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Offering progesterone contraceptive vaginal rings for postpartum women through integrated family planning and immunization services

Ishita Chattopadhyay Population Council

John Townsend *Population Council*

Saumya RamaRao Population Council

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Ishita Chattopadhyay John W. Townsend Saumya RamaRao





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Population Council 4301 Connecticut Avenue, NW, Suite 280 Washington, DC 20008

Tel: +1 202 237 9400 Fax: +1 202 237 8410

popcouncil.org

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This technical report is part of a series of reports investigating the introduction of the PCVR in the context of quality, choice, equity and improved access. Each report provides information about the product and its benefits in addressing the gap in postpartum family planning (PPFP); offers a pathway for marketing and assumes that products will be available from manufacturers and distributors to respond to women's needs in diverse markets. Other reports in this series include:

- An innovative financing model for the Progesterone Contraceptive Vaginal Ring through voucher programs
- Utilizing social marketing and social franchising models to expand access to the Progresterone Contraceptive Vaginal Ring

Table of Contents

Table of Contents	iii
Acknowledgments	iv
List of Abbreviations	iv
Background and Rationale	1
The PCVR FP/Immunization Integration Model (PCVR-FP/I)	3
Implementation of the model in 3 phases	15
Conclusion	17
References	18
Appendices	20

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The opinions expressed in this report are those of the authors and do not reflect the views of its funding or implementing agencies.

List of Abbreviations

BCS+ Balanced Counseling Srategy Plus

CHW Community Health Worker

CVD Community Voucher Distributor

DCVR Delivering Contraceptive Vaginal Rings

DHS Demographic and Health Survey

EBF Exclusive Breastfeeding

FP Family Planning

FP/I Family Planning/Immunization

HIP High Impact Practice

HTSP Healthy Timing and Spacing of Pregnancy
IEC Information, Education and Communication

IUCD Intrauterine Contraceptive Device

LAM Lactational Amenorrhea Method

LARC Long-acting Reversible Contraceptive

MCH Maternal and Child Health

MCHIP Maternal and Child Health Integrated Program

MDP Market Development Plan
MDG Millennium Development Goal

MoH Ministry of Health

PCVR Progesterone Contraceptive Vaginal Ring

PoP Progesterone only Pill

PPFP Postpartum Family Planning
PSA Public Service Announcement

RH Reproductive Health SM Safe Motherhood

TAC Technical Advisory Committee

USAID United States Agency for International Development

WHO World Health Organization

WTP Willingness to Pay

Background and Rationale

With the Millennium Development Goals (MDG) ending in 2015, the MDG 5 goal of 'Improving Maternal Health' through better access to reproductive health continues to lag in addressing the family planning needs of postpartum women. According to Demographic Health Surveys (DHS) conducted in 27 low-income countries, more than 65% of women who are 0-12 months postpartum and want to delay or avoid pregnancy are not using contraception (Ross and Winfrey, 2001). Failure to meet women's contraceptive needs during this critical period has consequences for maternal and infant health (WHO, 2014).

PPFP is the prevention of unintended and closely spaced pregnancies during the first 12 months following childbirth (MCHIP, 2012). During this period, these pregnancies have a high risk for the mother and baby. It is also a time when mothers bring their babies for vaccination services but often do not seek any postnatal checkup for themselves. (MCHIP, 2013; WHO, 2013).

The Progesterone Contraceptive Vaginal Ring (PCVR) is an effective, user-initated contraceptive option which helps meet the need for postpartum family planning (PPFP). It is exclusively designed for postpartum breastfeeding women who want to space or delay pregnancies in the first year following childbirth. The PCVR can be used by lactating mothers as early as 6 weeks postpartum and can be easily inserted and removed from the vagina without the need for clinical help or supervision. Each PCVR diffuses 10mg of natural progesterone per day (which suppresses ovulation). Women can use a ring continuously for up to 3 months and up to 4 rings in the first year following childbirth.

WHO recommends that PPFP be integrated into MCH services (2013). From a public health standpoint, it is crucial to take advantage of every contact with pregnant and postpartum women to offer them family planning products and services throughout the continuum of care (USAID/HIP, 2013; WHO, 2013). The "Continuum of Care" for MCH refers to integrated services delivery for mothers and their children from pre-pregnancy to delivery, the immediate postnatal period and childhood (WHO, 2013). The goal is to provide birth spacing and family planning information and services in the context of maternal, infant and child health care services (USAID/ACCESS-FP, 2014).

Including the PCVR in integrated maternal and child health services can improve access of pregnant and postpartum women to PPFP options. Along the continuum of care, there are several avenues to provide PCVR through integrated MCH services. While there are several possibilities for introducing PCVR throughout the continuum of care, the strategy to integrate family planning and immunization services presents a unique opportunity to reach a majority of the targeted postpartum women. This strategy has been recognized as a promising "high impact practice" (HIP) for family planning by USAID, UNFPA and MCHIP.

Both family planning and immunization services are important components of primary health care that address the health needs of recent mothers and their newborns (USAID/HIP, 2013). The timing of return to fertility after childbirth is often unpredictable, hence the need for multiple contacts between mothers and providers during this period is particularly important (FHI, 2012). A recent study of 5 countries in sub-Saharan Africa suggests that reaching postpartum women through immunization contacts could decrease

overall unmet need for family planning by up to 8.9% (USAID/HIP, 2013). According to WHO (2009), an estimated 80% of women will visit a healthcare facility to get their infants immunized in the first year following childbirth. These routine visits provide an opportunity for postpartum mothers to visit the center at least 5 or more times during the first year for family planning (WHO, 2009).

The objective of this technical report is to describe a model for providing the PCVR through integrated FP/Immunization (FP/I) services, the core components of the model, the types of inputs required and the steps for introduction and scale up. It also describes how the PCVR can be offered to breastfeeding women in their first year following childbirth.

A methodology for implementation of the PCVR-Family Planning/Immunization model (also referred to as PCVR-FP/I) has been designed to introduce PCVR in the context of accessibility, choice, equity and quality. A proposed structure to introduce and integrate PCVR has been outlined and described in 3 phases: the design phase, the start-up phase and the scale-up phase.

This report serves as a guideline to successfully introduce PCVR through the integrated FP/I services and may be used by FP/RH service implementers and program managers when implementing and integrating PCVR into their programs and policies. The implementing partners or managers have been referred to as the "project" throughout the document.

The following section will review the goals and objectives for this model.

THE GOAL OF THE PCVR- FP/IMMUNIZATION INTEGRATION MODEL

The goal of this model is to increase the availability and accessibility of PCVR through the integration of family planning and immunization services for children among postpartum women who are breastfeeding in the first year following childbirth.

Key Objectives

- To increase women's access to PCVR through FP/Immunization integrated services
- To integrate PCVR into the FP/Immunization model of care in the first year following childbirth
- To address the unmet need for postpartum contraception among target beneficiaries

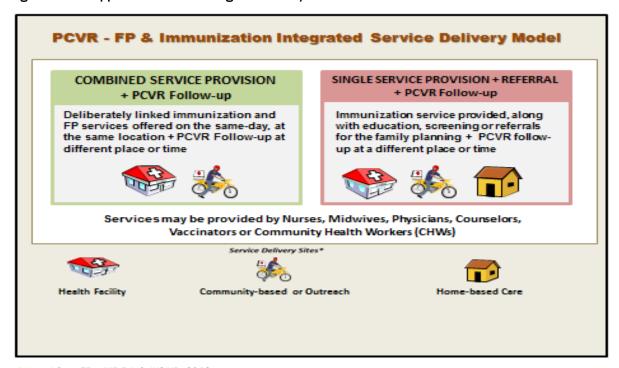
The PCVR FP/Immunization Integration Model (PCVR-FP/I)

The PCVR-FP/Immunization Integration model has been developed to address the contraceptive needs of postpartum women who want to delay or space their pregnancies in the first year following childbirth. The model has been strategically designed to introduce PCVR in the context of method choice; diversity in the range of outlets across the public and private healthcare facilities, and ensuring quality of care and increased access to availability of PPFP services.

Integration refers to combining related services that make the complete package of services more convenient, accessible and cost effective (Fathalla, 1998). According to the USAID "High Impact Practice" (HIP) brief, 2013, the "Integration of Family Planning and Immunization" (FP/I) approach can refer to either "combined service provision" (when both services are offered on the same day and location, through routine immunization services) or "single service provision plus referral" (when either family planning or immunization services are provided along with education, screening or referrals for the other service).

In the first year following birth, the immunization schedule includes at least 5 visits to a healthcare facility (at birth, 2 weeks, 6 weeks, 10 weeks, 14 weeks, and 9 months) when the baby gets vaccinated against the 6 common childhood illnesses such as polio, measles, mumps, diphtheria, influenza and pertussis (WHO, 2010). In addition, recently revised guidelines on "programming strategies on PPFP" developed by WHO, USAID and MCHIP (2013) recommend multiple contacts and immunization visits, through the various stages of pregnancy, childbirth, postnatal and infant care for up to one years of age (WHO, 2013). The routine immunization visits provide an opportunity to offer family planning services to the mothers who need them.

Figure 1: Two approaches of the Integration of FP/Immunization model



The two crucial components of this model are the "timing" and "place" of delivery as it relates to both PPFP needs for the mother and routine immunization visits for the child. Figure 1 represents the 2 types of approaches to the FP/Immunization integration model.

Approach 1: Combined service provision + PCVR Follow-up

In this approach, women will receive family planning counseling and services on the same day and location or facility that their children get immunization services. Women will be counseled and offered options that are relevant to their needs and desires, with the PCVR being one option. Qualifying women who choose to use PCVR may be provided the ring on the same day along with appropriate FP counseling and instructions for its use. During this visit the healthcare provider may schedule future follow-up visits within the continuum of care period (see Table 1), which may be independent of the future immunization visits. Alternately, women may be provided the next ring in following immunization visit closest to the expiration of the previous ring being used. The providers at healthcare facilities may conduct a basic FP follow-up during subsequent immunization visits to assess if PCVR is being correctly used and address any issues related to the use of PCVR and women's family planning intentions. In cases where women are unable to obtain the ring due to transportation issues, alternate arrengements for the provision of PCVR may be made through routine follow-up home visits by community health workers (CHWs). Furthermore, in cases where women may be hard to reach, upto 2 PCVRs may be given to each woman at a time. While both family planning and immunization services may be delivered at the same location or facility, they may be provided either by the same or different providers within different units of the health facility or location. For example: While an immunization visit may be an entry point for a woman to learn about basic FP services, she may be referred to a dedicated FP unit within the same facility to seek further counseling and obtain the contraceptive of choice.

Approach 2: Single service provision+Referral+PCVR Follow-up

In the second approach, women coming for routine immunization visits for their children may receive basic FP counseling and IEC materials related to PCVR. In this case, women who potentially consider PCVR as an effective family planning option and would like to think about their family planning options will be provided referral slips to obtain PCVR at a later date at the same or a different location. Similar follow-up and community-based service delivery approaches will need to be incorporated to provide the vaginal ring to women who decide on using the ring at a later point or who want to learn more during consequent immunization visits. Additionally provisions for offsite PCVR referrals or referrals requiring follow-up visits will be made in cases where co-located services are not feasible. It will be important to deliver FP services keeping in mind any privacy concerns and/ or cultural and religious barriers that these women may have. In such cases, appropriate referral and follow-up systems and counseling strategies will need to be created. For example, women may prefer to receive PCVR at their homes as opposed to clinics due to the stigma attached to obtaining contraceptives in healthcare facilities.

Table 1: PCVR-Family Planning/Immunization Integration Model (PCVR-FP/I)

	CONTINUUM OF CARE FOR POSTPARTUM FAMILY PLANNING										
	Antenatal Birth Postnatal Care (0 –1 year)										
Contact	ANC Visits: At pregnancy		PNC : At Birth [0-48hrs]		PNC: Weeks 2, 6, 10 and 14		PNC: 6 months		PNC : 9 months		PNC: Final Follow-up 12 months
Targeted Service Delivery by Providers	Identification of pre- existing conditions and pregnancy complications nutrition, disease prevention, counseling on family planning, birth preparedness and infant feeding		Skilled Maternal and Newborn care (hygiene, warmth, immediate and exclusive breastfeeding (EBF), resusciation, emergency preparedness, vaccinations- BCG and Polio 0		Physical exam of mother and child to check for ailments and healthy growth of child, treatment and management of diseases/complications. Iron and folic supplmentation, EBF advice, routine immunization visits for DPT/Pentavalent 1,2,3; Polio 1,23; HEP B 1,2,3 and FP counseling and provision		Routine immunization and nutrition visit - growth monitoring, weaning, Vitamin A dose and management of disease as appropriate , FP counseling and provision of contraceptives		Measeles vaccine, Infant and maternal nutrition and health, vit A (if not taken at 6 months). FP counseling and provision of contraceptives		Follow-up visit for infant and maternal nutrition and health and FP provision (measle vaccine if not given)
PCVR Integration with	Provide promotional material for PCVR. Integrate PCVR counseling (BCS+) along with counseling package for Healthy Timing and Spacing of Pregnancy (HTSP), EBF, lactational amenorrhea method (LAM)	•	Integrate PCVR counseling (BCS+) with LAM method, confirm interest in utilization of PCVR after timely counseling and informed choice		Integration of Immunization visit and PCVR & FP method choice counseling (BCS+) + promotion of breast feeding +LAM]. Provide 1 PCVR to consenting women. Follow-up with returning clients to check status of LAM + PCVR use, as appropriate. If clients start using PCVR by Week 14, an addtional PCVR will be given during this visit. [Provide appointment card to PCVR client for future follow-ups]		Integration of Immunization, Nutrition and PCVR + FP method choice counseling and provision. Provide 1 PCVR to new consenting women. Follow-up with clients using PCVR, review spacing intentions and provide 2- 3 rings as appropriate	•	Follow-up with clients using PCVR, review spacing intentions, breastfeeding and provide additional rings as appropriate. Provide counseling on NES/EE CVR and other contraceptive methods if woman stops breastfeeding	•	Follow-up with clients using PCVR, review spacing intentions, breastfeeding and provide additional rings as appropriate. Provide counseling on NES/EE CVR and other contraceptive methods if woman stops breastfeeding
PCVR Community Health Intervention	Pregnancy identification by CHWs and referral for ANC, danger signs. Birth preparedness/ complication readiness, introduce postpartum family planning		First home visit for PNC, referral for danger signs, Support for EBF/LAM. Provide 1 PCVR if delivery occurs at home (pre-packaged/ bundled along with birthing kit) - can be provided by skilled birth attendent/ midwife		PNC home visits: referral to healtcare facility for danger signs, EBF+LAM recommended upto 6 months, emphasize fertility will return prior to menses return as baby starts complementary food, mother still needs to breastfeed, but to prevent another pregnancy should start PCVR., Provide PCVR as an option if not following LAM method. Follow-up to assess if client is using PCVR		Provide counseling on PCVR & FP method choice + follow-up to assess if client is using PCVR and provide additional rings as appropriate		Provide counseling on PCVR & FP method choice + follow-up to assess if client is using PCVR and provide additional rings as appropriate		Provide counseling on PCVR & FP method choice + follow-up to assess if client is using PCVR and provide additional rings as appropriate
Promotion and Follow up for PCVR											

WHO (2013) recommends that counseling and support for 'exclusive breastfeeding' (EBF) and 'healthy timing and spacing of pregnancy' (HTSP) should discussed as part of each prenatal and postpartum care contact. Figure 2 describes some of the postpartum contraceptive options and the recommended time of use (WHO, 2013). The PCVR, which is a progestin-only method, can be used as early as the 6th week following childbirth. To offer high effectiveness, it will be necessary to educate postpartum breastfeeding women about the return of fertility and the available family planning choices should they desire to contracept (WHO, 2013).

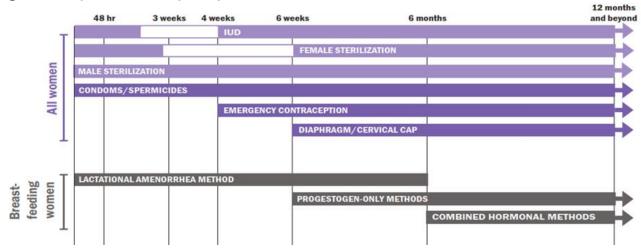


Figure 2: Postpartum contraceptive options

Source: Programming Strategies for Postpartum Family Planning, WHO (2013)

Following the continuum of care approach, PCVR information and counseling services can be included in this schedule during pregnancy [antenatal care visit], at birth [0-48hours]; and during postnatal-maternal and infant care visits [48hours -12months] through midwives, nurses, doctors or vaccinator or through outreach workers across the public and private health sectors. The proposed key contact points for the delivery and follow-up of PCVR will be during pregnancy, at birth, week 2, at week 6, week 10, week 14, 6 months and 9 months. Consenting postpartum women may be provided 2-4 PCVRs in the first year following childbirth depending on when the contact with the health system was made.

Another feature of this model is promoting breastfeeding through the bundling of the Lactational Amenorrhea Method (LAM) and PCVR promotion and messaging. Since both LAM and PVCR methods promote long-term breastfeeding, these methods support child growth and wellness. The LAM method is effective when a woman has not started menstruating post-delivery and is exclusively breastfeeding her child for the first 6 months following childbirth (IRH, 2013). Women who are not be able to breastfeed exclusively (e.g., baby gets supplementary foods or the woman is unable to nurse) might benefit from use of the PCVR. Both LAM and PCVR are effective only when a woman breastfeeds her child 4 or more times a day. The additional benefit of using PCVR is that women may slowly introduce other types of nutrition to her child along with breastfeeding. Following the continuum of family planning and contraceptive delivery, the PCVR may serve as an effective gateway contraceptive following the LAM method and help reduce the unmet need for family planning.

Intervention Strategy: The 4 P's of Marketing

The The PCVR-FP/I model as described above utilizes the "continuum of care" framework to lay out the different stages at which PCVR can be delivered to qualifying postpartum women, who may seek integrated prenatal and postpartum services.

Successful implementation of a PCVR - FP/I integration will require: a) a well-established health system and infrastructure; b) efficient referral mechanisms; c) supportive political and religious environment for integration; d) user-friendly job-aids for the different levels of health care providers e) regular monitoring and training of providers to maintain motivation and f) effective task-sharing and task-shifting mechanisms (USAID/HIP, 2013; Frontiers/ACCESS-FP, 2008; MCHIP, 2013).

Strategies to facilitate successful integration of FI/I services have been discussed utilizing the 4 P's of Marketing, which are: Providers, Promotion, Place, and Price and are also referred to as the "Marketing Mix" (Chattopadhyay et al, unpublished).

PROVIDERS

Providers are the various healthcare personnel providing maternal and child health services. The following section discusses the potential healthcare providers and stakeholders for delivering the PCVR, through the integrated Family Planning and Immunization service delivery model. It also incorporates task-sharing and task-shifting as recommended by the WHO for integrated maternal and child health (MCH) services (WHO, 2013). The benefits of this strategy are discussed below.

There are several key groups of healthcare personnel and stakeholders across the public and private sectors who are responsible for postpartum care (WHO, 2013). These include the:

- Ministry of Health and other national policy and regulatory bodies;
- Procurement and distribution agencies responsible for the delivery of contraceptive vaginal rings;
- Financial institutions to aid in project start-up and scale-up;
- NGO sector, community-based, faith-based and social marketing organizations that will help with promoting and marketing of PCVR within the "method mix" of other PPFP products and services; and
- The team of healthcare providers, who will directly deliver the vaginal ring to the target clients.

The PCVR-FP/I model will be vetted through national consultations with key stakeholders delivering family planning programs and services as well as high-volume maternity and postpartum healthcare centers. Prior to initiating the integrated service delivery program for PCVR, the project will need to identify and prioritize the roles and responsibilities of stakeholders involved in supporting these activities. It will be necessary to assess stakeholder buy-in, level of training and skills required for integrated service delivery and their potential level of impact and influence on the PCVR-FP/I model.

As a first step, a technical advisory committee (TAC) may be formed, which will serve as an effective mechanism to initiate and oversee several important project processes. These may include: a) engaging in initial advocacy efforts; b) raising stakeholder awareness of the PCVR; c) assessing readiness /appropriateness of integration within the country context; d) building buy-in for integrated service delivery; e) developing and strengthening coordination and collaboration across different teams within Ministries of Health and other healthcare agencies and across stakeholder groups and, f) planning for financing and for long-term sustainability of the PCVR-FP/I program.

An outcome of the consultative process described above will be to:

- Identify the healthcare providers within the healthcare facilities and at the community level which
 are currently providing integrated maternal and child health services in the targeted
 community/country;
- 2. Develop coordination between health workers at different points along the prenatal-to-postpartum continuum;
- 3. Define their roles and responsibilities;
- 4. Plan effective referral systems;
- 5. Appoint a project manager to ensure smooth functioning among the providers and monitor operational and programmatic functions

Most countries provide MCH services through physicians, nurses, midwives and community health workers, albeit with different distributions depending on the human resources in health and the geographic area served. Additional cadres of workers with varying roles may differ between countries. However, given the various roles and experiences of the providers, it will be important to map out these differences (in order to accommodate the variations) prior to implementation (Dawson et al, 2014).

According to a recently developed 'WHO health worker optimization framework for MCH' (2013), task sharing/shifting is an essential element for the delivery of integrated MCH services since it not only addresses worker shortage and increases access to contraceptives, but also reduces the overall cost of service delivery. WHO defines task shifting as "the rational re-distribution of tasks among health workforce teams" in which specific tasks are moved from highly qualified health workers to those who have fewer qualifications in order to make more efficient use of available resources. This mechanism is in line with the target product profile of the contraceptive vaginal ring since it can be easily delivered by mid to lower level cadres of healthcare providers. It will be necessary to maintain adequate coordination and supervisory mechanisms to ensure appropriate skill mix and teamwork, training, job aids and tools (Dawson et al, 2014).

WHO (2013) categorizes the different cadres for PPFP into high or mid to low level providers. These may include:

- High-level providers: Medical doctors, doctor's assistants
- Mid-level / Low-level providers: Nurses, midwives, auxiliary nurses, midwives and vaccinators,
 Community health, outreach workers or lay health workers.

Since the PCVR-FP/I intervention incorporates a "clinico-community approach" for delivering service, it is essential to incorporate effective task-sharing and task shifting mechanisms between the various healthcare providers. For example: for an Integrated FP/I program a vaccinator may refer women to a FP provider (midwife, nurse or CHWs) at the time of immunization contacts or provide both immunization and information on PCVR along with other PPFP contraceptive options (See Appendix 1 for an illustrative example of task sharing and taskshifting for PCVR).

PROMOTION

The main goal of promotion is to raise awareness and increase access to PCVR among the targeted providers, stakeholders and beneficiaries. Research suggests that demand for a product is often influenced by socio-economic and socio-cultural factors that determine the uptake of available services (Obare et al, 2012). The following section discusses the key strategies that will need to be incorporated in developing provider training manuals for a FP/I integration program as well as for the educational and marketing materials for promoting PCVR as an effective PPFP contraceptive option.

To effectively generate demand for PCVR through FP/I integration, a targeted marketing strategy will need to be incorporated on maternal and child health services.

The key elements for the promotion of the PCVR-FP/I Integrated services ought to include: a) development and dissemination of IEC materials for users and providers, b) mass-media marketing, c) capacity building of healthcare providers, d) development of job-aids and tools that will aid in the task sharing/shifting, and e) community mobilization through CHWs.

Development and dissemination of IEC materials: PCVR educational and training materials will need to be developed in the context of method choice, along with those for other contraceptives. It will be necessary to integrate PCVR into existing tools or job aids and to develop new tools based on the cadre of providers who will be delivering the contraceptive vaginal ring. Furthermore, educational tools and communication strategies for providers and consumers will need to be designed in consultation with public opinion leaders and program managers based on the local context.

As part of the dissemination strategy, PCVR may be marketed through the network of accredited providers and local community-based distributors. A marketing manual specific to the local context may be created to describe the various channels for promotion of PCVR. For example, promotional materials for PCVR such as posters, banners, leaflets, palm cards and brochures may be designed based on the local context and will also need to be made available in local languages. These materials may be disseminated through community meetings, events, door-to-door home visits and at healthcare facilities providing safe motherhood and integrated postpartum family planning and immunization services. Additionally, the marketing and promotional materials can be made available through various advocacy groups, community-based organizations, faith-based organizations, pharmacies, and social marketing organizations located within the targeted communities.

Mass media marketing: Mass media campaigns to launch PCVR may be carried out based on marketing budgets and concessions with the Ministry of Health and key stakeholders. For example, a local advertising agency may be hired to promote and increase awareness of PCVR as a new contraceptive option for postpartum mothers. Promotional materials on the benefits of PCVR will be made available at vaccination centers. Radio public service announcements (PSAs) and advertising through public transportation systems (putting up posters in buses and trains) and other mainstream media channels such as local newspapers, television, internet and social media may be used to promote this method of contraception.

Capacity Building of Providers: A training package for healthcare providers will need to be developed and tailored to match the local context of service delivery. This may include training modules on quality assurance benchmarks for PCVR delivery; counseling and role-play modules to educate postpartum women on family planning; breastfeeding/LAM method and the benefits of using PCVR; dispelling any myths and misconceptions about postpartum family planning, the task sharing/shifting mechanisms and the dissemination of IEC materials. The healthcare providers will need to be trained on strategies to

promote and provide information about PCVR to eligible clients in the community to ensure that targeted clients have a good understanding of the use and benefits of PCVR. Table 2 describes some of the key messages that may be developed for postpartum women.

Table 2: Key PPFP messages for the PCVR-FP/I Program

Key messages to be delivered to postpartum women:

- Healthy spacing of pregnancies
- Mother's risk for unintended pregnancy after a birth
- Timing of return to fertility
- LAM method and the transition
- Choosing a family planning option within the first month postpartum
- Availability of PCVR and other FP products during routine immunization visits and through community-based healthcare services
- Importance of postpartum care services referral and follow-ups
- Information on where PPFP services can be obtained

Adapted from USAID/Access-FP, 2008

Service delivery tools: Several effective service delivery tools can ensure the quality and prompt introduction of the PCVR into new markets. The following are some examples of the suggested tools (previously developed and tested) for the FP/I program:

- Balanced Counseling Srategy Plus (BCS+) developed by the Population Council employs FP
 counseling cards with simple instructions on how to use the products. A similar BCS+ card may be
 developed for PCVR and integrated into the counseling package.
- Job aids for vaccinators or CHWs (developed by Liberia/MCHIP) consists of a 1 page document with simple messages on PPFP contraceptive option and how to use PCVR
- FP/I Referral cards and ID cards may be developed for client follow-up and contraceptive adherence.
 Returning clients who choose to use PCVR may produce their ID card and/or referral card to obtain additional rings in any of the public and private locations providing contraceptives (see Place for additional details)
- Postpartum systemic screening tools (developed in India and Nigeria) would include a simple screening questionnaire about women's family planning needs and their eligibility criteria for the use of PCVR. These should be included in routine child immunization visits. (see Annex 2 for details)

The suggested tools and resources may be incorporated and developed for the effective communication and counseling for service delivery and promotion of PCVR.

Community mobilization through CHWs: CHWs play an important role in marketing PCVR at a community and household level. CHWs have greater contact time with the clients in providing detailed family education; on the other hand, vaccinators' time and messages are short due to their work demands. CHWs will use simple and user-friendly job-aids to ensure consistent message delivery on family planning education, screening or referrals during immunization contact (MCHIP/Liberia, 2013; USAID/HIP, 2013). Providing information on PCVR through home visits may be an effective strategy to promote PCVR in the community.

PLACE

Place represents all potential locations at which PCVR can be accessible to the clients. The goal of the PCVR-FP/I model is to make the contraceptive vaginal ring available through public and private healthcare facilities and distribution channels in low-income communities. Facilities or outreach services that offer integrated family planning and immunization services and/or healthcare facilities that provide integrated maternal and child health services are the most optimal types of service delivery points for this intervention.

A mapping of high-potential locations and MCH service delivery centers will need to be targeted to reach a maximum number of postpartum women with children scheduled for vaccination, who also have a need for family planning. Mapping will also take into consideration key socio-cultural and demographic factors, such as: determining the duration of early breast feeding/LAM practices; calculating the percentage of postpartum women who receive PNC for either mothers or infants; listing the routine immunization coverage through facility-based or outreach services; and evaluating the percentage of pregnancies that are spaced less than two years apart (WHO, 2013).

Key considerations for the delivery of FP/I integrated services include: ensuring adequate infrastructure, such as space for counseling rooms, user-friendly communications tools and sufficient staff training for family planning providers of FP/I and PCVR services. Educating the client and creating demand at the healthcare facilities can occur in group settings or one-on-one basis, depending on the infrastructure and client sensitivity to discussing FP issues in group as opposed to private settings (MCHIP, 2013; HIP, 2013).

Another key aspect of place is the need to map out the procurement and distribution systems for PCVR and how they may be integrated into the vaccine and FP services provided. A local logistic-management system will need to be identified and/or developed to ensure consistent supply of PCVR across the various service delivery points (WHO, 2013). It will be important to ensure that referrals are backed up by follow-up services, since women may not follow-up on a regular basis for family planning services. Additionally, since routine immunizations are not typically offered through household visits, community-based programs that offer door-to-door MCH or family planning services can be integrated for education and referrals for PCVR along with the FP/I program. It is recommended that both FP/I services and task-sharing activities be closely monitored to measure regular task-sharing activities in the healthcare facility (USAID/HIP, 2013).

Given the ease of the use of the ring and the non-clinical nature of its insertion, a skilled health provider is not required. The PCVR could be provided directly through home-visits made by CHWs if the country context permits. This home visits strategy will reduce the need for the client to travel to healthcare facilities and will eliminate further transportation and service cost. It is expected that postpartum mothers who choose to use the PCVR will require anywhere between 2-4 rings in the first year following childbirth. Therefore it is important to train the healthcare providers to refer the CHWs to clients who are using this method and prefer not to come into a healthcare facility and/or are not motivated to follow-up. The clients may also be given the option to obtain the PCVR through contracted social franchising outlets or pharmacies.

PRICE

The FP/I program is an effective method of reducing the labor and indirect cost of services, and it also reduces the overall cost and time of clients in procuring these packaged services at the same time (Adesina and Bollinger, 2013). Determining the right pricing strategy for the PCVR when integrated with other FP/Immunization services will be important for this integrated service delivery model to be successful. Country-specific pricing laws are regulated by the Ministry of Health and will vary from location to location. Factors that will feed into the pricing strategy of PCVR may include: To what extent are PPFP services funded in the country? Has the government allocated annual budgets for MCH or FP/RH services? Can the private sector be leveraged for FP/I integrated programs? What are the acceptable client fees? What is the price of other comparable contraceptives available to postpartum women?

In general, decisions about pricing levels at which PCVR will be provided to target clients will depend on several other factors including: manufacturing cost of the product; the volume of procurement and distribution of product; source of distribution and delivery channels, and infrastructure and staffing cost. Consumers may be provided PCVR at varying prices across the total market, depending on their level of income and the cost of service delivery. For example, the PCVR may be offered free through public health facilities, or at subsidized prices through social marketing and social franchising organizations and at full price through private clinics and pharmacies.

The PCVR-FP/I model consists of three primary cost components:

- the cost of the product, given the procurement mechanism (subsidized, free or at full price)
- the set up cost of the integrated service (to integrate PCVR within the FP/I program)
- the cost of actual service delivery (when bundled with other FP products and services)

Pricing for the contraceptive vaginal ring will also be based on user willingness to pay or the perceived market "value" of the ring, the income level of the target segment and the convenience of the health sector providing the service. Table 3 summarizes the range of pricing structures, sources of funding, delivery and distribution channels to market the products.

Table 3: Potential pricing structures, funding sources and channels of distribution1

PRICING	Public Sector	NGO/Social Marketing	Commercial Sector
Pricing Structure	Free or subsidized pricing	Pricing varies, ranging from subsidized rates, cost price or with a profit margin	Products sold to clients at market price
Product purchase and source of funding	Donor and government budgets for family planning	Revenue through contraceptive sales, businesses, subsidies from donors and governments to create demand and ensure supply at affordable prices	Out-of-pocket spending by consumers or voucher based reimbursement
Distribution and delivery channels	Public clinics, hospitals, community-based distribution networks	Not-for-profit clinics, community- based organizations, public sector facilities, commercial outlets	Private for-profit clinics, hospital, pharmacies, convenience stores and other commercial outlets

In addition, a tiered pricing model developed by Bayer HealthCare Pharmaceuticals (2009) for affordable contraceptives is an option. The model is designed around 4 market-segments and distribution tiers [Tier 1, Tier 2, Social Marketing Tier and Free Distribution Tier]. The tiers represent different product packaging and distribution channels. The model offers illustrative guidance for the marketing of PCVRs (Chattopadhyay et. al, unpublished).

¹ DCVR Market Development Plan, 2014 (Chattopadhyay et al, unpublished)

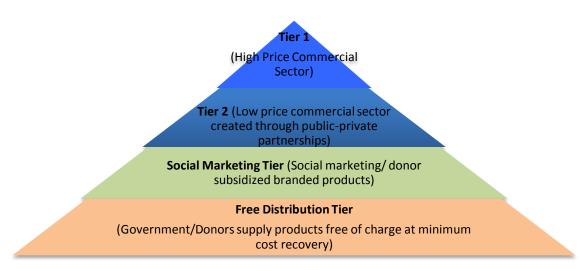


Figure 3: Tiered Pricing Model

Table 4 outlines the administrative and program management cost for introducing the PCVR into an integrated FP/I service delivery effort. These include some of the initial set-up costs as well as on-going cost to integrate and scale-up PCVR within the FP/I integration framework.

Table 4: Administrative and Program Management Cost for the PCVR-FP/I Model

Set up	costs to introduce PCVR-FP/I		Ongoing Costs for PCVR-FP/I				
4	Review and adapt to on-going FP/I programs	4	Program Management				
4	Develop training and advocacy materials	4	Continued training of providers				
4	Identify and train healthcare providers	4	Monitoring and evaluation				
4	Pre-launch planning with high-level advisory	4	Continued Marketing				
	group meetings to launch PCVR with MoH, donors	4	Scale-up plans				
	and key stakeholders	4	Integration into logistic and supply				
4	Identify donors and procurers for PCVR		systems				
4	External technical and programmatic support	4	Service provision				
4	Kick-off marketing/advertising campaign for						
	PCVR						
4	Adapt existing information systems for data entry						
#	Establish monitoring and evaluation plan						

In summary, the initial set-up cost to launch and integrate PCVR into the FP/I program will be higher during the initial implementation phase, but eventually the administrative costs of the integrated service delivery model will be reduced significantly because of increased customer demand and the more efficient management and monitoring of the program.

KEY PROGRAMMATIC CONSIDERATIONS AND RECOMMENDATIONS FOR THE IMPLEMENTATION OF PCVR-FP/I MODEL

The following are the suggested evidence-based recommendations based on past FP/I integrated programs suggested by the USAID/High Impact Practices for Family Planning, 2013: Integrated models are most successful when immunization programs have high coverage rates, sufficiently trained staff, an adequate supervision and monitoring system, and stakeholder support. It will be essential for the PCVR-FP/I project to have sufficient stocks of PCVR, adequate infrastructure, including private space for counseling, user-friendly communication tools, sufficient training for family planning and immunization providers on PPFP.

Political and community support is critical to building a supportive environment for integration, and it will be necessary to collaborate with the government, donors and service delivery groups to dispel any negative perceptions related to providing FP services in vaccination centers. Furthermore, stigma associated with obtaining contraceptives among certain religious groups may need to be adequately addressed on a case-by-case basis.

In places with a high patient volume, it is recommended to have a dedicated FP provider as part of a combined service delivery model to scale up access to sustained family planning use and to educate target clients on a range of contraceptive options including PCVR.

During the introductory phase the project may need to invest in locations or districts where there may be a higher interest among the providers and adequate infrastructure to run a PCVR-FP/I project as a pilot. This will also allow the project to evaluate the potential demand and supply-chain mechanism in the community. Also it will be necessary to monitor any regional differences in service uptake influenced by different levels of demand for certain services due to variations in level of knowledge on PNC or PPFP service needs. Keeping these variations in mind, a backup plan for unexpected staff turnover and stock outs will need to be managed as part of the logistics management strategy.

A number of guides and manuals for postpartum family planning and integrated FP/I integrated services have been developed by key industry partners. The following resources listed in Table 5 provide guidelines for developing and implementing FP/I integrated programs targeted towards PPFP. Program managers may adapt these strategies and reference these resources in the development and implementation of FP/I Integrated services.

Table 5: Resources on FP/I Integration Programs for PPFP

"Family Planning & Immunization Integration Toolkit" – This toolkit is managed by K4Health.org and is a repository of information on integrated family planning and immunization service delivery. It also provides a list of evidence-based information and tools that have been field-tested. https://www.k4health.org/toolkits/family-planning-immunization-integration/family-planning-needs-during-

nttps://www.k4neaitn.org/tooikits/family-planning-immunization-integration/family-planning-needs-during first-two-years

"Programming strategies for Postpartum Family Planning" – This document was developed by WHO and a number of international organizations in the field of family planning. This is a comprehensive guide, providing illustrative examples of PPFP throughout the continuum of care. http://apps.who.int/iris/bitstream/10665/93680/1/9789241506496 eng.pdf

"Integration of Family Planning and Immunization Services: Global Summary of Current Programmatic Experiences and Research Projects" – This document was developed by FHI and MCHIP (2010) to provide summaries of programmatic experiences and research projects on family planning and immunization integration in 16 countries around the world.

 $\underline{http://www.fhi360.org/sites/default/files/media/documents/family-planning-immunization integration-global-summary.pdf}$

Implementation of the model in 3 phases

The following section lays out a timeline for the implementation plan. It is proposed that the implementation of the PCVR-FP/I model be carried out in 3 phases:

- Phase 1: Design phase
- Phase 2: Start-up Phase
- Phase 3: Scale-up Phase

Each phase will review the three key components: duration of the project, quantity of rings, and the study site. Also each phase will be described in detail providing key recommendations for transitioning to the next phase and cohesively implementing the program.

Phase 1: Design Phase

The key goal of the design phase is to pilot test the PCVR-FP/I model to evaluate the process and program functions. Based on the findings of the pilot test, modifications may be made to improve the program.

Duration: 2 years

- 6 months pre-implementation planning
- 1 year program implementation (pilot test in select sites)
- 6 months program evaluation and modification

Quantity of Rings: 400

Study sites: 2-4 public and 2-4 private healthcare facilities

As part of the initial design testing phase – the PCVR-FP/I Model will be pilot-tested in 1 county or a particular district. From 4 to 8 study sites or healthcare facilities will be selected to implement the model. This model will be delivered through an equal number of public and private healthcare facilities to test the system across the total market. Essentially, 2 private-sector and 2 public-sector healthcare facilities will be selected to test the model. Given that every interested postpartum woman uses at least 2-4 rings in the first year following childbirth, the goal during this phase will be to reach anywhere between 100-200 women.

Initial planning and administrative/programmatic costs will vary by country. The goal of the PCVR-FP/I intervention will be to integrate PCVR into an ongoing FP/I program. Key personnel may be identified and trained for the initial pilot testing phase and to manage administrative and programmatic issues related to the implementation.

Phase 2: Start-up phase

During the second phase, the key goals of the PCVR-FP/I program will be to integrate PCVR as a contraceptive option within all FP/I integrated healthcare facilities. The PCVR-FP/I model will be implemented within all districts where there is sufficient interest and infrastructure for integrated FP/I services.

Duration: 2.5 years

- 6 months pre-implementation planning
- 1.5 years program implementation across districts
- 6 months evaluation and reporting

Quantity of Rings: forecasted number based on the geography and size of the target population Study sites: introduce at healthcare facilities across the districts where integrated FP/I services are currently operational

Phase 3: Scale-up Phase

The goal of the scale-up phase is to introduce the PCVR-FP/I service delivery model to new locations where there is a high unmet need for postpartum family planning. Secondly, depending on the success of the PCVR-FP/I programs, strategic communication and negotiations will be conducted with the government to incorporate the model as part of their national action plan. The success of the program may dictate how the program may be expanded to other areas. An overall strategy will be to look for related funding opportunities and to negotiate with the Ministry of Health the integration of this program with other existing national action plans.

Duration: 2 years

- 3 months pre-implementation planning
- 1.5 years program implementation across existing and new districts with efforts to integrate program into national action plans
- 3 months evaluation and development of a policy guideline to integrate PCVR-FP/I into the national action plan

Quantity of Rings: forecasted number based on the geography and size of the target population Study sites: introduce at healthcare facilities in new districts

Conclusion

The FP/Immunization integration model presents an opportunity for mothers to obtain quality family planning services following childbirth at the same time they seek immunization services for their infants. PPFP is often a neglected area of healthcare, which needs attention to raise awareness among clients, and also needs attention within health delivery systems in most developing countries. The FP/I model is a proven high impact practice which allows for FP and Immunization services to be integrated along the MCH continuum of care.

It will be necessary for the project to involve the governing bodies and donors from the outset, in the design and management of PCVR-FP/I program. Doing so will help build their knowledge and understanding of the importance of PCVR and will also increase the chances of gaining their support in the development of sustainable approaches (Grainger, 2014). The project will need to invest in research among both providers and clients to assess their PPFP-related knowledge, service use patterns, perceived needs, barriers and willingness-to-pay when designing the FP/I program. A strategy that will need to be explored is to see how we might bundle PCVR with other, high-demand services, such as a birthing kit or nutrition programs.

Larger health system constraints to quality service delivery will need to be regularly monitored and addressed as well. Also, when the PCVR is available over the counter, strategies to educate and distribute the contraceptive vaginal ring through pharmacies and drug stores will need to be incorporated.

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Appendices

APPENDIX 1

AN ILLUSTRATIVE EXAMPLE OF THE PROCESS OF INTRODUCING WOMEN TO PCVR THROUGH THE INTEGRATED FP/I SERVICE DELIVERY MECHANISMS

PCVR Information dissemination:

Targeting postpartum women for family planning during immunization visits

At the clinic: Women who visit healthcare facilities for routine immunizations will be informed about the availability of postpartum family planning services by the vaccinator (through pictorial job-aids) and referred to a family planning room. Women who are interested in seeking FP services on the same day will be given a referral card and directed to the FP room by the vaccinator. In the family planning room, women will be presented with an array of PPFP methods currently available along with PCVR, along with information about how the product works and user instructions. PCVR instruction leaflets will be handed to women, which will have a pictorial description on how to insert and remove the ring.

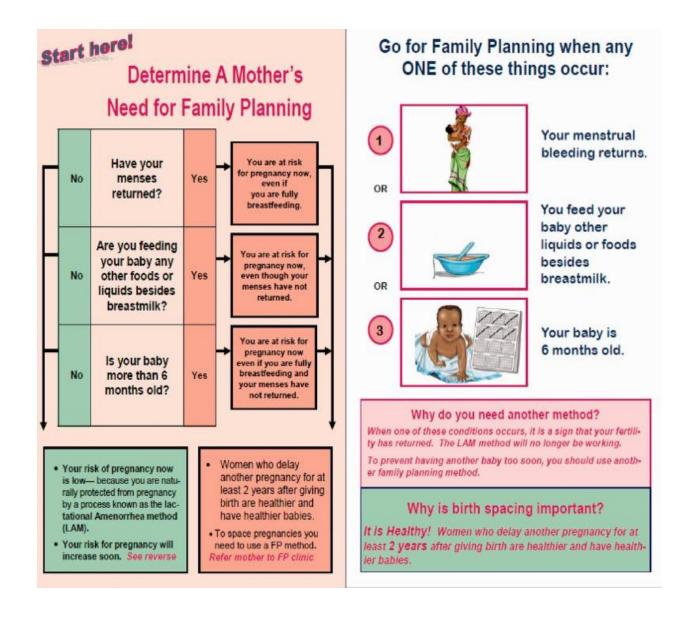
Choosing PCVR for FP: Once the woman has chosen PCVR as her method of choice, the healthcare provider will counsel the women on how to insert the ring in the vagina and remove it at will, as well as how to respond if she feels slippage while wearing the ring. She will be instructed that PCVR is to be worn continuously for 3 months before being replaced with a new PCVR and that women should be breastfeeding at least 4 or more times a day for the ring to be effective. She will also be encouraged to avail additional rings during future follow-up visits or FP/Immunization visits or through local community based sources. Once the woman receives her first vaginal ring, the HCP will provide her with an ID # and referral card to avail additional rings in the future from the designated private or public healthcare facilities or community based outlets.

Follow-up visits: Women who are not able to make future visits to the clinics will be followed by healthcare providers, using their ID# to track the date and time around which the women will need the next PCVR. Women who face issues with the ring may directly contact the HCP through a healthcare visit, via the phone or mHealth services. Furthermore local CHWs and dedicated mid to low level cadre of workers may pay home visits to women who as lost to follow-up.

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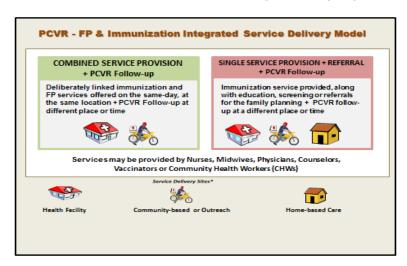
APPENDIX 2

EXAMPLE OF A FP/IMMUNIZATION INTEGRATION SCREENING TOOL



SYNOPSIS OF THE PCVR - FAMILY PLANNING/IMMUNIZATION INTEGRATION MODEL

The PCVR-FP/I Model represents the integration of postpartum family planning (PPFP) and infant immunization



services among breastfeeding women, in the first year following childbirth.

The PCVR FP/I Model includes two key approaches of service delivery:

Approach 1: Combined service provision for Immunization and PPFP/PCVR + PCVR Follow-up

Approach 2: Single service provision of Immunization+ PPFP/PCVR Referral + PCVR Follow-up

The **key strategies for implementation** of the PCVR-FP/I model have been described utilizing the 4 P's of Marketing:

Providers

- Identify and prioritize key healthcare personnel and stakeholders across the public and private sectors
- ✓ Conduct a stakeholder analysis to determine infrastructural, training and staffing needs
- ✓ Form a technical advisory committee (TAC) to oversee the coordination and implementation of the model
 - o TAC will identify a cadre of health workers and plan for referral systems and task sharing mechanisms
- Provide training and capacity building to the identified cadre of health workers

Place

- Map out the places where there are on-going immunization and maternal health services
- ✓ Build on an efficient procurement and logistic-management system of PCVR supplies
- ✓ Identify options for availability of PCVR in the private sector including social franchising outlets and pharmacies
- ✓ Provide follow-up services (home visits), in cases where women do not follow-up or continue PNC services

Promotion

- ✓ Develop PCVR IEC materials in the context of choice
- Integrate PCVR materials with existing job-aids and tools based on the local context
- Plan a strategy of dissemination through the different channels of communication
- Plan for mass media marketing through radio, local newspapers, television, internet and social media

Price

- Determine pricing decisions based on manufacturing cost, volume of procurement and funding availability
- ✓ Determine client willingness to pay and cost of PCVR in comparison to other products available in the market
- ✓ PCVR may be marketed at full price in the private-commercial sector; at a subsidized cost through private-social marketing sector or at no cost through the public sector
- ✓ Factor in initial set up cost and on-going cost to introduce and integrate PCVR into the FP/I integration program

The **key stages of implementation** of the PCVR-FP/I intervention (3 phases):

- ✓ **Design phase:** Pilot test the model in one district or county
- ✓ **Start-up Phase:** Integrate PCVR as a contraceptive option in districts with interest in the product and with sufficient infrastructure for integrated FP/I services
- ✓ Scale-up Phase: Introduce PCVR-FP/I model to new locations where there is an unmet need for PPFP