ORIGINAL RESEARCH ARTICLE

Introducing the Progesterone Vaginal Ring (PVR) as a New Option for Postpartum Family Planning in Sub-Saharan Africa: Insights from Engagements with Stakeholders

DOI: 10.29063/ajrh2018/v22i2.7

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Abstract

The progesterone vaginal ring (PVR) is a ring-shaped device designed for use by women in the postpartum period to regulate fertility by complementing and extending the contraceptive effectiveness of lactational amenorrhea to suppress ovulation.[1] It is available in eight Latin American countries for use by breastfeeding women who want more effective modern contraceptives in addition to contraceptive benefits provided by lactational amenorrhea alone.[1] The PVR is a method that can be suitable to women in sub-Saharan Africa, given the near-universal practice of breastfeeding and the current level of unmet need for contraception in the postpartum period. Efforts are currently underway to introduce the PVR in Africa and south Asia. To ensure a seamless introduction, scale up and sustainability of the PVR in the region, the Population Council conducted pre-introductory activities with stakeholders in Kenya, Nigeria and Senegal to determine the level of interest in the ring, potential facilitating and mitigating factors and identify solutions to address challenges. The research team combined three approaches: in-depth interviews with family planning stakeholders; desk review of reports and policy guidelines; and in-group meetings. The stakeholders reached included public sector officials including policy makers and program managers, implementing partners, regulators, women and religious networks. All three countries had a promising policy and programmatic context that was supportive to PVR introduction. The exercise provided insights on socio-cultural and religious factors that could potentially impact how the PVR is perceived within communities and identified possible remedies to address misperceptions. It also paved the way for the conduct of an acceptability study of the PVR among breastfeeding women in these countries. The high acceptability rate in each country and the support expressed by government and other stakeholders have provided impetus for registration of the product in each country. Learning from this process could also direct how other family planning and reproductive health commodities would be introduced in the future. *(Afr J Reprod Health 2018; 22[2]:68-75).*

Keywords: Progesterone Vaginal Ring, postpartum family planning, sub-Saharan Africa

Résumé

L'anneau vaginal de progestérone (AVP) est un dispositif en forme d'anneau conçu pour être utilisé par les femmes pendant la période postpartum pour réguler la fertilité en complétant et en augmentant l'efficacité contraceptive de l'aménorrhée lactationnelle pour supprimer l'ovulation[1]. Il est disponible dans huit pays d'Amérique latine Les AVP sont une méthode qui peut convenir aux femmes en Afrique subsaharienne, étant donné la pratique quasi universelle de l'allaitement maternel et le niveau actuel du besoin non satisfait de contraception pendant la période post-partum. Des efforts sont actuellement déployés pour introduire le RVP en Afrique et en Asie du Sud. Pour assurer une introduction, une mise à l'échelle et une pérennité du RVP dans la région, le Population Council a mené des activités de pré-introduction avec des parties prenantes au Kenya, au Nigeria et au Sénégal pour déterminer le niveau d'intérêt des solutions pour relever les défis. L'équipe de recherche a combiné trois approches: des entretiens approfondis avec les parties prenantes de la planification familiale; examen documentaire des rapports et des lignes directrices; et réunions en groupe. Les parties prenantes touchées comprenaient des responsables du secteur public, notamment des décideurs et des responsables de programmes, des partenaires d'exécution, des régulateurs, des femmes et des réseaux religieux. Les trois pays avaient un contexte politique et programmatique prometteur qui était favorable à l'introduction du RVP. L'exercice a permis de mieux comprendre les facteurs socioculturels et religieux susceptibles d'avoir une incidence sur la façon dont le RVP est perçu au sein des collectivités et d'identifier les solutions possibles pour corriger les perceptions erronées. Il a également ouvert la voie à la réalisation d'une étude d'acceptabilité du PVR chez les femmes allaitantes dans ces pays. Le taux

élevé d'acceptabilité dans chaque pays et le soutien exprimé par le gouvernement et d'autres parties prenantes ont stimulé l'enregistrement du produit dans chaque pays. L'apprentissage de ce processus pourrait également indiquer comment d'autres produits de planification familiale et de santé reproductive seront introduits à l'avenir. *(Afr J Reprod Health 2018; 22[2]: 68-75).*

Mots-clés: Anneau vaginal de progestérone, planification familiale post-partum, Afrique subsaharienne

Introduction

Despite the progress made over the last few decades, up to 210 million women globally[1-2, 3] and as high as 30% in many African countries, experience unmet need for contraception[4]. The need is even greater in the immediate postpartum period with about two-thirds of women, and as high as 74% in sub-Saharan African countries not using a modern contraceptive[5]. Sub-optimal birth spacing has deleterious effects on maternal and child health as complications are more common in pregnancies that occurred within two years of the previous birth[1]. Evidence suggests that uptake and continued use of modern contraceptive methods increases when additional methods are added to the mix[6-7]. This is also true for postpartum contraception from experiences in West and East Africa[8]. Therefore, the World Health Organization has recommended expanding contraceptive options during the postpartum period[9]. In the last few years, there has been increased attention for meeting contraceptive needs of women in the postpartum period by expanding the available choices. For a new product to be introduced successfully in each country, local stakeholders must be engaged from the beginning and briefed continuously along the entire process as they provide valuable information and guidance. Previous studies from Africa and Asia have espoused the benefits of early engagement with in-country stakeholders as a strategy for understanding local contexts to properly position new contraceptive products within the appropriate framework[10-11].

In this respect, Population Council conducted a stakeholder mapping exercise in three countries in sub-Saharan Africa namely Kenya, Nigeria, and Senegal to determine the program and policy contexts as well as in-country level of interest for the progesterone vaginal ring (PVR) as a new method for postpartum contraception.

The PVR is a ring-shaped device used by women in the postpartum period to regulate fertility by complementing and extending the contraceptive effectiveness of lactational amenorrhea to suppress ovulation. It diffuses a continuous flow of low doses of natural progesterone through the vaginal walls into the bloodstream. The ring is inserted in the vagina after 4 weeks postpartum and is used continuously for 3 months. The used ring can then be replaced with a new 3-month ring, up to three times, if breastfeeding is sustained adequately and continued contraception is desired.[1] Although the PVR has been available and used in a few countries in central and south America, it is not widely available in Africa or Asia. In these regions, breastfeeding is near universal and for long durations and the product may serve the needs of the women in these settings as it was designed for nursing women. As the PVR is a self-initiated and user-controlled method, it would be suitable for many settings in Africa and south Asia where health infrastructures are weak. Due to the simplicity of its use, it can be provided through multiple outlets such as pharmacy and local drug shops. The Reproductive Health Supply Coalition (RHSC) identifies the PVR as an under-utilized reproductive health commodity[12]. As part of the stakeholder mapping, assessments of financing environment and procurement mechanisms for family planning and reproductive health commodities, analysis of existing socio-cultural and religious beliefs that could impact the PVR and assessment of policy and program environments in the respective countries were conducted. This paper highlights the processes, successes and potential challenges, as revealed through engagements with the stakeholders, and lessons learned that could shape the way the PVR and other new reproductive health and family planning commodities can be introduced in sub-Saharan Africa.

Methods

From February 2012 through 2014, the Population Council's research teams conducted landscaping assessments in Kenya, Nigeria, and Senegal to

map out the family planning program and support for contraceptive technologies available in each country with the view to determining potentially supportive and limiting program, policy, and culturally relevant factors in each country. The research team carried out in-depth interviews and in-group meetings with stakeholders and reviewed numerous other policy documents and guidelines on contraceptive procurement and financing, local policy context and prevailing local sociocultural and religious beliefs and practices. A range of public and private sector stakeholders were consulted including government officials, regulators, policymakers, manufacturers and distributors, social marketing organizations, development partners and donors, research institutions, and civil society representatives such as advocacy groups, and members of the community. In all countries, a structured interviewer guide and check-list were developed and used for the interviews and reviews. Table 1 summarizes the affiliations of stakeholders interviewed in each country.

Results

The following describes the results of the landscaping assessment organized under the following thematic areas: 1. Supply side (Local policy context, procurement mechanisms, financing) and 2. Demand side (Socio-cultural and religious factors).

Local policy context

In each country, interviews with stakeholders confirmed a commitment of national authorities to position family planning as a priority strategy for reducing maternal and neonatal morbidity and mortality. For example, in Senegal in 2012, the Ministry of Health elevated the division of reproductive health to the rank of Directorate of Reproductive Health and Child Survival (DSRSE). The new Directorate developed an FP action plan for the period 2012–2015 with the ambitious objective of increasing contraceptive prevalence rate (CPR) from 12% in 2012 to 27% by 2015 and 45% by 2020. Increasing CPR for postpartum contraception is an integral part of this initiative, and the PVR was considered a valued addition. At the same time, Nigeria was renewing its commitment to reposition family planning by pledging to provide $3 million annually from 2012 onward for procurement of contraceptive products with the aim of raising the country's CPR from 10% in 2012 to 36% by 2018 through making FP commodities available and accessible routinely, especially during postpartum period. In line with the FP2020 objectives, the government of Nigeria also pledged to provide additional $8.3 million for procurement of contraceptives. In Kenya, meeting contraceptive needs in postpartum period was already on the country's list of priority policy and programmatic actions. Stakeholders believed that there was a need for additional contraceptives to enhance contraceptive options since the last method to be introduced in the country was the sino-implant which was registered in 2008 and introduced in 2009. Kenya is committed to realizing the FP2020 goal by reaching an m-CPR of 58% by 2020 and an m-CPR of 66% by 2030. If the PVR were introduced, women would have one additional option. It is assumed that FP usage will increase given the high prevalence of breastfeeding in the country, and as noted earlier, the PVR requires the user to breastfeed at least four times a day.

In Nigeria, stakeholders observed that the sudden shift in attention and funding to emerging issues such as HIV/AIDS in the late 1990s, have derailed the implementation of the National Health Policy whose mandate was accelerating health and growth through improving access and use of family planning services. With the renewed commitment to re-position family planning services, especially during the postpartum period, the PVR is been regarded as a welcome addition. The family planning program in Nigeria has many challenges including limited skills of providers, weak supply chains, and stock-outs of contraceptives that can reduce the choice for a prospective user. The simplicity of the PVR administration in terms of not requiring sophisticated health system structure for its provision resonated well with stakeholders, given the fragile service environment especially in the northern part of the country.

All these observations provided the necessary information that informed strategies for

Table 1: Stakeholders Interviewed and their Organizational Affiliation, by Country

	Affiliations		
Types of stakeholders	**Kenya**	**Nigeria**	**Senegal**
Government officials and policymakers	Ministry of public health & sanitation- Reproductive health division	FMoH, National primary health care development agency, Federal legislators	MoH-Directorate of reproductive health and child survival (DSRSE) MoH-Division of alimentation, nutrition and child survival (DANSE),
Regulatory agencies	Pharmacy & poisons board	National agency for food and drugs administration and control, Pharmacy council of Nigeria	Directorate of pharmacy and medicines
Private sector FP providers	Organization for health, education and research Services	Community Pharmacists	Association of private physicians
Private/public partnership for health	Kenya urban reproductive health initiative	Nigeria urban reproductive health initiative	Senegalese urban health initiative project (ISSU)
FP providing NGOs	MSI, IPPF	PI, MSI, PPFN, Association for reproductive health and family health	Childfund, Mariestopes International, Association Sénégalaise pour le Bien-Être Familial-ASBEF
Development agencies and donors	USAID, WHO, UNFPA, Kreditanstalt für Wiederaufbau (KfW)	USAID, UNFPA, DFID, WHO, Global affair Canada, UNICEF	UNFPA, USAID
Technical support agencies	FHI 360, JHPIEGO		IntraHealth, the program for appropriate technology in health (PATH), FHI360, PROGRESS project
Social marketing organizations	PSI	Society for family health	Agence pour le Development du Marketing Social (ADEMAS)
Community and advocacy groups	Maendeleo Ya Wanawake Organisation (MYWO)	Federation of Muslims women association of Nigeria (FOMWAN)	Islam and population network Siggil Jiggen Network
Professional associations	Kenya Obstetrics & Gynecology Society- FIGO affiliate	Society for Obstetrics & Gynecology of Nigeria, National association for nursing & midwifery of Nigeria	Senegalese midwives' association
Research institutions	-	National institute for medical research	Centre de Formation, de Recherche et de Plaidoyer en santé de la reproduction (CEFOREP),
Drugs manufacturers/distributors	Bayer – East Africa	-	-
Media organizations	-	Center for Communication Program (CCP)	-

introducing the PVR in these countries. For example, the ongoing efforts in the three countries to increase availability and access to postpartum contraception provide impetus for programs that seek to introduce postpartum family planning methods such as the PVR.

Socio-cultural and religious factors

In Kenya, some of the stakeholders, especially community-based organizations, reported that rural women are usually reluctant to touching their private parts, and may have difficulty in inserting the PVR by themselves. As such, they expressed the need for a strong behavior change communication strategy for PVR introduction. In Senegal, socio-cultural obstacles and religious beliefs remain challenges to accessing FP services. For example, a study showed that more than 90% of male and female respondents agreed or strongly agreed that only God can decide the number of children a couple will have, and nearly half of married male respondents believed that family

planning is harmful to women's health[13]. However, there are some positive cultural beliefs and practices such as the near-universal breastfeeding practice, and the desire for long birth intervals in the community.

In Nigeria, the cultural and religious factors identified were both facilitators and barriers to uptake of family planning services. The existing practice of inserting vaginal substances as aphrodisiacs in northern Nigeria can facilitate women's desire to try the PVR as an intra-vaginal method. But even the barriers were not thought to be insurmountable to the PVR's use. For example, stakeholders indicated that in northern Nigeria, communities prefer female providers to minimize interactions between female clients and male providers for religious reasons. Interactions between a client and a provider that warrant vaginal procedures or other forms of intimate contacts are particularly problematic. The PVR does not require such procedures and intimacy as the woman can be instructed on how to insert and remove the ring by herself. As experience from the local communities indicates use of vaginal aphrodisiacs to be a relatively common practice, the concern around women touching their genital areas was not considered a barrier to women using the PVR. This entrenched practice could facilitate PVR adoption.

In all countries, interactions with stakeholders provided deeper understanding of how practices and beliefs rooted in religion and culture of the people could be harnessed to ensure that the PVR is introduced with minimal friction and tension. Commencing community awareness campaign in Kenya ahead of the PVR introduction, for example, could ameliorate women's anxiety around touching the genitals. Also, families in northern Nigeria would be more receptive to the PVR if they know that the ring is woman-initiated - and controlled.

Procurement mechanism

Based on conversations with stakeholders, the requirement for the PVR to be procured by the private sector is similar across the three countries, which is prior registration of the product in the respective countries. The mechanism for public sector procurement are similar across the three countries with minimal variations. In Kenya, the endorsement of the PVR by the World Health Organization through inclusion in its Essential Medicines Lists (EML) would facilitate public sector procurement both directly by the government and by donors who support the national FP program in the country. In Senegal, public sector procurement will require a prior incorporation of the PVR into the national commodity security plan which is managed by a designated commodity security committee, a multi-disciplinary committee that operates through the National Procurement Pharmacy. In Nigeria, a pre-condition for public sector contraceptive procurement, including the PVR, is inclusion into the country's EML. Once this is achieved, public sector procurement can take place either via a direct government procurement or a public-sector procurer such as the UNFPA. However, in all three countries, initial in-country registration is required for subsequent inclusion into the EML. Due to the insights gained from stakeholder discussions, the research team has begun collaborations with national partners in the three countries to ensure the inclusion of the PVR on each country's EML. The PVR's inclusion into WHO guidelines and documents such as the latest edition of the EML, the fifth edition of the Medical Eligibility Criteria, and the 2017 Edition of the FP Handbook are facilitating factors.

Financing of contraceptive commodities

In Kenya, the government has a regular budgetary allocation for contraceptive products which was about $26 million and $37 million for the 2011-2012 and 2012-2013 financial years respectively. Budget for contraceptive procurement are generally implemented in Kenya, and stakeholders believe that the total budgetary allocation for FP commodities would increase to accommodate the PVR that is being registered and introduced in the country. UNFPA and USAID procure contraceptive commodities for the public and the private sector respectively. In Nigeria, family planning financing for public procurement is predominantly donor-driven. Although the government of Nigeria pledged a sum of $3 million per annum for financing FP products procurement and distribution since 2012, donor

financing continues to be the main source of funding for public sector financing. In Senegal, USAID and UNFPA are the main procurers of FP commodities. They procure approximately 99% of the contraceptive products (above $3 million) through their own specific channels, while the government procures for less than $100,000 of products through the national procurement pharmacy. In addition, Senegal is engaged in various innovative financing systems, such as the Global Financing Facility (GFF) initiative with the World Bank. These initiatives will contribute to supporting FP program implementation. Concomitantly, the private sector has its own channels for FP products procurement and pricing.

Synopsis

Dialogue with key stakeholders provided a roadmap for progesterone vaginal ring (PVR) introduction that reflects national priorities and needs. It helped identify country-level opportunities and potential challenges, as well as the roles that different stakeholders could play. The dialogue also contributed to prioritizing activities that need to occur including understanding how family planning commodities are financed and procured, and the required resources for successful introduction.

Discussion

Understanding the various elements and processes around contraceptive procurement, financing, delivery, and uptake in a given system is an important initial step for a successful contraceptive introduction as observed in all the three countries. This initial engagement with stakeholders enabled us to determine and select countries in the region where there would be need and interest for the introduction of a new FP product. It also sheds light on intermediary activities and pathways existing in each country that determine how commodities reach their target beneficiaries wherever they live. Ensuring cultural and religious harmony with a given contraceptive product has been highlighted in a previous study[12]. The realization that some women in Kenya may be reluctant to touching their genitals calls for the need to commence behavior change communication programs ahead of time. The lessons and experience from Kenya will also be relevant to Nigeria, Senegal and other countries. Such programs will also be needed in Senegal where up to 90% of couples still believe that it is only God that determines the number of children a woman can have, and where nearly half of men believe that family planning products are harmful to women's health[13]. The adoption of a national family planning communication plan in the Senegal in the year 2012 is already yielding results with the recent surge in family planning use. This creates a highly receptive environment for the PVR and other FP and RH commodities that may newly arrive in the country. The preference for a female provider in northern Nigeria would not adversely affect the PVR as the product does not require vaginal procedures or other intimate contacts between the provider and the clients; the PVR can be initiated and discontinued by the woman herself. Also, the practice of vaginal insertion of substances such as aphrodisiacs shows that women are already used to touching their genitals, a practice that could accelerate the uptake of the PVR.

Introducing a product in a new setting also requires a thorough understanding of the policy and programmatic context to build on existing opportunities and synergize impact. The policy environments in the three countries were conducive to introducing new contraceptives. All the countries had formulated policies and program strategies for increasing access to contraceptive use and raising their CPR. Unmet need during the immediate postpartum period is high in sub-Saharan Africa, including Kenya, Nigeria, and Senegal[5]. Interestingly, all the countries also have robust plans for improving access to contraception after delivery. The PVR is considered an important addition to the mix in this period given that breastfeeding is almost universal in the first year postpartum in these countries[14-16.] As the PVR is being prepared for introduction using a total market approach, it was vital to determine what it takes to get the product available through both the public and the private sectors. It appeared that private sector distribution only requires in-country registration. Although the criteria for a public-sector procurement and distribution vary slightly

across countries, the main cross-cutting requirement is getting the product on the countries' EML. Now that the PVR is on both the WHO EML[17] and WHO Medical Eligibility Criteria (MEC) for contraceptive products[18], the process for individual country getting the PVR on their respective EML is deemed simplified.

Financial support for contraceptives products procurement and distribution from public budget is not always forthcoming in Nigeria and Senegal. An important proportion of family planning use comes from the private sector accounting for 60% of contraceptive use in Nigeria[19]. And in both countries, donor funding covers most of the public sector need in terms of procurement, distribution and training of family planning providers. The PVR introduction process will leverage the private sector market while continuing to collaborate with civil society organizations such as the Civil Society for Family Planning in Nigeria (CiSFP) and the Siggil Jiggen Network in Senegal, for continuous advocacy to government for increased financing and spending for family planning services. This also calls for early collaboration with public sector procurers in Nigeria and Senegal to ensure the PVR is being included on the contraceptive procurement list of government in the two countries. Given the high proportion of women who expressed willingness to pay for the PVR even at about $2 per cycle in each country[20], the commodity should be expected to generate high clientele in the private sector while a public-sector response is being anticipated.

Conclusion

Kenya, Nigeria, and Senegal presented promising policy and programmatic context for PVR introduction. For example, Kenya has already officially identified postpartum period as the period with the greatest unmet need requiring urgent attention augurs well for the PVR. Their near-universal breastfeeding culture and the large unmet need for contraception among breastfeeding women indicate a potential for the PVR in these settings. Their commitment to several global and local initiatives such as the FP 2020 declaration, repositioning of family planning program in Nigeria and the DSRSE in Senegal are ongoing opportunities to leverage as the ring is being introduced into the respective country' FP programs. However, to ensure sustainable integration of the product into the method mix, it will be necessary to conduct the introduction process systematically. A practical approach would entail initial introduction in private sector to be followed by the public sector. We anticipate that the product will be available through multiple outlets ranging from tertiary to primary care facilities and through pharmacies, drug stores and community-based distribution networks. In a nutshell, engagement with country-level stakeholders has proven useful in providing information that set the stage for the PVR registration and introduction, elucidating financing needs and procurement strategies not only for the PVR but potentially for other FP and RH products in the pipeline.

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