

INTRODUCING CONTRACEPTIVE METHODS IN LOW-RESOURCE SETTINGS: NEW OPPORTUNITIES IN KENYA

PROJECT DESCRIPTION

In October 2013, USAID awarded the *Delivering Contraceptive Vaginal Rings* project to the Population Council to foster the introduction of two contraceptive methods. The objectives of this project are to:

- 1) improve availability and affordability of a three-month Progesterone Vaginal Ring (PVR) for postpartum breastfeeding women, and
- 2) facilitate regulatory approval and introduction of a one-year contraceptive vaginal ring containing Nestorone® and ethinyl estradiol (NES®/EE)—a long-acting method for non-breastfeeding women that is in the late stages of development.



MILESTONES ACHIEVED



Continued progress was made in preparing the New Drug Application for the investigational NES®/EE CVR for submission to the US Food & Drug Administration (FDA).

Findings from Acceptability and Willingness to Pay studies were widely disseminated at national and global levels.



The PVR has been added to the World Health Organization's Expression of Interest (EOI) following inclusion in WHO's MEC and EML.

Project partner WomanCare Global (WCG) began compilation of the PVR dossier in preparation for registration with Nigeria's regulatory body, the National Agency for Food and Drug Administration and Control (NAFDAC).



WCG also identified a Market Authorization Holder (MAH) for the PVR to ensure compliance with relevant regulatory requirements, post-registration.

Three-Month Progesterone Vaginal Ring



The three-month PVR, a user-initiated contraceptive, can be used safely by postpartum breastfeeding women to help space pregnancies. The ring contains natural progesterone and does not affect a woman's ability to produce breast milk. Each ring can be used continuously for three months, and four rings can be used successively

the first year after childbirth. Fertility generally returns shortly after discontinuation. The PVR is approved in eight Latin American countries, and efforts are underway to introduce it in more countries where contraceptive choices during breastfeeding are limited and where prolonged lactation is prevalent.

One-Year NES/EE Contraceptive Vaginal Ring



The one-year NES/EE CVR is a long-acting contraceptive in the late stages of development. It contains Nestorone® (NES), a new progestin that has been shown to be effective in suppressing ovulation, and ethinyl estradiol (EE), an approved, marketed hormonal compound. Once inserted by

the woman, the NES/EE CVR is designed to be left in place for three weeks, removed for one week to allow for a monthly menstrual cycle, and then reinserted by the woman. The same ring can be used for up to 13 cycles (one year), with the goal of minimizing product cost and time spent visiting a provider or pharmacist. Phase 3 clinical trials have been completed, as have additional clinical and product specification studies required by the FDA. The Population Council is preparing a New Drug Application to submit to the FDA for regulatory review.

YEAR 4 ACTIVITIES

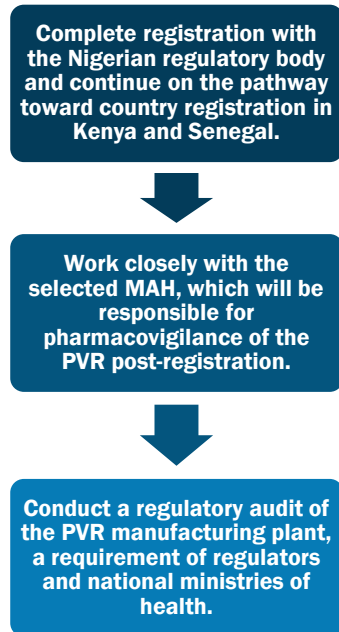
(OCTOBER 2016 – SEPTEMBER 2017)

2.1 Implementation research on product introduction

No activities proposed.

2.2 Register the PVR in Kenya, Malawi, Nigeria, Senegal, and Zambia

Project partner WomanCare Global (WCG) will:



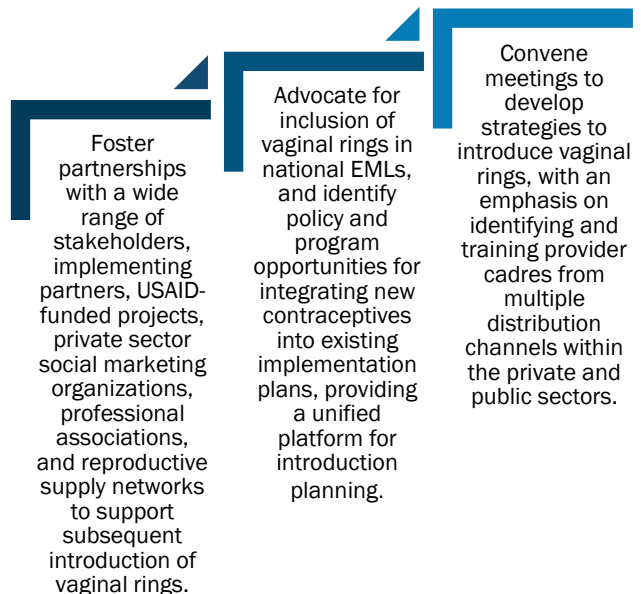
2.3 Technical assistance for WHO Pre-Qualification of the PVR

- Project staff continue to provide technical assistance to PVR manufacturer Grünenthal in many thematic areas including a PK study, stability testing, and validation of analytical methods. Grünenthal will seek WHO-PQ to

facilitate PVR procurement by a wider number of agencies including UNFPA, USAID, ministries of health, and social marketing organizations.

- Results of a clinical trial conducted by the Population Council in India in collaboration with the Indian Council of Medical Research comparing the safety and efficacy of the PVR versus the IUD will be finalized for inclusion in the WHO-PQ application.
- Project staff will continue analysis of used PVRs and compare with data collected from acceptability studies in each country. The secondary analysis will reveal the extent to which women adhere to PVR use; results will inform refinement of user instructions, including those related to ring disposal.

2.4 Design introductory strategies for contraceptive vaginal rings



KEY PROJECT CONTACTS

The Population Council will lead the proposed project activities, along with a consortium that includes WomanCare Global, Grünenthal, and QPharma. For more information about the products or *Delivering Contraceptive Vaginal Rings* project, contact Harriet Birungi, John Townsend, or the USAID/Washington project management staff.

Population Council staff leading this effort in Kenya:

- Dr. Harriet Birungi (hbirungi@popcouncil.org)
- Mr. Wilson Liambila

US-based Population Council staff directing the project:

- Dr. John Townsend, Principal Director (jtownsend@popcouncil.org)
- Dr. Saumya RamaRao
- Dr. Ruth Merkatz

Office of Population and Reproductive Health, USAID/Washington project management staff:

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