to apply in wider-scale introduction:

- Counseling of users is a critical component of the success of the PVR's use, especially in insertion and removal. Proper insertion is required to minimize feelings of slippage.

- Although some women did use the PVR covertly for a period of time and most men did not feel it, when the PVR is introduced it will be prudent to inform potential users that some men can feel the ring. By providing this information, potential users can decide for themselves whether to select the method and how to inform their male partners.
- Introduction should proceed in phased steps so that there is sufficient product support from providers to users. In the initial phases of product uptake until the time a critical mass of users and user experience has accumulated, it will be necessary to provide support to users of this new product.
- It will be important to focus introductory efforts on those communities where women have used the PVR, where outreach has already occurred, and where community champions have been identified. It will be just as important to leave out those communities where there continues to be resistance and suspicion of family planning from the first phase of activities. Second, it will be helpful to build the introductory strategy from the existing platform of trained providers and supervisors who participated in the study.
- The PVR is a contraceptive that can contribute to integrated Maternal, Newborn, and Child Health (MNCH) services (prenatal care, postnatal care, well-baby clinics, growth monitoring, and nutrition) because it promotes breastfeeding as well as contraceptive protection, thereby ensuring healthy mothers and babies.
- Training of providers and other stakeholders will need to emphasize that there are no restrictions on the use of the PVR as indicated by the 2015 WHO's Medical Eligibility Criteria for Contraceptive Use (MEC) guidance.
- Given the ongoing discussions in the field regarding the association between hormonal contraceptive use and HIV, it will be important to note that the 2015 WHO MEC indicates that women at high risk of HIV infection or living with HIV or on antiretroviral therapy (ART) can use hormonal contraception without restriction.
- There is a potential market for other vaginal contraceptive products, including Multipurpose Prevention Technology rings (MPT), given the interest expressed by users.

Introduction

Global and national policies have refocused attention on postpartum family planning as an important component of ensuring healthy outcomes for women and babies (WHO 2013; Cleland et al. 2015). The progesterone contraceptive vaginal ring is used to extend the contraceptive effectiveness of lactational amenorrhea among breastfeeding women. Progesterone vaginal rings are inserted in the vagina 30–90 days (6–9 weeks for the purpose of this study) postpartum for continuous use for up to 3 months and replaced with a new ring if breastfeeding is continued and extended contraception is desired. Women can use four rings successively for up to one year. The progesterone vaginal ring functions by diffusing a continuous flow of 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, inhibiting sperm penetration into the uterus. Clinical trials have proven the PVR to be an effective contraceptive; furthermore, it is currently registered in eight countries in Latin America. The PVR has also been included in the 2015 WHO Essential Medicines List and the Medical Eligibility Criteria guidance.

Although demonstrated to be safe and effective in clinical trials, there is a need to assess acceptability prior to introduction into country programs. To this end, the Council conducted acceptability studies of the PVR in Kenya, Nigeria, and Senegal. This report represents the results from a pooled analysis of data from the three countries.

The acceptability study is one component of a number of activities that are part of pre-introductory efforts. Other activities include global and national consultations, assessments and documentation of the regulatory and procurement frameworks, and market segmentation and demand analysis. As part of the acceptability assessment described in this report, information was collected from various stakeholders to evaluate factors influencing acceptability, including PVR users, health care providers, partners, and community members.

STUDY OBJECTIVES

The primary objectives of this acceptability study were to:

- Assess factors influencing acceptability and perceptions of the PVR by participating women
- Assess the perceptions of the PVR by husbands of the women participating in the study
- Assess factors influencing providers' knowledge and attitudes about the PVR and its use
- Assess factors influencing community members' perceptions about the PVR
- Assess factors influencing method choice and attitudes about the PVR by nonusers

SETTING

The study was conducted at 15 sites located in Kenya (6 sites), Nigeria (2 sites), and Senegal (7 sites). Countries were selected based on their strong breastfeeding practices (needed to support the efficacy of the method), government interest and commitment to the research, presence of the Urban Reproductive Health Initiative (URHI), and Council presence. Sites were a mix of public and private hospitals and health clinics and predominately urban, although a few rural sites in Kenya were included.

The sites were selected in conjunction with the Ministries of Health (MOH) based on onsite availability of postpartum family planning services, a reasonable caseload of women seeking family planning before nine weeks postpartum, no other new contraceptive being introduced, feasibility of following up participants, being project sites of the URHI, ability to meet Population Council research standards and global Good Clinical Practice (GCP) guidelines, as well as ability to absorb the workload necessitated by the study such as documentation and follow-up.

Methods

This acceptability study collected both quantitative and qualitative data from users, providers, and key influentials as described below.

STUDY DESIGN

PVR users were followed prospectively for method acceptance for up to 6 months (2 ring cycles) or to discontinuation if that came earlier. Primary data were collected from users of the ring by means of a quantitative survey questionnaire. To complement the quantitative data, qualitative data were collected from up to five women in each country to better understand the intricacies of everyday use of the ring. These data were collected through an in-depth interview (IDI) questionnaire. IDIs were also conducted in each country with up to five partners of women who agreed to do the interviews. Providers were interviewed pre- and post-training and at the end of the study using a questionnaire guide. Finally, focus group discussions (FGDs) were held with other stakeholders who may have some influence on user behavior, to capture their perspective.

Unlike most acceptability studies that are embedded within clinical trials, this research activity was conducted as a stand-alone piece because the PVR had already undergone clinical trials and is currently registered and sold in several Central and Latin American countries. In addition, since the acceptability research was one component of a range of preparatory activities for the eventual introduction of the PVR in the countries, we developed a methodology that included a wider range of stakeholders.

This study was conducted in Kenya (6 sites), Nigeria (2 sites), and Senegal (7 sites). Sites were selected based on consideration of the following criteria: onsite availability of postpartum family planning services, a reasonable caseload of women seeking family planning before 9 weeks postpartum, no other new contraceptive being introduced, feasibility of follow-up, project sites of the Urban Reproductive Health Initiative (URHI), ability to meet Council research standards and global Good Clinical Practice (GCP) guidelines, and ability to add this study to the site's workload. Throughout this report, the term "site" or "study site" is used to refer to the health facility where the study was conducted (hospitals, health centers, and clinics). In all countries, MOH partners ensured that all contraceptive methods normally offered at the facility were in supply for the duration of the study; this was to make certain that study participants were exposed to the full range of contraceptives available and were able to make their choice in an informed manner.

STUDY PROCEDURES

Ethics Clearance

The study protocol was first approved by the Population Council's Institutional Review Board (IRB) on November 12, 2012, with subsequent renewals through the end of the study period. In addition, the protocol was reviewed and approved by each country's research and ethics boards. Revisions per each country review were incorporated into the protocol. In Kenya, the protocol was approved by the Pharmacy and Poisons Board (PPB) and the University of Nairobi College of Health Sciences and the National Council for Science and Technology. In Nigeria, it was approved by the Federal Capital Territory (FCT) Health Research Ethics Committee and the Institute for Advanced Medical Research and Training (IAMRT). In Senegal, the protocol was translated into French and approved by the Comité National d'Ethique pour la Recherche en Santé (CNERS) or the National Council of Ethics for Research in Health. In each case, the approval was renewed to accommodate a delay in commencing the study.

Ring Importation

As the PVR is not yet registered in these countries, importation for study rings directly from the manufacturer in Chile, Grünenthal (Empresas Andrómaco at the time of importation), was obtained. Importation approval was granted in Kenya by the Pharmacy and Poisons Board; in Nigeria by the National Agency for Food and Drug Administration and Control (NAFDAC), and in Senegal by the Ministry of Health. Rings were shipped directly to the Population Council in-country and subsequently distributed to the study facilities.

Training of Providers

Two different categories of trainings were conducted prior to commencing this study. First, a select group of obstetricians and gynecologists were trained and will serve as national trainers when the ring is finally registered and becomes available in the country. Second, study trainers along with the national trainers trained family planning service providers (mainly nurses who also provided counseling) in the study sites. These trainings took place from November 2013 to January 2014 just prior to commencement of the study. A total of 141 providers and supervisors were trained.

Monitoring

Throughout the study, close monitoring was conducted to ensure: the rights and safety of participants, compliance with global GCP standards and local ethics boards, and accuracy of data. Three types of monitoring visits were conducted: site initiation, interim monitoring, and site close-out. Site initiation visits were conducted from November 2013 to January 2014 to assess each site's capacity and readiness to accommodate the study, including adherence to GCP. The sites were assessed in terms of capacity to provide 24-hour service, availability of a private space for provider/client interaction (including counseling), availability of pregnancy and HIV screening kits, availability of a lockable cabinet where data and research commodities could be kept confidential, and a key and sufficient client load. A corrective action plan was written for any issues that needed to be addressed prior to study start.

Regular interim monitoring visits were conducted during the study to ensure the study was being conducted in accordance with the protocol and GCP standards as well as to address any questions or issues the site staff may have had. At these visits, monitors trained in GCP, checked the master study binder for completeness, reviewed case report forms (CRFs) for accuracy, and provided technical assistance regarding study procedures if required. Finally, at the conclusion of the study, a close-out visit was conducted at each site to ensure that all documentation was properly filled out and stored in accordance with global and national standards, the master study binder was complete, and all unused PVRs and CRF forms were destroyed or removed from the sites.

Recruitment

Women who came to the health facilities for family planning 6–9 weeks postpartum were counseled on the benefits of postpartum family planning and offered the full range of contraceptives, including the PVR. Often, women visiting the facility for well-baby visits were referred for family planning services as part of the routine continuum of care. At some sites, women who sought antenatal care or delivery services were informed about the study and told they could return if they were interested in learning more. Women who chose the PVR as a method of contraception were recruited into the study after providing informed consent.

Data Management and Analysis

Research assistants were trained in data collection prior to the start of the study. They were trained in the objectives of the study including research ethics. Data were collected and maintained per the Data Management Guide developed by the Council. Personal Data Assistants were used for collecting quantitative data. Immediately after collection, quantitative data was converted to Stata, SPSS, R, XLS, or CSV formats based on the in-country choice of analysis tool. Other paper-based responses were converted to one of the above formats after appropriate data entry.

Documentation was deposited in PDF, or plain-text formats, to ensure long-term accessibility. Sound files from the in-depth interviews were also stored without individual identifiers. The associated data type was captured using ODK and analyzed using SPSS or Stata data analytics tools. The study team complied with all the requirements for responsible data management and use practices, including extensive technical and administrative procedures to ensure consistent and systematic information security. Good practice requirements include system security requirements (e.g., password protection, controlled access) and regular auditing and review. All aspects of security including procedural controls, technical controls, confidentiality concerns, access control rules, and restrictions on use were monitored and implemented during the course of the study.

This report includes univariate and bivariate analysis of the quantitative data, complemented by findings from the qualitative data collected.

Results

We begin by providing a brief summary of the data collected and a description of the study participants, followed by findings on PVR acceptability.

OVERALL STUDY METRICS

A total of 252 women were screened across all participating sites in the three countries. Of these, 76% (n=191) passed screening and provided informed consent to participate in the study; they comprise 176 women who participated in the quantitative part of the study and 15 who participated in the qualitative part. Since all study sites were routine family planning service centers, the standard clinic registers do not record if the clients are in the first year postpartum, and if so, how many months postpartum. Thus, it is not possible to estimate the proportion of clients who are postpartum family planning clients, and among those the proportion that chose the PVR. Further compounding the issue is that all sites offer integrated maternal and child health (MCH) and FP services, thus a single client could have received multiple services on the same day. Multiple registers maintained at the clinic record various facets of service delivery, including overall client intake and services provided (counseling, counseling and services, referral) broken down by service center (FP, MCH, HIV, growth monitoring) so that it is difficult to differentiate the proportion of study participants drawn from the universe of all clinic attendees. An additional 178 women who had availed of family planning services at the study sites and chose a different method were interviewed after they had received services and had provided informed consent. These 178 women formed a separate sample than the women who participated in the acceptability study.

Data collected through the follow-up interviews at 3 and 6 months indicate that 124 of the 191 women completed one full ring cycle and 108 women completed two ring cycles. Thirty women were lost to follow-up after enrollment either because they had moved out of the study catchment areas and thus did not avail of services or participate in the study, or because they did not return for scheduled visits. Some of the study participants had provided false addresses and mobile phone numbers, thus limiting the possibility of tracing them. Five women missed one of the two follow-up interviews. Data from the CRFs maintained by the study providers recorded a total of 24 adverse events (AEs) reported over the study period and across the sites, and one serious adverse event (SAE) in one site (described later in report).

TABLE 1 Rate of enrollment and participation in study

Variable	(n)	Percent
Number of women screened	252	—
Number of women enrolled	191	76
Number of women who chose a different method	178	na
Number of women who completed one ring cycle	124	65
Number of women who completed two ring cycles	108	57
Number of Adverse Events	24	—
Number of Serious Adverse Events, if any	1	—

Data source: Baseline survey; CRF; nonuser data

DEMOGRAPHIC CHARACTERISTICS OF STUDY PARTICIPANTS

More than two-thirds of the women who participated in the study were under the age of 29, with about one-third under the age of 25 (Table 2). Over four-fifths of the women lived in urban or peri-urban areas of their respective countries reflecting the mix of family planning facilities from which they were recruited into the study. In terms of educational attainment, 68% had either primary school (30%) or secondary school (39%) education, and 25% reported having gone to a college or university. These aggregated data mask differences in schooling attainment across the three countries, with the Senegal sample having two-thirds of women who were primary-school educated and the Nigerian sample having more than half who had at least a college degree. Marriage was near universal in our sample, with no country specific differences. Over 40% of the respondents were stay-at-home mothers, and of those that reported working, most were engaged in petty business. Nearly all the husbands/partners of the study respondents were working, with most engaged in petty business, agriculture, or manual labor.

TABLE 2 Demographic characteristics of study participants

Variable	(n)	Percent
Age		
15–19	7	4
20–24	56	32
25–29	53	30
30–34	47	27
≥ 35	13	7
Place of residence		
Urban	83	47
Peri-urban	72	41
Rural	21	12
Education		
None	11	6
Primary or lower	52	30
Secondary	69	39
College/university	44	25
Marital status		
Married or cohabiting	174	99
Respondent's occupation		
Not working	74	42
Nonprofessional	58	33
Professional	44	25
Partner's occupation		
Not working	4	2
Nonprofessional	105	60
Professional	66	38

Data source: Baseline survey.

(N=176)

REPRODUCTIVE AND FAMILY PLANNING HISTORY

Table 3 indicates that for close to two-fifths of the study participants, the index child was the first child ever born; with 69% reporting having up to two children. This reflects the age distribution of the sample as well, which is predominantly young. When asked about the intendedness of the index baby, 38% of the women reported that the pregnancy had not been intended with a significant majority (80%) indicating that they would have preferred to wait. As a point of reference, in all three study countries national unmet need for spacing as measured by the DHS is at least 12%. More than 90% of the women wished to wait at least two years before having the next child and these findings are in line with other multicountry analyses that have reported that 97% of postpartum women do not want to have a baby in the next two years (Ross and Winfrey 2001). In this study, communication between partners regarding child spacing is also high at 92%. A noteworthy finding is that at least half of the study participants had never used a contraceptive, with the PVR being their first method.

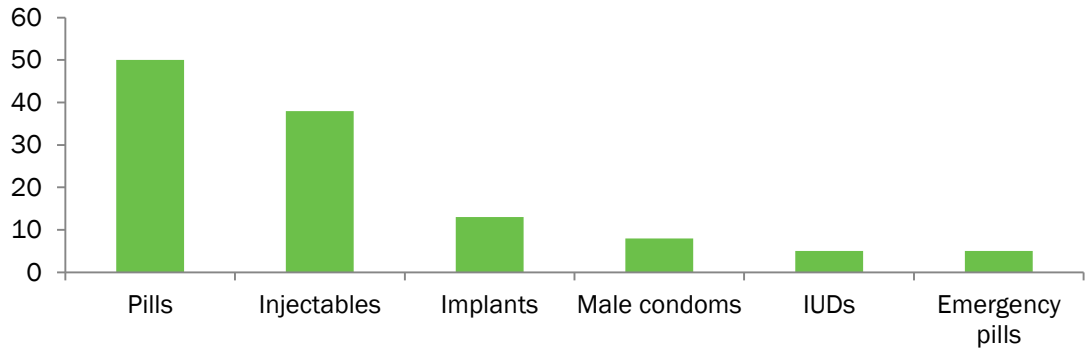
TABLE 3 Reproductive history and family planning use

Variable	(n)	Percent
Children ever born		
1	67	38
2	54	31
3 or more	55	31
Number of living children		
1	70	40
2	53	30
3 or more	53	30
Pregnancy was intended		
Yes	109	62
No	67	38
Preferred spacing of next birth*		
Within a year	15	9
2–3 years	60	34
4–5 years	61	35
> 5 years	20	11
Discussed pregnancy spacing with partner		
Yes	155	92
No	13	8
Prior use of a method		
Ever used	86	49
Never used	90	51

Data source: Baseline survey.
*Excludes missing values.

Among the women who had used a method of family planning prior to joining the study, pills (50%) and injectables (38%) were the most widely reported, with slight variation across the three countries reflecting the focus of that country's family planning program and method mix. Less frequently reported were implants (13%), with wide variation in use across the three countries with the highest level reported in Nigeria (22%) and the lowest in Senegal (8%). Other methods such as male condoms (8%), IUDs (5%), and emergency contraceptives (6%) were also reported. The use of any contraceptive should also be seen in the light of the levels of unmet need for spacing in the three countries ranging from 12% in Nigeria and 13% in Kenya to 22% in Senegal.

FIGURE 1 PREVIOUS METHOD USE



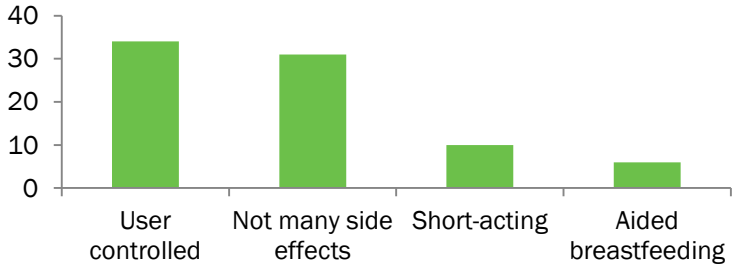
Data source: Baseline survey.

METHOD CHOICE AMONG PVR USERS AND NONUSERS

More than 81% of study participants reported that the PVR was the first method of choice. However, a significant minority (19%) preferred an alternate method (injectables, implants, pills, or IUD) or had not thought of using a contraceptive postpartum. Our data do not allow us to determine why they would have preferred an alternate method; we speculate that they could be more familiar with these existing methods and/or not familiar with the timing of postpartum contraception.

Among those who chose the PVR, the most cited reasons were that it was user-controlled (35%), did not have many side-effects (31%), and that it was short-acting (10%). Some women cited that it did not interfere with breastfeeding and in fact aided it (6%). Novelty of a new method was apparent as well; some women wished to try a new method albeit in smaller proportions (5%). Interestingly some women (6%) also said that they wished to try a method other than pills, injections, and implants because of the side-effects they had experienced with these contraceptives or because they found them cumbersome to use. Some of the responses indicated above could in part be due to the information provided during the family planning consultation as part of the study process.

FIGURE 2 REASONS FOR PVR CHOICE

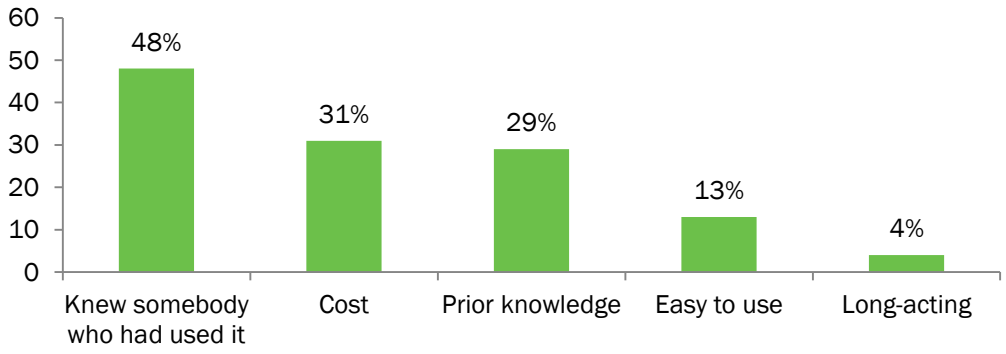


Data source: Baseline survey.

The study collected information on the first 58–60 women in each country who visited the study sites and chose a contraceptive other than the PVR. A total of 178 women chose other methods and were interviewed after they had provided informed consent. Those who did not choose the PVR tended to be similar to those who chose it. Non-PVR users were either married or in domestic partnerships (98%) and had similar childbearing histories (65% had two children or fewer). There were slight differences in schooling in that non-PVR users tended to have a more even spread from no schooling (12% compared to 6% among PVR users), primary schooling (21% versus 30%), secondary schooling (27% versus 39%), and college and beyond (40% versus 25%).

Non-PVR choosers were asked about which method they had chosen and the reason behind the choice. Injectables were the most common method chosen (34%) followed by implants (26%). IUDs and pills were equally chosen by 18 percent of the women. In the entire sample, only one woman chose LAM alone, which is consistent with DHS findings that LAM users tend to be less than 5% of all contraceptive users. Figure 3 shows that the chief reasons women choose a particular contraceptive was because they knew somebody who had used it (48%), its cost (31%), they had prior knowledge of the method (29%), and that they felt that it was easy to use (13%). Four percent of the women reported that they chose a method because of its long-acting contraceptive protection.

FIGURE 3 REASONS FOR OTHER METHOD CHOICE



Data source: Nonuser.

Even more interesting were the reasons for not choosing the PVR. Perceived discomfort was a prominent theme, whether related to perceived discomfort with vaginal insertion (7%), or discomfort during sex (35%) or while toileting (33%). A minority also reported a general sense of unease about trying a new product (3%) and others preferred a longer-acting method (4%).

IMPRESSIONS ABOUT THE RING

Study participants were asked to give their first impressions of the ring—its size, color, and texture—and their perceptions were recorded after having seen and felt the ring for the first time. The participants were also asked the same question when they left the study, at the time of their last interview—either at the end after completing two cycles of use or when they had discontinued use and hence were leaving the study. The rationale for repeating the questions was to determine if there were changes in perception after the women had some experience using the rings.

At baseline, most women had no specific perception of the color of the ring, with 85 percent indicating that it was just fine, and a minority indicating that it was either too pale or bright (Table 4). On the other hand, the size of the ring and its texture seemed to be of importance, as there were variations in perceptions. For example, just about half the women thought its size or texture was fine (49% and 52%, respectively); close to half thought it was too big, and a third perceived it to be too soft. A noteworthy point is that these perceptions changed considerably after use. At follow-up, perceptions had changed remarkably to a more positive viewpoint—with greater proportions reporting that the size (49% to 77%), color (85% to 93%), and texture (52% to 85%) were fine. Clearly experience of a product can shape and alter initial perceptions. This finding has relevance for the methodology of acceptability and market research—experience of a product may be a more reliable marker of new product uptake than reactions measured at a display of products. Reactions captured at product displays may be a useful tool for product design but may not be predictive of uptake or sustained use after product launch.

Analysis not shown here found that there were no significant differences in perception on these three aspects between women who had used two rings and those who used one. For example, 50 percent of those women who had used one ring thought the size was fine, compared with 53 percent of those who had used two rings. A similar result was found concerning the color of the ring: a greater proportion (89%) of women who had used two rings thought that the color was fine compared with those who had used one ring (77%), although the difference is not statistically significant. Similar results were obtained on texture as well. These results imply that the physical characteristics of the ring in terms of how it looks and feels may not be associated with its continued use.

TABLE 4 Impressions about the ring before and after use

Variable	Baseline (N=176) %	Follow-up (N=101) %
Impressions about size		
Just fine	49	77
Too small	1	2
Too big	47	20
Impressions about color		
Just fine	85	93
Too bright	11	4
Too pale	2	2
Impressions about texture		
Just fine	52	85
Too hard	14	3
Too soft	33	11

Data source: Baseline and follow-up surveys.

PERCEIVED QUALITY OF CARE

We elicited information on those key aspects of the consultation between the family planning provider and the study participant that could have an effect on the latter's ability to use the PVR effectively. Table 5 shows study participants' reports of what the provider had told them during their consultations. More than 90 percent of study respondents recalled being told of the minimum number of times they needed to breastfeed to be able to use the ring and when the ring had to be replaced. Almost all the women felt that their providers had allowed them to ask questions. Since knowing about insertion and removal are important aspects of using vaginal rings, we probed about this. All study participants reported being shown how to insert the ring and a just a bit fewer (88%) were shown how to remove it. Most of the women (87%) also reported that the provider had encouraged them to insert it themselves. Since the product is meant for self-use, this was an important part of the family planning consultation that can facilitate use. In summary, these data indicate that study participants had sufficient and accurate knowledge about the PVR to be able to use it effectively as they entered the study. Furthermore, providers comprehended the core elements that they had received training on and were able to pass along the information to the women they served.

TABLE 5 Perceived quality of care

Domain	Item	Response	(n)	Percent
Counseling on the method	Provider conveyed minimum breastfeeding requirement	Yes	165	94
	Provider conveyed when to replace	Yes	173	98
	Provider allowed respondent to ask questions	Yes	171	97
	Provider mentioned side-effects of ring	Yes	149	85
	Provider mentioned ring does not protect against HIV	Yes	147	83
Counseling on use	Provider showed how to insert	Yes	177	100
	Provider showed how to remove	Yes	155	88
	Provider encouraged respondent to insert	Yes	153	87

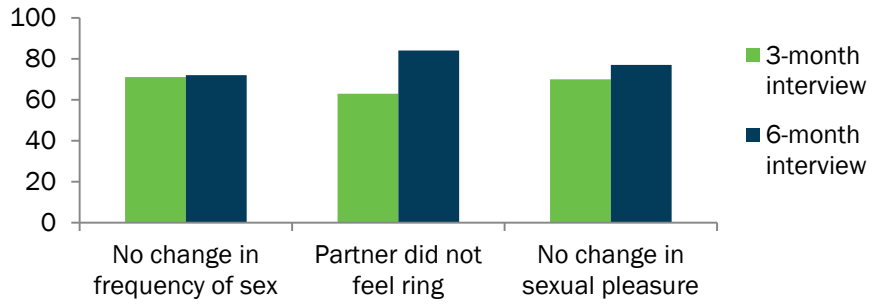
Data source: Baseline survey.

PARTNERS' SUPPORT AND EXPERIENCE

When interviewed 3 months after entering the study, more than 90% of study participants reported having resumed sexual relations with their partners. This pattern of resumption of sex post childbirth is consistent with other studies, although they were conducted with different populations in Nigeria and Kenya (Ndugwa et al. 2010; Anzaku and Mikah 2014). For example, the Kenyan study of women from two Nairobi slums reported that 50% and 75% of the women had resumed sex by 3 and 5 months, respectively (Ndugwa et al. 2010), and the Nigerian study of attendees of a child health service reported a median time for resumption of sex of 8 weeks (Anzaku and Mikah 2014). The women were asked to report if wearing the ring had any effect on sex, including their husband's reactions. Prior to the study, husbands' reactions to vaginal rings had not been explored.

Figure 4 indicates responses on three indicators measured at the 3-month and 6-month follow-up interviews: frequency of sex, husbands' responses to pleasure felt during sex, and husbands' responses to feeling the ring.

FIGURE 4 PARTNER'S REACTIONS ON PVR USE



At the 3-month interview, 71% of participants reported that there was no change in the frequency of sex since they started using the ring, although 15% reported an increase and 5% reported a decrease. More than three-fifths of the women reported that their husbands did not feel the ring, although one-fourth reported that their partners did so. In terms of sexual pleasure, most indicated that there was no change and 17% of the women indicated an increase in pleasure. Similar patterns were also observed at the 6-month interview. While the frequency of sex between the two interviews was similar, there was a substantial increase in the reports of no change in sexual pleasure. Most importantly, husbands' perceptions of feeling the ring declined over this period suggesting that as users and partners continue to use the ring they are less likely to be aware of its presence.

In summary, these data indicate that the PVR has limited to no effect on sexual behavior and in some cases has contributed to increasing reported sexual pleasure. Husbands have been supportive of their wives' use of the ring, as they have not felt any detrimental effects.

ACCEPTABILITY

This section reports on the acceptability of the PVR to four types of stakeholders beginning with the user, her husband/partner, the study provider, and the community at large. Each of these stakeholders has a unique perspective. While the user's experience is central to the ring's acceptability, the opinions and behaviors of the others can either support or hinder the user's access to and use of the product, and hence are important.

Women Participants

The following section reports on two measures of acceptability from the user's perspective. The first measure covers aspects of the use experience, such as the ease of use and comfort, expulsions, and effects on intercourse, all of which can determine continued use. The second measures intentionality of future decisions, such as intention to use the ring in the future and willingness to pay for it. Both quantitative and qualitative evidence is presented.

Most women (89%) reported overall satisfaction with the ring with 3 months of use, which increased to 98% at 6 months of use. Many aspects of the use experience were also positive, as shown in Table 6. For example, more than three-fourths of study participants reported that the ring was easy to insert, remove, and reinsert. In terms of ring expulsion, while a few women (4%) did report experiencing this, the greater majority did not experience expulsions. However, feeling that the ring was slipping was reported by half the women in the study. Since the PVR is a vaginal method, women's reports of feelings of the ring during intercourse are important. Over four-fifths of the women reported not feeling it during intercourse (87%), while a little less than a fifth (16%) reported

feeling it either occasionally or all the time. In addition, 31% of the women indicated that their husband/partner felt the ring, and the greater majority (68%) reported that their partner did not feel it. More importantly, study participants reported that there had been no change in the frequency of sex (98%) and in sexual pleasure (99%) at six months of use, thus confirming that the presence of the ring had no detrimental effect on intimacy.

In terms of intentionality for future use, based on their experience of using the ring for 3 months, four-fifths of study participants reported that they would use the PVR once approved by regulatory authorities, while the remaining one-fifth of women were uncertain or unlikely to use it in the future. On being asked about whether they would recommend the ring, 87 percent of the women indicated that they would recommend the ring to others. Of the 13% of women who were unlikely to recommend the product, two-thirds reported not being satisfied with the PVR as an explanation for their reluctance. Recognizing that intentionality is different from realized action, study participants were also asked to report if they had recommended the method over the past 3 months: 64 percent of the women had recommended the ring to other women.

As shown in Table 6, responses to various aspects of use remain positive or get better after 6 months of use indicating greater familiarity with the product and knowledge about how to manage its use. For example, users reported feeling more comfortable with insertion and removal. There were no changes in how the ring felt during sex; and most importantly slightly greater proportions reported no changes in the frequency of sex or sexual pleasure. The most compelling evidence is that users who have used the ring for more than 3 months are more likely to recommend the ring to others.

TABLE 6 Responses by 3 months and 6 months of use

Domain	Item	3 months of use (N=141) %	6 months of use (N=106)* %
Ease of use	Ease of inserting	84	88
	Ease of removing	73	74
	Ease of reinserting	77	80
Expulsion	Ring came out on its own	4	4
	Felt ring was slipping	52	50
Sexual intercourse	Never feel ring during sex	62	87
	Partner does not feel ring during sex	51	68
	No change in frequency of sex	70	98
	No change in sexual pleasure	70	99
Future intentions	Likely to use	81	96
	Would recommend	87	98
Family support	Family would support use	78	90
Recommendation	Already recommended	64	88

*Sample includes women who used the ring for two full cycles or for part of Cycle 2.

In-depth interviews with PVR users bear out the results of the quantitative survey. Five users were interviewed three times after they had enrolled in the study (1 month, 3 months, and 6 months) to solicit their opinions on their experience with the ring, including any exchanges they may have had with their husbands. Listed below are selected responses from all three countries arranged by domain to illustrate the range of perceptions and opinions. It is to be noted that since there are no respondents who had discontinued use who were willing to be interviewed, there is a potential bias toward positive reports.

TABLE 7 Responses by experience of use

Domain	Comments
Experience of the ring	"It is very comfortable. You don't feel any movement. It is just there." (Kenya, user 2, third interview)
	"Is easy to put and easy to remove. And when you insert it you will not feel it, it will not give you any stress to remove it, or you will not even remember that you insert something. Even when you are meeting with your husband you will not feel it, and your husband will not feel it. It will be as if you are normal." (Nigeria, user 3, second interview)
	"During these first three months, I have no problems in the use of the ring. This is an easy method to use." (Senegal, user 2, three-month interview)
	"Okay, the only fear I have is becoming pregnant. It is the only fear I am having." (Kenya, user 3, first interview)
	"Yes, two times [the ring slipped]. I washed my hands and handled the ring immediately because I had no problems to reinsert it." (Senegal, user 1, one-month interview)
Reasons for choosing the ring	"When that Sister [nurse] explained to me and she told me that after some time it can be removed, that is one of the things that made me like it. Because when I feel it is not good for me, then I can remove it and shift to another method." (Kenya, user 2, first interview)
	"Okay, first of all, it is new in the market. So it was like, wow, let me try it, because I have tried the others but they are not good for me. So maybe this one will be the one for me." (Kenya, user 3, first interview)
	"Hmm, the one that really makes me decide to choose it is because of this, my baby, the floating (means flowing) of my breast." (Nigeria, user 3, first interview)
Relative to other contraceptives	"I decided to choose this method because I had been using the pill. Sometimes, I would forget [to take it]; sometimes, I would feel nauseous—and, for one, it is very comfortable, and you don't have to keep on stressing yourself." (Kenya, user 2, first interview)
	"I will feel it in my body. I know it is inside, even if I have a problem, I don't feel it, I know I will understand. Not like the implant or the injection, you see all this type I will not know what is going on, but this one I will feel it. If I have issues, I will call and complain." (Nigeria, user 1, first interview)
	"Following the explanations of the provider, this method can be inserted by the woman herself, unlike others where you have the presence of a service provider. The fact that its effectiveness depends on breastfeeding is also a good thing because we know the benefits of breast milk on infant health. The fact that this is a new method has also motivated my choice because it's always good to try something new (feminine curiosity)." (Senegal, user 1, first interview)
Husband's feelings about the ring	"On the experience, I would tell women that if they use this ring, even their husbands, they'll say, 'Ah!' Okay—the act in bed—they say it's good. Yes, the act.'" (Kenya, user 3, first interview)
	"My husband tells me that when we have intercourse, he feels something—when the ring touches him, he feels something." (Kenya, user 3, second interview)
	"Honestly he has never complained to me." (Nigeria, user 1, first interview)
	"I had to inform my husband over the method and mode of action and the fact that the ring had no effect on breast milk. He was very happy because he had always thought that contraceptives could pass into breast milk and be harmful to the health of the child." (Senegal, user 2, one-month interview)
Sharing experiences with friends	"I would tell them to at least try this one. Because some women use other contraceptives and complain that their milk stops coming, so they can try this one." (Kenya, user 3, third interview)
	"Yes, I am encouraging them to, because the thing is helping me a lot and that is why I am calling them. If the thing is giving me problem, I will not tell them and even if I am telling them, I will also be [talking about the problems]." (Nigeria, user 3, first interview)
	"Health benefits to the mother and [that it is] the new [method]. [It is] ease of use and [provides] autonomy of women." (Senegal, user 1, first interview)
Interest in MPT rings	"Do you have it [MPT ring]? Of course they would be interested. Because you know, nowadays, men, you can't trust them very much." (Kenya, user 3, third interview)
	"Yes, women would be interested [in an MPT ring]. If the men are the ones putting on the condom and they want to infect you, they can just remove it. But with such a ring, the woman would be the one in charge." (Kenya, user 4, third interview)

Data source: In-depth interviews with users.

Male Partners

The following presents insights from the perspective of husbands of PVR users who were willing to be interviewed. In-depth interviews with the husbands of users reveal that they were supportive of their wives' use of the ring and did not have any major concern. It is noteworthy, though, that some of them expressed fear because the method was to be inserted in the vagina and would remain in the body; some had doubts about its efficacy since it was a new product. Some of the fears were grounded in an overall unease about family planning. Most importantly, the husbands reported not feeling the ring during sex for the most part; and even those who felt the ring did not find it intrusive or disruptive. These findings are consistent with those reported by other studies.

TABLE 8 Responses by experiece of ring use

Domain	Comments
Ease of use	"It was very easy to use since you can insert it on your own and still remove it when you want to. It's user-friendly compared to others where you have to visit a medical center to be inserted and also when removing." (Kenya, husband 2)
	"I think it is easy. Because sometimes I asked her, but this thing is not disturbing you or so…. She said no. She is not feeling anything. So I said okay. I ask her whether she feels something else, but she say no, she not even know whether something inside her." (Nigeria, husband 1)
	"My wife throughout the period had no trouble using the ring. It was easy to use. Sometimes the ring slipped (though it was not common), but she had no problem to reinsert the ring when it was happening." (Senegal, husband 3)
Fears	"One thing is that you fear it might hurt. Another fear was that I did not trust the gadget at first, so I was worried she might get pregnant. I told you it was like gambling. I didn't understand the science, but decided to go use it as per what I saw." (Kenya, husband 2)
	"I was so scared, having heard a lot of rumors about FP. It might hurt during sex, might cause excessive bleeding, and might reduce the sexual desire of your woman." (Kenya, husband 3)
	"Wow! *(Laughter)* I thought it was metal! So I now come and … come to the section when they showed how the thing will fold when they are putting it inside her and I now ask … Won't this thing fall out? Can she walk well with it? You know, will it be painful?" (Nigeria, husband 3)
	"When I first saw the ring I had misgivings about its use. My question was: How do you use such a product, especially considering its size and that it had to be placed in the body of the woman." (Senegal, husband 2)
Sexual intercourse	"At first I told you it was not comfortable but it had a lot to do with the mindset because I knew there was something inside there, so I didn't trust at first. So it was a bit tricky. I could feel it, but the feeling was not painful or anything, just something soft. But once you get used to it now you become comfortable. There was also the sucking effect. I did not know if it was just from my end, but I could feel it from the ring itself. If you touch it, of course you happen to penetrate in between the ring, you feel like something is sucking. It's a good feeling." (Kenya, husband 2)
	"Yes, it was comfortable and had my wife had it inserted without my consent, I would not even have noticed it." (Kenya, husband 3)
	"No problem. It was the normal experience." (Nigeria, husband 3)
	"For the first time, I was apprehensive but it was quickly dispelled in practice. In fact, sometimes if I felt the ring it did not bother sex." (Senegal, husband 3)

Data source: In-depth interviews with husbands.

Providers

Providers are important stakeholders who play a role in how a new product such as the PVR is delivered. They can either facilitate or hinder women's access to this innovative product. We interviewed the family planning service providers who participated in the study twice—once prior to study initiation, and once at the end of the study. During the course of the study, providers learned about the PVR and how to counsel women, and got accustomed to offering the product. The following table presents quantitative and qualitative data on select aspects of provider knowledge and attitude as illustration of the changes that occurred over time in all three countries. In general, across study sites in all three countries, providers' knowledge increased significantly indicating that the training was successful in imparting correct information and that the knowledge was retained several months later.

Furthermore, providers were able to reinforce the knowledge learned during classroom training with actual experiences during service delivery. For example, in Kenya, providers' knowledge about the safety of the PVR for mothers and babies increased from 57% to 100%. Similarly, in Senegal, knowledge of the mechanism of action increased from 81% to 96%. Attitudes also changed over time; in the beginning providers in both Kenya (9% to 87%) and Senegal (3% to 68%) were reluctant to provide the PVR to unmarried women, but by the end of the study they were not as hesitant. Although we did not probe the reason for the reluctance prior to the start of the study, we conjecture that providers were uncertain about the safety of the PVR since it was a new product and wished to safeguard the fertility of their clients.

TABLE 9 PROVIDERS' RESPONSES BY SATISFACTION RELATED TO USE

Domain	Baseline %	Endline %
Knowledge		
Is safe for postpartum women (Kenya)	57	100
Is safe for baby (Kenya)	57	100
Know the mechanism of action (Senegal)	81	96
Know the duration of use—3 months (Senegal)	75	93
Attitudes		
Would dispense to unmarried women with no contraindications		
Kenya	9	87
Senegal	3	68
Nigeria	17	80
Perception		
Lactating women will like the PVR (Nigeria)	94	100

Data source: Provider interviews at baseline and endline.

Community Stakeholders

Focus group discussions with community members were held in a variety of settings across the three countries. Illustrative quotes on salient features of these discussions are shown in Table 10. In all communities, there was widespread support for breastfeeding and the need to space births for the health of the mother and the baby. Of importance is that community members also offered suggestions about how the product could be introduced into their communities and the role that community members could play.

TABLE 10 RESPONSES BY SATISFACTION RELATED TO USE

Domain	Comments
Importance of FP and breastfeeding	"Because carrying a pregnancy is a big responsibility. The woman can lose her life and her child. God said that the mother should not harm her child. Harming her child in this case is to carry another pregnancy while the baby she has is not yet weaned. On one, she carries the pregnancy is risky, of two the child who is not yet weaned is in danger." (Senegal, Community FGD 1)
Support for and potential for uptake	"With the pill, there are some who take every other day. They want to use it, but they do not respect what they are told. Whereas with this method, once it is placed, it takes three months to remove. And it does not bother you at all. And women love ease. They are lazy to stand in queue for a method or to purchase tickets [to see the provider]. I think it will be better accepted." (Senegal, Community FGD 3)
	"The way I see it, they prefer pills since they will swallow them and their husbands won't know. But you know, there is a problem with men and it's good to talk about it since men complain a lot that their wives may not have the urge for sex and are "cold" [sexually—low libido], or sometimes overly wet. They look for mistresses since they see something wrong with their women. We would prefer this new method that we have learned about today since I do not see a lot of complaints that can interfere with sex, since it's not good for men to have mistresses. The new method is good since I haven't seen anything that will suppress the sexual urge in women, since we both are entitled to enjoying the act. So I would prefer this." (Kenya, Community FGD 3)
Strategies for product introduction	"When the female condom was introduced, they didn't appreciate the fact that the ring was big. This made us introduce the ETL (Education Through Listening) method. We talked to a group of women who agreed to try it. We need to introduce ETL also. The group should consist of about 10–20 women." (Kenya, Community FGD 2)
	"I will speak as a community. If we want to popularize such a method, I think that community actors have a role to play. Think now to involve community volunteers, the "*badienu gox*" and train them on this method." (Senegal, Community FGD 2)

Data source: Focus group discussions with community members.

CONTINUATION

A third measure of acceptability that complements and extends the use experience and intentionality is the extent to which women continue to use the product. Since the study protocol allowed a maximum of two ring cycles of use, it is possible to gauge the proportion of participating respondents who completed one ring cycle, two ring cycles, and partial use resulting in discontinuation.

A total of 113 of the 176 (64%) participating women used one ring, and 97 women (55%) completed the study by using two rings. Experience with using the ring has an effect on how long it will be used. Women who had completed one full cycle were more likely to complete a second cycle; 86% of those who had completed the first cycle went on to complete a second cycle thus availing of 6 months of contraceptive protection. It is to be expected that women will discontinue to use the ring, especially as infant feeding patterns change as the baby gets older; if women reduce the number of times they breastfeed their baby daily, they are more likely to discontinue using the PVR.

Table 11 presents the results of an analysis that explored the relationship, if any, between key aspects of the use experience and continued use through two ring cycles. The hypothesis being tested is that a positive use experience will have a positive effect on continuation. Women who found it easy to insert and remove the ring completed two cycles of use at higher proportions than those who discontinued use. Other analyses also revealed that women who expelled the ring or felt it during intercourse were less likely to continue use compared with those who did not; since the numbers of women who experienced ring expulsions and/or felt the ring during sex were small, the analyses are not shown.

TABLE 11 RESPONSES BY CONTINUATION RELATED TO RING USE

Domain	Item	Response	Completed 2 cycles %	Terminated %	p-value*
Ease of use	Ease of inserting	Easy/Very easy	88	76	0.09
	Ease of removing	Easy/Very easy	75	67	ns
	Ease of reinserting	Easy/Very easy	81	67	0.06

Data source: Follow-up interviews 1 and 2. * Fisher's Exact Test. ns = Not significant

A total of 28 women across the three countries stopped using the PVR in the first cycle of ring use—i.e., they did not use it for the entire 3 months of its potential use. Most of the discontinuations occurred early—within the first month (17); this is consistent with other data on discontinuation of family planning indicating that those who discontinue tend to do it earlier than later. The rest of the discontinuers used it for just over a month (5) or over two months (6). Reasons for discontinuing use ranged from discomfort (9), to inadvertent expulsion of the ring (9), to feeling that the ring was slipping (5). Of the 28 women who discontinued, two reported that they had stopped because they wanted a different method; three indicated that their husband objected to their using the ring. On being asked who had made the decision to stop using the ring, 7 of the 28 women indicated that their husband had made the decision for them.

Those who discontinued were also asked about their use experience in an effort to understand other factors that could determine duration of use. More than half (16) of the 28 women reported that they had felt the ring while wearing it, and 12 reported that they had on occasion removed it. About a third of the women (10) reported that the ring had come out by itself—sometimes during toileting or while they had been squatting.

Discontinuation reduced in the second cycle; just 4 women stopped using the method after they had received the second ring, and did not use it for the entire 3-month period. Of these 4 women, 2 reported bleeding issues (irregular or heavy bleeding) and 2 had inadvertently left the ring out and as per study protocol had to discontinue.

STUDY LIMITATIONS

There are a few study limitations. First, despite the efforts of the study team, there were 30 women who were lost to follow-up in the period between enrollment and the first follow-up at 3 months. Some of the loss to follow-up was a result of migration out of study sites and incorrect addresses. However, we speculate that an additional reason is better screening and enrollment as the study progressed; the loss to follow-up was highest in the first country to start the study and lowest in the last country, implying that the study team had learned from the initial experience and improved upon subsequent training, enrolling, and monitoring of study participants. Second, the husbands who were interviewed were partners of women satisfied with the PVR and also likely to have been supportive. Interviewing partners who were dissatisfied may have yielded different results. Third, the analyses presented here have been descriptive. Additional analyses will be conducted on additional variables of interest, including quality of care received at baseline and its effect on continuation.

ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

Prior to study initiation, participating providers had been trained to record all adverse events (AEs) that study participants might report, and study participants were encouraged to report any adverse event that took place while they were in the study. An adverse event is any medical occurrence that the study participant reported to the provider during the course of the study.

Sixteen AEs were recorded across the three countries and are listed in Table 12. Most of the AEs were handled by the study providers as per the standard of care that is available in the study sites. The types and range of AEs observed over the course of the study are similar to what family planning providers manage with hormonal contraceptive use. The AE most often reported was vaginal bleeding/spotting, which accounted for 5 of the 16 AEs. Other less reported AEs were abdominal/pelvic pain (4), prolonged bleeding (2), urinary tract infection (2), and vaginal itching (1).

TABLE 12 ADVERSE EVENTS

Description	Kenya	Nigeria	Senegal	Total
Losing weight			1	1
Expulsions			1	1
Lower abdominal pain/pelvic pain	1		4	5
Prolonged bleeding	1		1	2
Urinary infection	1		1	2
Abscess			1	1
Leucorrhea			1	1
Nausea			1	1
Headache/body pain			1	1
Vaginal itching			1	1
Spotting		3	2	5
STI			1	1
Fever		1		1
Nonspecific		1		1
Total	3	5	16	24

Data source: Case report forms.

TABLE 13 SERIOUS ADVERSE EVENTS

Number	Description	Treatment
1	Severe headache and psychosis	Treatment provided in nonstudy participating facility

Data source: Case report forms.

There was only one serious adverse event (SAE) recorded from one site in Kenya. The SAE came to light when the study participant did not return to the study facility for scheduled follow-up visits and the research team made a home visit. At the home visit, family members indicated that the study participant had been hospitalized at a private facility. As per the research protocol, the hospitalization was categorized as an SAE and duly reported to the Population Council's Safety Desk. The site investigator reviewed the medical records of the participating woman and determined that the SAE was unlikely to be related to ring use. The Council's Safety Desk developed a report that was shared with the Kenyan health and regulatory authorities.

Discussion

This three-country research initiative across 14 family planning service centers has generated a lot of information about the acceptability of contraceptive vaginal products.

At the initiation of the acceptability study in Kenya, Nigeria, and Senegal little was known about how a vaginal contraceptive would be perceived in these contexts. Hypotheses abounded that women would be uncomfortable and unwilling to use a vaginal product since it would require touching the genitalia, potentially sensitive in these cultural contexts. Second, the reaction of male sexual partners was unknown. Questions ranged from if they would feel the ring during intercourse and object to its use to being unaware of the ring thus allowing the potential for covert use by the woman. Third, questions remained on the service delivery and health system requirements to support the introduction of the new contraceptive even though it was well recognized that the PVR addressed existing needs. The acceptability study generated evidence on all these facets and more, and the key findings and lessons learned are highlighted below.

ACCEPTABILITY

The aggregated sample across the three countries reflected a young demographic with over two-thirds of study participants being under age 29. Consistent with the youthful sample, nearly two-fifths of participants reported their first child to be the index child. A noteworthy point is that nearly half of the study participants had not used a contraceptive prior to joining the study. These results imply the potential for the PVR to appeal to a younger demographic and to attract new users to adopting contraceptives. Attraction of new users will contribute to the FP2020 goal of adding 120 million additional contraception users.

The evidence on the drivers of women's choice of the PVR indicates that over a third of study participants cited the user-controllability of the PVR as an appealing feature. To one in ten women, the ability to use the PVR for 3 months and discontinue at will if they did not like it was an important feature; the theme of ability to discontinue was especially strong in those communities where there seemed to be an underlying discomfort and fear concerning contraceptive use. Six percent of the women liked the fact that they could use the PVR as they nursed and that the method relied on their breastfeeding. To a small minority (4%), the novelty of a new contraceptive, and especially an alternative to pills, injections, and implants, made the PVR an attractive choice. The implications of these results are that the PVR has the potential to enhance contraceptive choice; the extent to which the addition of the PVR to the existing method mix will lead to substitution from other contraceptives will need to be balanced against its ability to attract new users.

In terms of acceptability, the look and feel of the PVR did not seem to have an effect on its uptake or use by women. Perceptions of its size, texture, and color became more positive from the time it was first seen to the time it was used. Among women who used the ring, 89% reported an overall satisfaction with the method at 3 months, which increased to 98% at 6 months of use. More than 70% of women found it easy to insert and remove. Furthermore, the great majority of women did not report any expulsions of the ring; 5 percent of the women reported expulsions. Although some women reported feelings of ring slippage, they learned to reinsert or reposition the ring so that they did not feel it slipping. Equally importantly, about four-fifths of PVR users did not feel the ring during intercourse, although one-fifth reported feeling it occasionally or all the time. Even more noteworthy is that the presence of the ring did not change either the frequency of sex or sexual pleasure. In terms of duration of use, 64 percent of the participating women used one PVR for the entire cycle and 55 percent used two PVRs for the entire cycle. Those women who discontinued did so early, within the first month of use; others were discontinued due to lack of adherence to study protocol, including not returning for scheduled follow-up visits at the health centers.

These findings on the multiple aspects of acceptability are consistent with those reported by other studies conducted with other rings and in other cultural and social contexts. The universality of these findings suggests that irrespective of their social or cultural background, women will find vaginal contraceptives easy to adopt and use. The implication of these findings is that there is a potential market for the PVR in the three focus countries and other similar developing countries.

Most of the husbands of participating women were supportive of the use of the PVR. Some men did object to their wives' using the ring and these women terminated the study. In terms of feeling the ring during sex, 68% of women reported that their husbands did not feel it, although the rest reported that their husbands did feel it. In-depth interviews with a few men indicate that most men did not feel the ring during sex and did not object to its presence during sex. They did report trepidation in the first intercourse session, but this subsided with experience. These results of sexual partner responses are in line with those reported by other studies.

Responses from focus group discussions with community members in the three countries indicate that there is support for breastfeeding and spacing births for the health of mothers and babies. There is support for the PVR in those communities where family planning is an accepted norm, and less so in those communities where family planning is still an issue of debate.

Providers are important stakeholders and their knowledge and opinions of the PVR is critical because they can facilitate or hinder its adoption by users. Exit interviews with the PVR users after they had been counseled by service providers revealed that they had been informed on all the important aspects of use including how to use the PVR, the side-effects to expect, and the duration of use. This indicates that the curriculum prepared for the training of service providers was comprehensive and that the training was successful, because providers were able to counsel the women well. Providers were also able to manage side-effects, such as spotting, that some women reported. Providers' attitudes regarding which type of user could use the PVR changed as their experience with the method increased. The implications of the information gathered from providers are that it will be feasible to train frontline family planning service providers in the counseling and dispensation of the PVR. Providers are interested and engaged in learning about a new contraceptive and including it as part of the repertoire of methods.

A total of 24 adverse events were recorded across the course of the study and these were managed as per the standard of care in each of the study facilities. One serious adverse event was recorded and deemed to be unrelated to the PVR; it was reported to the appropriate authorities as per study protocol.

In summary, by the end of the study the questions posed at the initiation of the study were answered. The PVR is an acceptable method of contraception in Kenya, Nigeria, and Senegal and we can extrapolate that it will be just as acceptable in other developing countries. Husbands, too, find the ring to be acceptable and are supportive of their partners' use of the method. There is widespread community support for the product, and it is feasible to integrate it into existing health systems.

LESSONS LEARNED FOR FUTURE INTRODUCTION OF RINGS

Some lessons emerged from the three-country experience, as follows:

- Counseling of users is a critical component of the success of the ring's use. Family planning providers will need to teach all women how to insert and remove the ring at the health facility at the time of accepting the method. Insertion and removal in the presence of a trained service provider bolsters women's confidence in their ability to use the ring. In particular, women learn about the correct placement of the ring so as to minimize feelings of slippage or expulsion.
- Although some women did use the PVR covertly for a period of time and most men did not feel the ring, when the PVR is introduced it will be prudent to inform a potential user that some men can feel it. By providing potential users with this information, they can decide for themselves whether to select the method and to inform their male partners. Furthermore, women can also decide if they and their partners would benefit from joint counseling. Thus, women's autonomy to freely choose and decide will be protected.
- Introduction should proceed in phased steps so that there is sufficient product support from providers to users. In the initial phases of product uptake until the time that a crucial mass of users and use experience has accumulated, it will be necessary to provide support to users for this new product category. Since vaginal contraceptives are a new product category in sub-Saharan Africa, it will be of the greatest importance that the initial experiences are positive and that no negative buzz is created that will mar the uptake of the PVR and subsequent vaginal rings.
- The choice of the first communities to roll out the introduction program will be critical. It will be important to focus efforts on those communities where women have used the PVR, outreach has already occurred, and community champions have been identified. It will be just as important to leave out those communities where there continues to be resistance and suspicion of family planning from the first phase of activities. Second, it will be helpful to build the introductory strategy off the existing platform of trained providers and supervisors who participated in the study. Third, it will be important to grow the community of advocates, including health and rights activists and natural allies such as breastfeeding support groups, and the community.
- The responses to the PVR and the research generated on the perceptions to the NES/EE and MPT rings suggest there is interest in these new products. Women, men, and community stakeholders have unanimously indicated that such products address local needs and priorities.
- The research also highlighted additional areas of inquiry especially as related to the source of PVR supplies and services. Since the PVR is a contraceptive that has the potential for distribution by pharmacists, drugstore vendors, and community health workers, more needs to be known about the acceptability of the product to these cadres as well as women's opinions about accessing these service points. A second area of inquiry relates to the feasibility and interest of health systems in including the PVR in services that integrate maternal and child health (MCH) and family planning, as well as user preferences in accessing integrated service points. A third area is related to the type of product support that can be provided (e.g., mobile phones, in-person). A fourth area is related to whether PVRs can be provided prophylactically when women access antenatal care and delivery services for use postpartum, and, if so, the number of rings that can be provided.

References

Anzaku, A.S. and S. Mikah. 2014. “Postpartum resumption of sexual activity, sexual morbidity, and use of modern contraceptives among Nigerian women in Jos,” *Annals of Medical and Health Sciences Research* 4(2): 210–216.

Cleland, John, Iqbal H. Shah, and Lenka Benova. 2015. “A fresh look at the level of unmet need for family planning in the postpartum period, its causes and program implications,” *International Perspectives on Sexual and Reproductive Health* 41(3): 155–162.

Ndugwa, Robert P., John Cleland, Nyovani J. Madise, Jean-Christophe Fotso, and Eliya M. Zulu. 2010. “Menstrual pattern, sexual behaviors and contraceptive use among postpartum women in Nairobi urban slums,” *Journal of Urban Health: Bulletin of the New York Academy of Medicine* 88 (Suppl. 2): S341–S355.

Ross, J.A. and W.L. Winfrey. 2001. “Contraceptive use, intention to use and unmet need during the extended postpartum period,” *International Family Planning Perspectives* 27(1): 20–27.

World Health Organization (WHO). 2013. *Programming Strategies for Postpartum Family Planning*, Geneva: WHO.

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