

What do women want?

EMERGING TECHNOLOGIES IN REPRODUCTIVE HEALTH PANEL DISCUSSION

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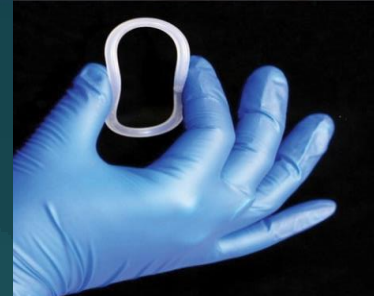
POPULATION COUNCIL

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Population Council's Progesterone Vaginal Ring

women

A contraceptive to meet the needs of breastfeeding

Target Product Profile

- Active Ingredient: Progesterone identical to that naturally produced
- Route of Administration: Concealable vaginal use, average steady dose of 10 mg/day for 3 months
- Mechanism of Action: Prevents ovulation, enhances inhibitory effect of breastfeeding
- Contraceptive Efficacy: Typical use efficacy of 95%



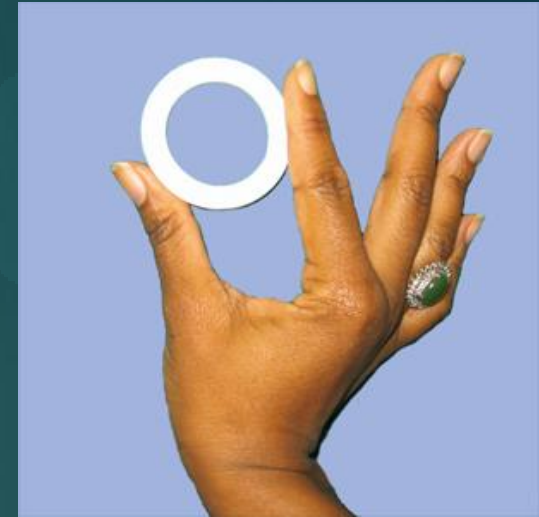
Population Council's Progesterone Vaginal Ring

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A contraceptive to meet the needs of breastfeeding

Addressing Gaps in the Method Mix

- Appropriate for lactating women
- Mid-acting and reversible
- Not coitally dependent, no daily intake
- Woman-controlled
- Reduced dependency on health care provider



Population Council's Progesterone Vaginal Ring

women

A contraceptive to meet the needs of breastfeeding

Product Status

- Registered and sold in 8 Central and Latin American countries
- Acceptability studies planned in Kenya, Nigeria and Senegal
- Ongoing Phase 3 clinical trial in India (20 sites); includes acceptability study



Evofem's Amphora Contraceptive Gel

Target Product Profile

- Active Ingredients: Alginic Acid, L-Lactic Acid, Benzoic Acid, Citric Acid
- Route of Administration: 5 ml vaginally one hour before intercourse
- Mechanism of Action: helps maintain vaginal pH below 4.5 even after entry of alkaline ejaculate
- Contraceptive Efficacy: target 85% for typical use

Evofem's Amphora Contraceptive Gel

Addressing Gaps in the Method Mix

- Non-hormonal
- Short-acting and reversible
- Used pericoitally, on-demand
- Woman-controlled

Evofem's Amphora Contraceptive Gel

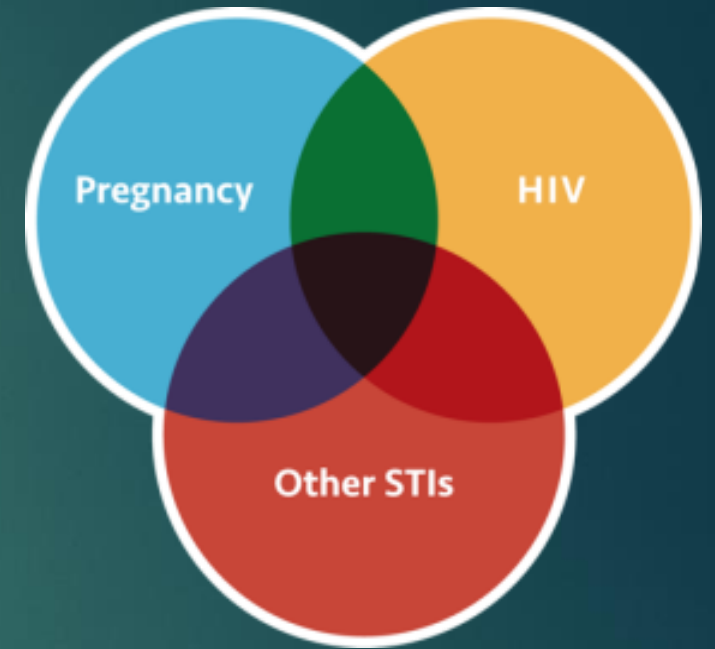
Product Status

- Phase 3 Trial as a contraceptive, with 3000+ women
- Already FDA approved as a lubricant
- Expected dates for FDA submission 2014

What are Multipurpose Prevention Technologies (MPTs)?

▶ Products and strategies configured for at least two SRH prevention indications:

- ✓ **Unintended pregnancy**
- ✓ **HIV**
- ✓ **Other STIs**



WHY MPTs?

- **Greater *efficiency* in terms of cost, access and delivery of SRH prevention products**
- **Capitalize on the demand in populations using one product type to achieve *uptake and use* of a second “product”**

MPTs in the pipeline

- ▶ Drug Combinations
- ▶ Drug/Device Combinations
- ▶ Multipurpose Vaccines
- ▶ Bacterial Therapeutics
- ▶ Nanoparticles



Priorities for 1st generation MPTs

“On Demand”



- Used around time of intercourse
- For women who have intermittent sex or want more direct control over their protection

Sustained Release



- User-initiated, does not require daily action
- Should increase adherence and effectiveness

Prioritization Criteria: MPT TPP

Critical Attributes Considered:

Indications	Target Population
Efficacy	Adherence
Route of Administration	Dosage Form & Schedule
Side Effects	Storage Conditions
Reversibility	Other Health Benefits
Contra-indications & precautions	Use by preg./lactating women
Product Provision (Rx vs. OTC vs. ?)	Acceptability Measures
Shelf Life	Medical Support
Time to Market	COG/Total Cost
Product Presentation	Packaging
IP Status	Disposal/Waste
R&D Costs	Development Entity

Priority Indications:

- Pregnancy + HIV
- Pregnancy + HPV
- HIV + STI (HSV, HPV, BV)

Dosage Forms:

- US preference for oral
- Indian preference for sustained release
- African preference across several dosage forms (which may help to foster greater acceptance / use)

Merck's Free Family Planning Phone Counseling

Service Profile

- Objective: increase the use of modern methods of family planning through the transmission of relevant essential information to the population, especially resource-poor women
- How the system works:
- System developed by Human Network International & Dept. of Child Health & Maternal Reproduction, with funding and expertise provided by MSD
- Service Mandroso a Search Engine used in locations without internet access
- Client call “321” & selects options/topics of interest



Merck's Free Family Planning Phone Counseling

Addressing Gaps in Service delivery

- Provides free access to FP information to those without Internet access.
- For the first time, rural, poor, illiterate audiences have on-demand access to information they need – anywhere, anytime, nationwide in their own language.
- Can be easily updated and improved based on caller feedback and interest
- Is anonymous and discrete for callers' privacy
- Delivers unbiased, standard and well thought out messages



Merck's Free Family Planning Phone Counseling

Developed and implemented in

Madagascar

Service Status

Key results:

- Average of 18,000 calls/month
- FP & Importance – 3,100
- Use of FP & Benefits - 1,513
- Tips on using FP – 2,113
- FP Methods – 3,052
- Referrals – 1,500
- Calls with no further choices – 6,443



Q&A: Understanding Marketing and Distribution of New Technologies

1. Who is your target audience?
2. How will you reach these women?
3. What will you do to address price barriers?
4. What other barriers might there be to rolling out these products?
5. Do you have any information, at this point, about the acceptability/ease-of-use of your product/service?

