

Multipurpose Prevention Technologies:

Aligning Investments in R&D

Judy Manning, PhD

Office of Population & Reproductive Health
USAID

Joe Romano, PhD

NWJ Group, USA;
independent consultant to CAMI

MPTs for HIV panel session

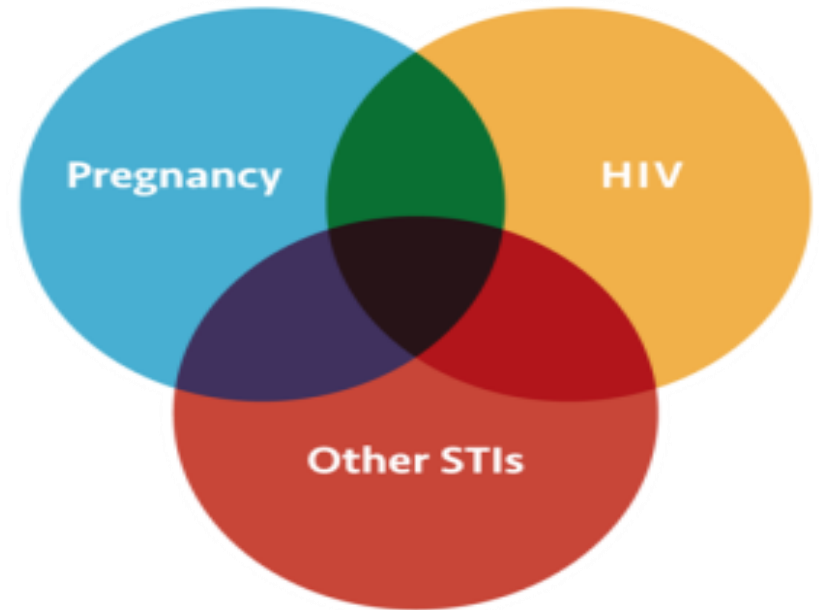
Women Deliver International Conference

May 28-30, 2013

Kuala Lumpur, Malaysia

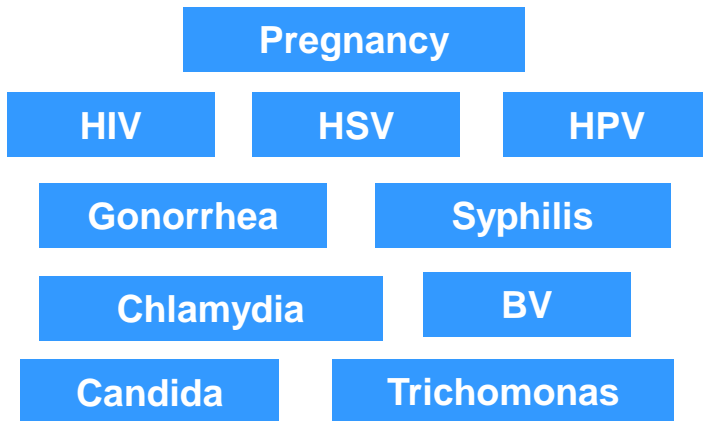
Why Develop MPTs?

- 1. To meet women's multiple SRH needs in one product***
- 2. To achieve efficiencies in cost of delivery of prevention products***
- 3. To leverage existing delivery channels to achieve higher levels of prevention product uptake and demand***

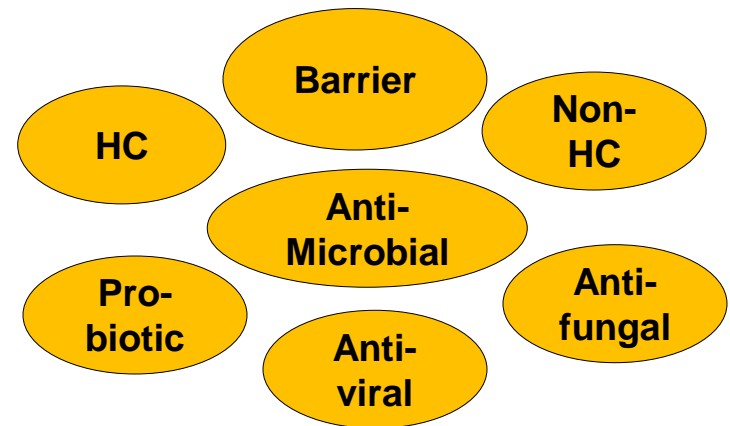


Complexity of developing MPTs

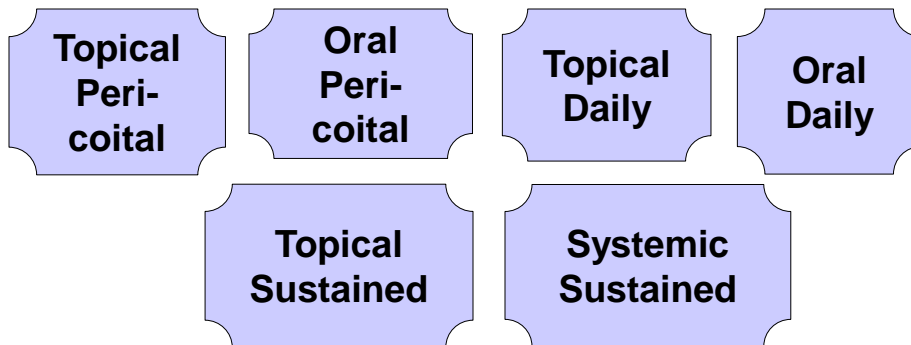
INDICATION



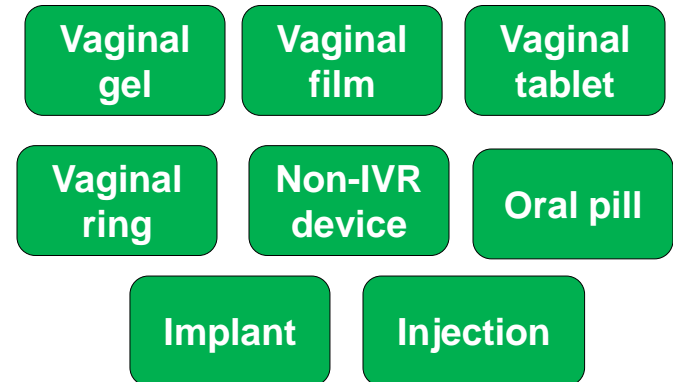
MECHANISM OF ACTION



DOSAGE & ADMINISTRATION



FORMULATION & DELIVERY



Developing Target Product Profiles (TPPs) for MPTs

➤ *Why a TPP?*

- To identify key attributes/parameters for MPT products that would lead to the highest potential public health impact (i.e., prioritization)
- To guide product development and donor investment strategies

Initiative for MPTs (IMPT) TPP Working Group Process:

- Solicited expert review from domestic and international SRH researchers on ideal and minimally acceptable thresholds of product attributes / parameters
- Surveyed US and African providers as to key priority attributes for MPTs:
 - **593 US providers** who are members of the Association of Reproductive Health Professionals (U.S.-based)
 - **289 African providers** attending the 2011 International Conference on Family Planning in Dakar, Senegal
 - **34 Indian providers** attending the Regional Conference on MPTs in New Delhi, India (Dec 2012)
- Consolidated consensus views

TPP Input from SRH Researchers

Critical Attributes Considered:

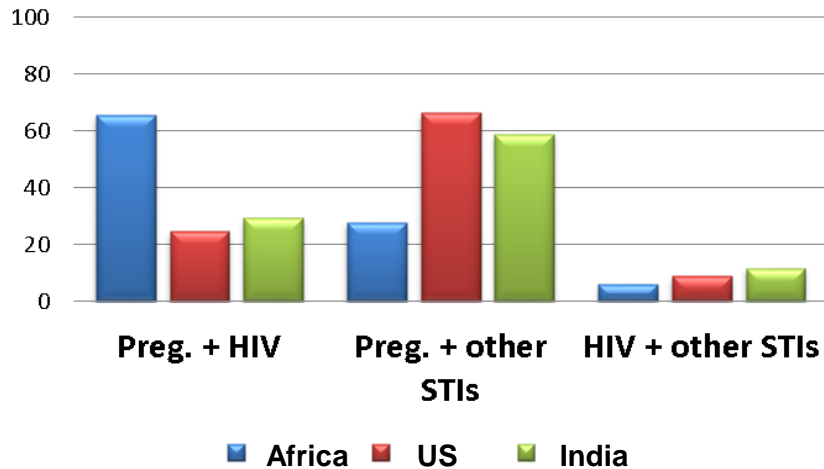
Indications	Target Population
Efficacy	Adherence
Route of Administration	Dosage Form & Schedule
Side Effects	Storage Conditions
Reversibility	Other Health Benefits
Contra-indications & precautions	Use by preg./lactating women
Product Provision (Rx vs. OTC vs. ?)	Access Potential & Restrictions (testing?)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

Key Attributes of MPTs:

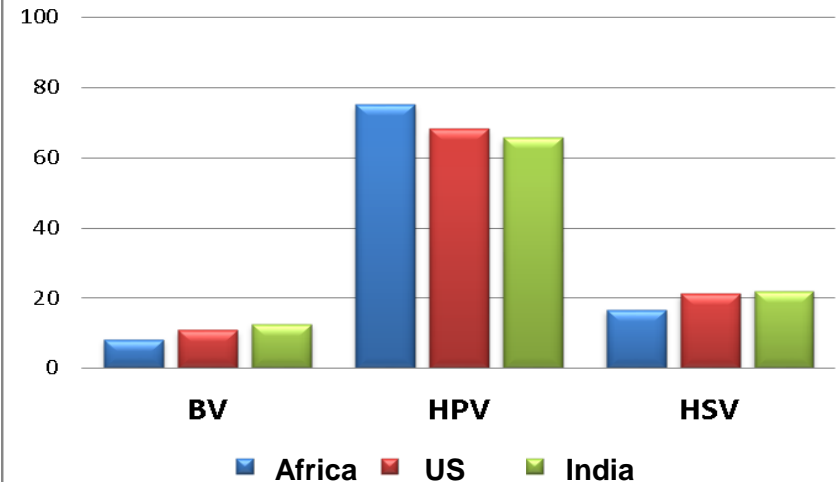
- **Indications:**
 - HIV & Pregnancy
 - HIV & STI
 - HSV, HPV, BV
 - STI & Pregnancy
- **Dosage Forms:**
 - Sustained release
 - Topical over oral
 - On demand over daily
- **Product Related (egs.):**
 - 40°C storage
 - 36 month shelf life
 - Concealable presentation

TPP Input from Regional Providers

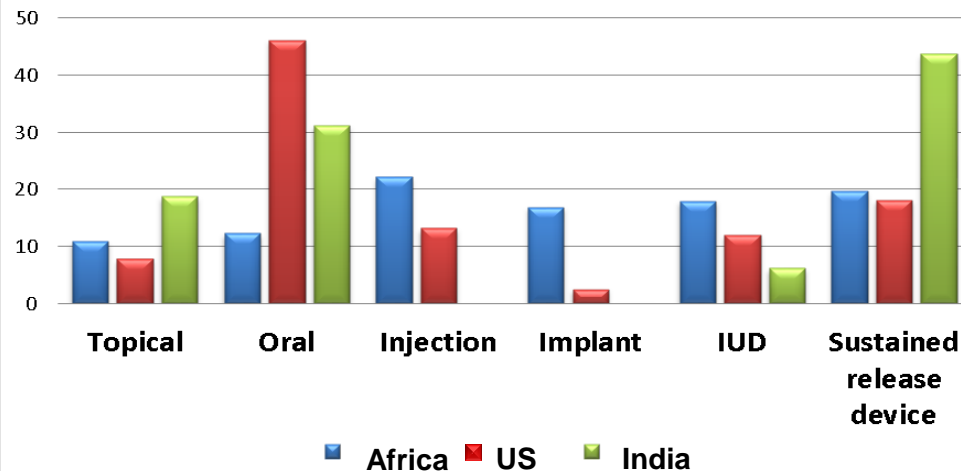
Priority Indications for MPTs



Priority STI (other than HIV)



Priority Dosage Form



Summary of TPP Priorities

SRH Researchers:

- ✓ Priority Indications:
 - Pregnancy + HIV
 - HIV + HSV
- ✓ Dosage Forms:

Major determining factor is PRODUCT ADHERENCE, so highest development priority is Sustained Release

US, Indian and African Providers:

- ✓ Priority Indications:
 - Pregnancy + HIV
 - Pregnancy + HPV
- ✓ Dosage Forms:

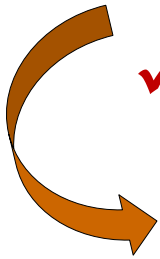
US preference for oral; Indian preference for sustained release; African preference across several dosage forms (which may help to foster greater acceptance / use)

Conclusions from the MPT TPP process:

Although challenging, it is possible to identify general development priorities and product design targets for MPTs

Why prioritize product design targets for MPTs?

- ✓ Useful to funders in determining investment potential
- ✓ Useful to developers in focusing R&D efforts



The IMPT Scientific Agenda Working Group (SAWG) conducted a ***Product Development Prioritization and Gap Analysis*** April – October, 2012

SAWG Members	
Donor Representatives	
BMGF	DFID
NIH/NIAID	NIH/NICHD
NIH/OAR	USAID
Regional Representatives	
Africa	China
India	
IMPT Coord. Committee	

SAWG MPT Pipeline Prioritization Process

➤ Assemble comprehensive list of MPT-related products/components

10 MPT IVR	10 Single Indication IVR	31 HIV Entry Inhibitors
3 On-Demand MPT	12 On-Demand HIV Only	11 Enzyme Inhibitors
2 Barrier MPT	2 Injectable HIV Only	7 Other HIV Inhibitors
23 HC products	2 Lacto-based Products	29 non-HC products

- Evaluate for development feasibility, and number per product types (MOA, chemical class, dosage form, etc.)
- Evaluate per general TPP findings
- Evaluate per other criteria
- Access expertise from contraceptive field

Outside the SAWG Scope:

- Study-section type review of specific MPT products or component products and technologies
- Recommendations on funding for specific products or technologies

SAWG MPT Prioritization and Gap Analysis: General Summary

Top Priorities

- **Suite of product types:**
 - ✓ On-demand formulations
 - ✓ Vaginal rings
 - ✓ Long-acting injectables
- **Active Pharma. Ingredients (APIs):**
 - ✓ ARVs for HIV
 - ✓ Hormonal contraceptives
 - ✓ STI-specific APIs

Long term R&D needs

- STI-specific APIs
- Non-ARV based HIV prevention
- Lactobacillus-based products
- Non-hormonal contraceptives
- Novel on-demand product configurations

Process Priorities

- ✓ Consensus on development objectives across donors and developers
- ✓ ID single leads through common R&D pathways using TPPs specific to product types
- ✓ Coordinated investment and collaborative development
- ✓ Pooling of capacity, expertise, and other resources between MPT R&D partners
- ✓ Early and proactive engagement of regulatory authorities