fact sheet

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

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 project seeks to:

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

The project intends to build collaboration with commercial outlets, social marketing providers, and not-for-profit providers to ensure broad availability of and access to these contraceptive methods.

MILESTONES ACHIEVED

- Substantial progress has been made in preparing and accelerating the one-year investigational NES®/EE CVR new drug application (NDA) for submission to the US Food & Drug Administration (FDA).
- Descriptions of postpartum family planning programs, policies around task sharing, and service delivery models for integrating the PCVR have been completed.
- The PCVR has been submitted for consideration for inclusion into WHO's Medical Eligibility Criteria.
- The PCVR has also been submitted for consideration for inclusion on the WHO's Essential Medicines List.
- Project partner WomanCare Global (WCG) has conducted the relevant regulatory assessments for registration of the PCVR in Kenya.

The Three-Month Progesterone Contraceptive Vaginal Ring (PCVR)

The three-month PCVR is a user-initiated contraceptive that can be used safely by postpartum breastfeeding women to help space pregnancies. The PCVR uses natural progesterone and does not affect a woman's ability to produce breast milk. Each PCVR can be used continuously for three months, and four rings can be used successively in the first year after childbirth. Fertility returns shortly after discontinuing use. The PCVR is approved in eight Latin American countries, and efforts are underway to introduce the PCVR in more countries where contraceptive choices during breastfeeding are limited and where prolonged lactation is prevalent.

The One-Year NES/EE Contraceptive Vaginal Ring (NES/EE CVR)

The one-year NES/EE CVR is a late-stage contraceptive. It contains Nestorone® (NES), a new progestin that has shown to be effective in preventing ovulation, and ethinyl estradiol (EE), an approved, marketed hormonal product. 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 bleeding cycle, and then reinserted by the woman. A single ring can be used consistently for up to 13 cycles (one year), with the goal of minimizing product cost and time spent visiting a provider or pharmacist. Pivotal Phase 3 clinical trials have been completed, and the Population Council is preparing a New Drug Application for regulatory review by the US Food and Drug Administration.

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YEAR 2 ACTIVITIES
(OCTOBER 2014 – SEPTEMBER 2015)

Activity 2.1 Implementation Research on Product Introduction

- Refine and expand upon existing curricula and materials for frontline family planning service providers (nurses and midwives) to aid in the provision of the Progesterone Contraceptive Vaginal Ring (PCVR) in Kenya, Nigeria, and Senegal. Input from leading service partners and service delivery projects such as MCSP and SIFPOs will be sought in curriculum development. We will also vet the curricula within each country.
- Engage with pharmacists and patent drug vendors to assess their interest in and feasibility of selling the PCVR through their outlets.

Activity 2.2 Register the PCVR in Kenya, Nigeria, Senegal, Malawi & Zambia

- Project partner WomanCare Global (WCG) will register the PCVR in Kenya, Malawi, Nigeria, Senegal, and Zambia. WCG will conduct assessments in each country to prepare the dossier for regulatory submission and will work with the manufacturer and the relevant regulatory authorities in each country to be in compliance with regulatory requirements.
- WCG will also produce locally relevant medical detailing material for use in each country to complement the work in registration.

Activity 2.3 Technical Assistance for WHO Pre-Qualification of the PCVR

- The PCVR has been submitted for consideration for inclusion in the WHO's Medical Eligibility Criteria. Inclusion in this global technical guidance document will pave the way for future inclusion in service delivery guidelines and other country-level technical documents.
- The PCVR has also been submitted for consideration for inclusion in the WHO's Essential Medicines List. Should the application be successful it will facilitate procurement of this innovative contraceptive.

Activity 2.4 Design introductory strategies for contraceptive vaginal rings

- In consensus with national partners, we will design strategies to introduce contraceptive rings in each country. The strategies will reflect country frameworks, priorities and resources so that synergies can be built into ongoing efforts. It will also outline the specific phases and steps to introduction: from registration, procurement, integration into the health system, including determining which sector is best suited for introduction, through demand creation and education.
- We will continue to engage with constituencies such as providers in public and private sectors, professional associations, MOH, health advocates, and civil society to build a network of champions. In particular we will engage with platforms such as the Ouagadougou Partnership and SECONAF.

KEY PROJECT CONTACTS

The Population Council will lead the proposed project activities, along with a consortium that includes WomanCare Global, Grünenthal, and QPharma.

Population Council staff leading this effort in Senegal:

- Dr. Nafi Diop (ndiop@popcouncil.org)
- Mr. Babacar Mané

US-based Population Council staff directing the project:

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

The project's management staff in the Office of Population & Reproductive Health, USAID/Washington include:

- Dr. Judy Manning, Agreement Officer's Representative (jmanning@usaid.gov)
- Ms. Tabitha Sripipatana, Technical Advisor (tsripipatana@usaid.gov)
- Mr. Imran Mahmud, Program Analyst (imahmud@usaid.gov)

For more information about the products or the *Delivering Contraceptive Vaginal Rings* project, please contact Dr. Nafi Diop, Dr. John Townsend, or the USAID/W project management staff.