



The Dapivirine Ring: Key Learnings from Like-Product Introductions

Jack Clancy¹, Emily Donaldson², Neeraja Bhavaraju³, Mitchell Warren², Elizabeth Gardiner²

¹ Formerly AVAC, New York, NY USA; ² AVAC, New York, NY USA; ³ FSG, Boston, MA USA

**OPTIONS refers to PrEP as the product category (inclusive of all formulations of ARV-based HIV prevention), and refers to specific products by formulation designation and/or name (e.g. oral PrEP/TDF-FTC, topical PrEP/dapivirine ring, injectable PrEP/cabotegravir, etc.).*

BACKGROUND

Learning from Other Product Introduction

One form of pre-exposure prophylaxis (PrEP) for HIV negative women is the dapivirine ring, a flexible silicone ring containing the ARV dapivirine. It is inserted by a woman into her vagina where it slowly releases the drug for HIV prevention over the course of a month.

Vaginal insertion and partial efficacy are two challenges that could limit the uptake of the dapivirine ring. Analyses of the introductions of other vaginally inserted products and other partially efficacious products provide useful lessons to inform planning for rollout of the dapivirine vaginal ring. This analysis provides information for implementers, funders, providers of technical assistance, and others to build a product introduction agenda for dapivirine ring and help avoid mistakes made with previous, similar products. While product introduction processes are not directly analogous in all cases, we can expect that similar challenges and solutions will arise repeatedly with vaginally inserted or partially efficacious products.

This analysis reviews the following products

- **Partially efficacious:** In clinical trials the dapivirine ring safely reduced HIV infection by 27-31% among over 4,500 women participants in Malawi, South Africa, Uganda and Zimbabwe. Among women who used it as instructed, the ring reduced the rate of new HIV infections by 37-56%.¹
 - Products having partial efficacy included in this analysis include:
 - Voluntary Medical Male Circumcision
 - RTS,S Malaria Vaccine
 - Rotavirus Vaccine
- **Vaginally inserted:** Few products currently in use are vaginally inserted, so knowledge of and experience with such products is limited. Having to touch the genitals to insert the dapivirine ring is an added potential barrier to use given cultural and social norms.
 - Vaginally inserted products include:
 - Progesterone Contraceptive Vaginal Ring
 - Menstrual products (tampon, menstrual cup)
 - Female Condom

METHODS



Image courtesy of IPM

58 papers and studies on vaginally inserted products including female condoms, tampons, contraceptive rings as well as partially-efficacious products such as the RTS,S malaria vaccine, VMMC, and the rotavirus vaccine were reviewed. Studies were categorized and themed to identify key messages and lessons learned. Nine key informant interviews were conducted with experts on these products. Findings and interviews were analyzed and lessons and conclusions drawn based on the case studies summarized here.

Lessons are drawn from both historical product introduction (e.g. the tampon in the United States) as well as ongoing learning from products in the midst of pilot, introduction and scale up.

RESULTS

Table: Lessons from Partially Efficacious and Vaginally Inserted Product Introduction

	Critical Issues	Lessons from Partially Efficacious Products	Lessons from Vaginally Inserted Products
	Product/ Stakeholder Messages	<ul style="list-style-type: none">• Promote as part of a suite of options; use in combination with other products• Focus on positive product attributes• Use product to help attract clients for other services	<ul style="list-style-type: none">• Promote added benefits of product (e.g. engage clients for HIV testing)
	Data for Decision-Makers	<ul style="list-style-type: none">• Conduct modeling of cost effectiveness and impact on HIV• Identify cost efficiencies	<ul style="list-style-type: none">• Demonstrate that adding another method/choice increases use of prevention
	Provider Training	<ul style="list-style-type: none">• Use pre-existing training mechanisms (e.g. associations, health officials, etc.)	<ul style="list-style-type: none">• Conduct research to understand what is needed• Tailor training to anticipate anti-product bias
	Service Delivery	<ul style="list-style-type: none">• Gain provider buy in via early engagement• Identify time-saving efficiencies to make it easier for the provider to offer the product	<ul style="list-style-type: none">• Engage alternative providers/peer educators• Engage providers as advocates for product to persuade/support other providers• Identify ways to reduce the burden on providers
	Message Dissemination	<ul style="list-style-type: none">• Use trusted sources to distribute messages• Focus on interpersonal communications	<ul style="list-style-type: none">• Have pictures of anatomy and pelvic models available
	Consumer Research	<ul style="list-style-type: none">• Understand perception of efficacy in context of other options, steps to be taken	<ul style="list-style-type: none">• Align delivery channels with consumer preferences• Identify appealing product characteristics
	Consumer Messages	<ul style="list-style-type: none">• Consider featuring non-HIV messages (e.g. hygiene, modernity, responsibility, preferences of partners) which may highlight product's other attributes	<ul style="list-style-type: none">• Develop and use IEC materials to explain the product• Provide training and information on anatomy• Test messages that address taboos about inserting products in vagina (e.g. 'purification')• Provide ideas about settings for insertion/removal
	Product Champions	<ul style="list-style-type: none">• Call on individuals who have specialized expertise <i>and</i> know the product to address product limitations	<ul style="list-style-type: none">• Bring in users as important advocates for an unfamiliar product• Involve providers as product champions
	Gatekeepers/ Influencers	<ul style="list-style-type: none">• Engage providers who can positively influence product uptake	<ul style="list-style-type: none">• Include men in planning and introduction

RESULTS

Partially Efficacious Products

Rotavirus

- Promoting rotavirus within a comprehensive package of diarrheal prevention strategies (rather than a standalone intervention) has increased uptake.
- Focusing on the positive attributes of the product is paramount to strengthening consumer trust and driving demand.
- Conducting cost-effectiveness studies has created an effective advocacy tool for championing the rotavirus vaccine, as it is proven to cut health costs.

RTS,S Malaria Vaccine

- Promoting the vaccine with other malaria interventions (e.g. mosquito nets, spraying, etc.) integrates the vaccine into a comprehensive prevention package.
- Creating a successful marketing strategy for the vaccine highlights the product benefits while also acknowledging the limitations.

Voluntary Medical Male Circumcision (VMMC)

- Providing communications and training for providers on new technologies is key. Streamlining the product's training requirements and optimizing service delivery can substantially increase provider buy-in.
- Diversifying demand creation messages to highlight non-HIV benefits of VMMC (e.g. hygiene, modernity, responsibility, preferences of partners) and incorporating product champions helps drive demand.

Vaginally Inserted Products

Female Condom

- Creating peer-to-peer communications in South Africa, through a community health worker or another product user, was effective in recruiting new users to use the product. Talking about vaginal insertion was more comfortable with a peer than with a physician or unfamiliar provider.
- Targeting men and other key influencers with messaging that helps them to accept and understand the product will ultimately enable stronger uptake among women. Reframing the messaging to benefit all stakeholders is key.

Progesterone Contraceptive Vaginal Ring

- Using the product themselves enabled providers to act as powerful advocates and increase acceptability in Central America.
- Engaging product champions who act as the face of product recruitment and communications campaigns is important because information is more convincing and acceptable coming from a peer or user.

Tampon/Menstrual Cup

- Providing comprehensive training on reproductive anatomy is necessary for the introduction of a vaginally inserted product like the ring. Experience with menstrual cup introduction in South Africa indicated such training can help adolescent girls and women learn where their cervix is and overcome nervousness of "inserting things too far."

CONCLUSIONS

The analysis of like products provides actionable guidance to the planning for dapivirine ring introduction. The table to the left summarizes potential messages and mechanisms for communication, ideas for data collection, approaches to training and research, and reasons for engagement of critical players relevant for the introduction of dapivirine ring as a partially efficacious and vaginally inserted product. Potential implementers of the dapivirine ring can consider the relevance of these successful strategies when planning for introduction. These ideas can help planners efficiently and effectively engage decision-makers, consumers, providers, influencers and other stakeholders.

References: ¹ Baeten, J. M., Palanee-Phillips, T., Brown, E. R., Schwartz, K., Soto-Torres, L. E., Govender, V., Hillier, S., et al. (2016). Use of a Vaginal Ring Containing Dapivirine for HIV-1 Prevention in Women. *The New England Journal of Medicine*, 375, 2121-2132. doi:10.1056/NEJMoa1506110 and Nel, A., Niekerk, N. V., Kapiga, S., Bekker, L., Gama, C., Gill, K., . . . Rosenberg, Z. (2016). Safety and Efficacy of a Dapivirine Vaginal Ring for HIV Prevention in Women. *New England Journal of Medicine*, 375(22), 2133-2143. doi:10.1056/nejmoa1602046.