

# One Product. Simultaneous Protection. Multipurpose Prevention Technologies (MPTs) for Sexual and Reproductive Health

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## Background

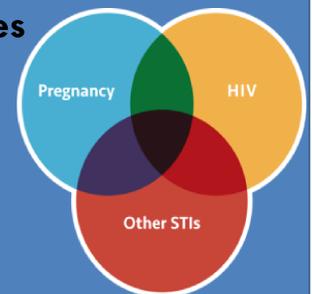
Across the globe, women often struggle to meet their reproductive health needs. While their needs vary according to where they live and their stage of life, women would all benefit from improved prevention methods for sexual and reproductive health.

### RISKS WORLDWIDE:

- Each year, 1.6 million people die from AIDS and there are 2.3 million new HIV infections.
- Young, married women are the fastest growing group of HIV+ people worldwide.
- Women are 5 times more likely to get sexually transmitted infections than men.
- Each day, close to 500,000 young people, mostly women, contract a sexually transmitted infection.
- Each year, approximately 290,000 women in developing countries die from complications related to pregnancy and childbirth.
- 222 million women have an unmet need for contraception.

## WHAT ARE MPTs?

**Multipurpose Prevention Technologies (MPTs)** combine protection in a single product to prevent at least two sexual and reproductive health risks: unintended pregnancy, HIV and other sexually transmitted infections (STIs).



## Methods & Research Strategy

**HYPOTHESIS:** Different global regions have different epidemiological dynamics, reproductive health needs and public health priorities, so priorities for MPT research and development will also differ.

### OBJECTIVES:

- Identify MPT products with highest potential for public health impact.
- Provide guidance for donors, product developers & regulators regarding strategies for MPT R&D and investment needs.

### MATERIALS AND METHODS:

- Established Target Product Profile (TPP) Working Groups.
- Constructed TPPs defining ideal & minimally acceptable product attributes; critical technical parameters; considerations of costs, time, regulatory complexity, manufacturing & distribution.
- Strategic sequence of quantitative surveys and qualitative interviews among sexual and reproductive health researchers and providers in Africa, Asia, Europe, and USA.
- Expert review, consolidation of consensus views, capture of outlier positions.
- Established Scientific Agenda Working Group (SAWG) to compile and describe integrated “pipeline” of candidates with contraceptive, anti-HIV & anti-STI activity, and relevant “platform” components.
- Review of existing guidance on combination products, ongoing interaction with regulatory authorities, to clarify clinical path.

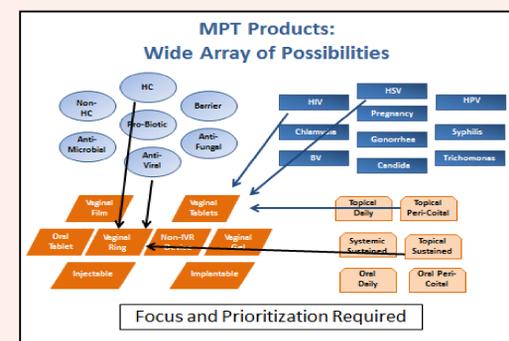


Figure 1. Priority Indications: According to ad hoc ePolls conducted among reproductive health experts at key convenings in 2011.

Critical Attributes Considered:		Priority Indications:
Indications	Target Population	1. HIV and Pregnancy 2. HIV and STI ■ HSV, HPV, BV 3. STI and Pregnancy
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 Entry	

Figure 2. MPT Target Product Profile prioritization criterion as adhered to by the IMPT Scientific Agenda Working Group (SAWG).

## Results & Key Findings

### PRIORITY INDICATIONS

1. HIV and unintended pregnancy
2. HIV and STI (HSV, HPV, BV)
3. STI and unintended pregnancy
4. Other STIs, with contraception not a priority

### DOSAGE FORMS

- Sustained release
- Topical preferred over oral
- Pericoital preferred over daily
- Major determining factor: adherence
- Highest development priority: vaginal rings

### VARIABILITY IN PRIORITIES/NEEDS

- Sub-Saharan Africa: HIV and unintended pregnancy; STI emphasis on HSV-2, BV, TV, HPV
- India: Unintended pregnancy and HIV
- China: HIV and other STIs; unintended pregnancy
- USA (health-care providers): Unintended pregnancy/non-HIV STIs (65%), pregnancy/HIV (25%)



## MPTs in the Pipeline

- A ‘one size fits all’ diaphragm combined with a microbicide gel, which has been shown to be effective against HIV and Herpes Simplex Virus (HSV).
- Easier to use vaginal rings that offer more than just contraception, but also provide prevention against STIs, including HIV.
- Innovative and effective gels that provide protection against HIV and other STIs could be used in combination with diaphragms and other contraceptives.
- Injectables for contraception and infection prevention that provide long-acting protection.

## Conclusions

**PROGRESS:** Innovative, interdisciplinary approach has built the framework for:

- Identifying priorities needs & preferences (TPPs)
- Analyzing MPT pipeline
- Identifying gaps
- Mapping a plausible “critical path”
- Guiding investment

### REMAINING CHALLENGES FOR MPT DEVELOPMENT:

- Regional differences
- Regulatory considerations
- Resources (money, trial capacity, participants, development partnerships)

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