Moving Toward an MPT

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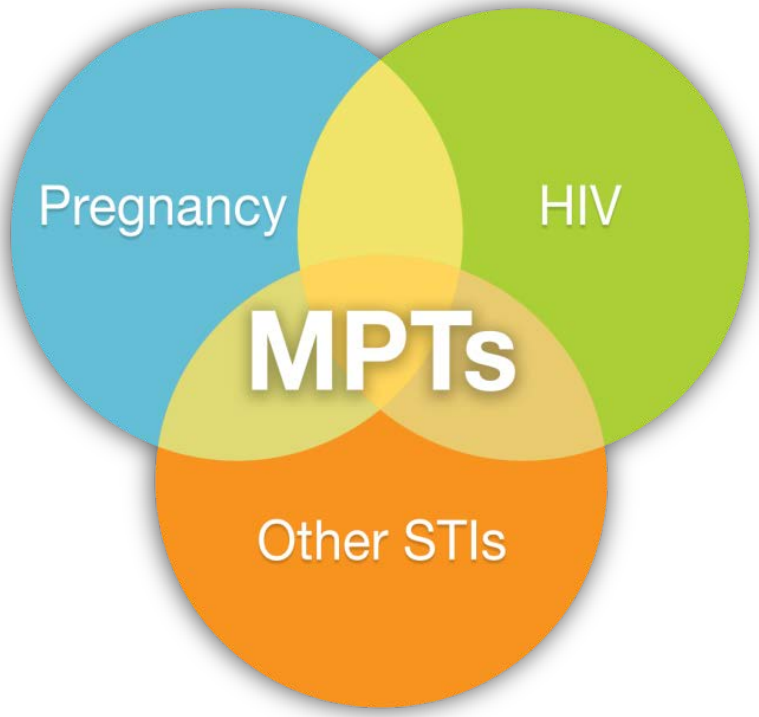
MTN microbicide trials network

Multipurpose Prevention Technologies

Functional Definition:

Products or product strategies that address more than one SRH indication including contraception, STI prevention, and HIV prevention



Existing MPTs

Male and Female Condom

Why MPT's?

Primary Hypothetical Advantage:

Interest and demand for contraception can be used to achieve meaningful uptake and committed use of an HIV prevention intervention in younger populations of women

- Increased MPT **demand/uptake** vs HIV prevention only
- Increased **adherence** with MPT vs HIV prevention only
- Efficiencies in delivery and access with MPT
  - Versus two (or more) separate products

Why MPTs?

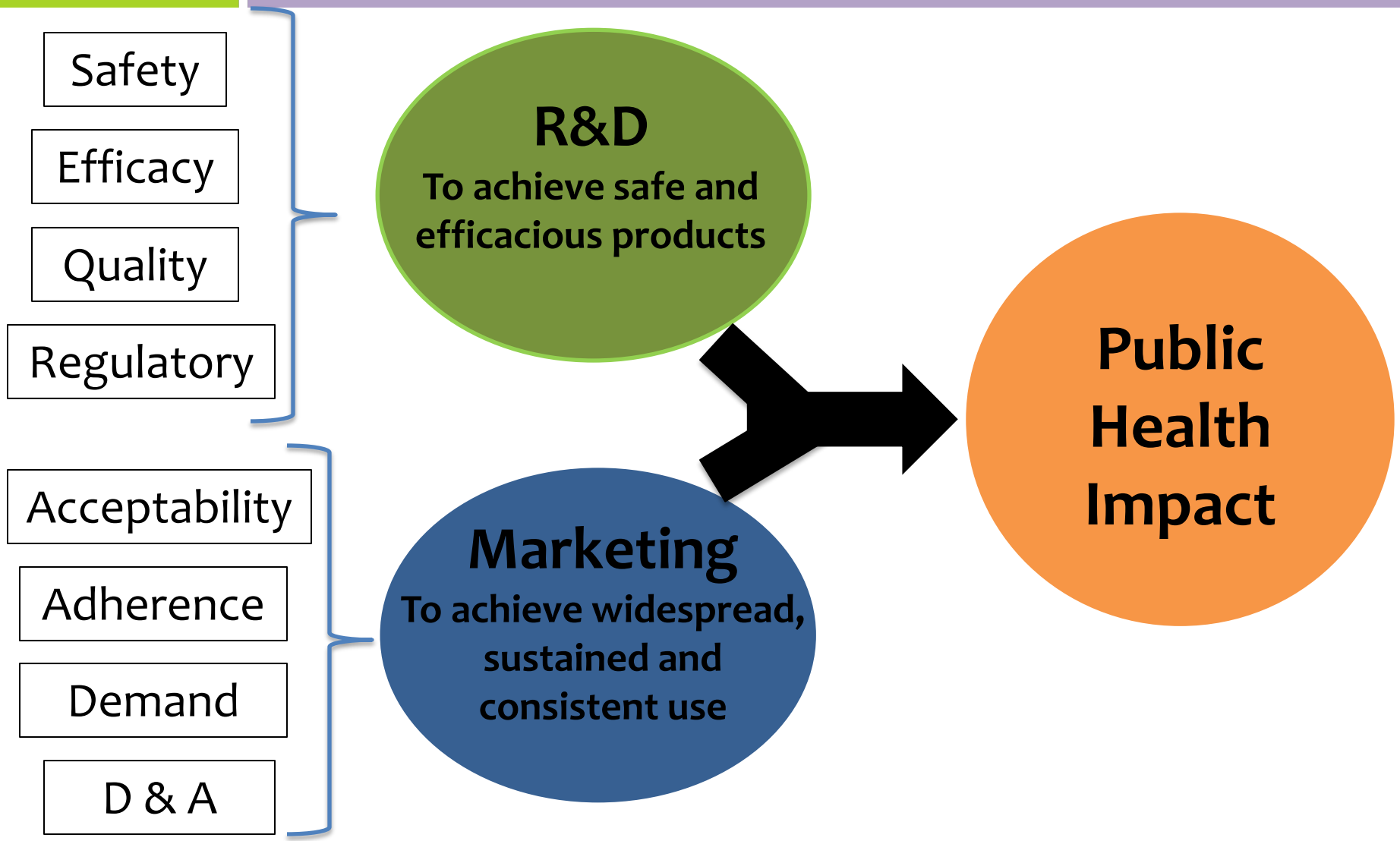
More Simply:

A woman-controlled, easy to use, broadly acting product is more desirable to women than using 2-3 different products!

How Reasonable are the Hypothetical Advantages of an MPT?

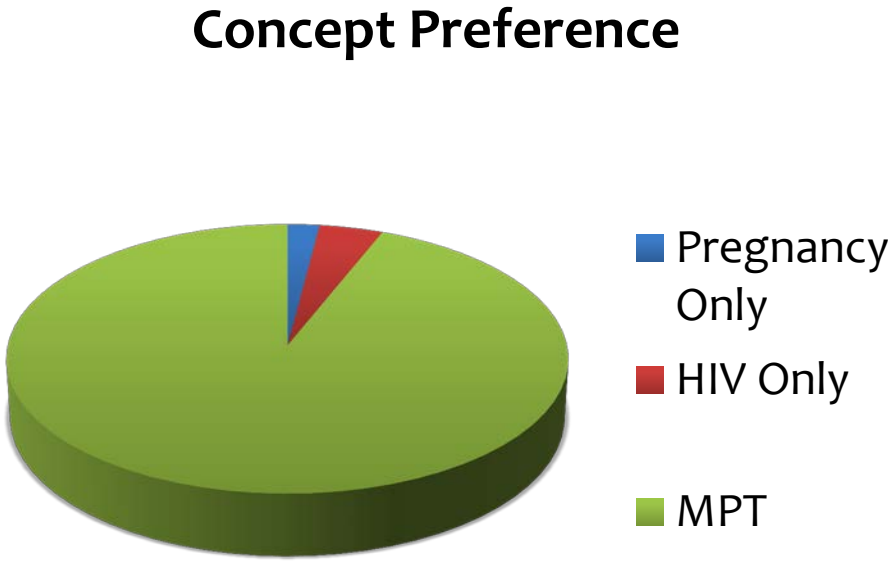
- **Pro's**
  - Many women at risk for HIV use modern contraception
  - Younger women express greater concern over unintended pregnancy vs HIV infection
  - High percentage of women state a preference for MPT
- **Con's**
  - Will HIV indication stigmatize the contraception indication in an MPT?
  - MPT cannot sacrifice contraceptive efficacy
  - Can MPT be delivered outside of HIV settings?

Moving from Reasonable Option to Impactful Reality



What Do We Know About MPT End Users?

- Ipsos Market Study* :
  - Quantitative market survey of 1722 women (15-35 yrs) in South Africa, Uganda, Nigeria; 60 min interviews
  - Concept Preference (all):
    - MPT: 93%
    - HIV Only: 4%
    - Pregnancy Only: 2%



*http://www.theimpt.org/documents/UnderstandingPotentialMPT-HIVpregnancy.pdf

What Do We Know About MPT ? End User Preference

Other IPSOS Learnings:

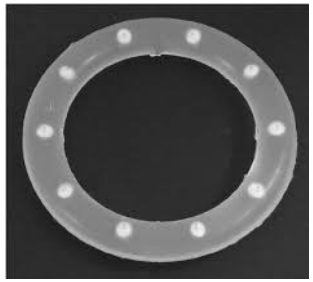
- Side effects to avoid:
  - Fatigue
  - Headache
  - Diarrhea
  - Migranes
  - Unexpected Bleeding
  - Discharge
  - Effects on ability to work%
- Dosage form preference:
  - Implant 41%
  - Injectable 28%
  - Film 20%
  - IVR 9%
  - None 2%

- What is still to be learned?

Sizes, shapes colors, packaging, duration of effect, impact on menses, ability to remove (IVR), desired point of access, etc…

How Robust is the MPT Pipeline?

- Vaginal Rings:
  - TNF, TNF/LNG Segmented IVR (CONRAD): P1 complete
  - TDF Segmented IVR (AECOM): Phase 1 complete
  - DAP/LNG Matrix IVR (IPM): Phase 1 planned late 2016
  - MZCL IVR (PC): HIV, HSV, HPV, contraceptive; preclinical
  - MPT POD IVR (Oak Crest): TDF, ACV, EE, NES; preclinical
  - GRFT IVR (PC): HIV, HSV, other STI
  - AB-based IVR (MAPP): MB66 (P1) + sperm Ab (concept)



How Robust is the MPT Pipeline?

- Other Dosage Forms:
  - MZC Gel + SILCS (PC): Gel at Phase 1; SILCS approved: HIV, HSV, HPV (MZC gel alone for HIV, HSV, HPV)
  - TFV based insert products (CONRAD): HIV, HSV
  - PPCM Gel (Yaso): Contraceptive, HSV, HIV; preclinical
  - AB-based vaginal film (MAPP): MB66 for HIV/HSV (P1) + sperm Ab (concept)
  - GRFT Insert/gel/film (Pop Council; U. Louisville): HIV + STI

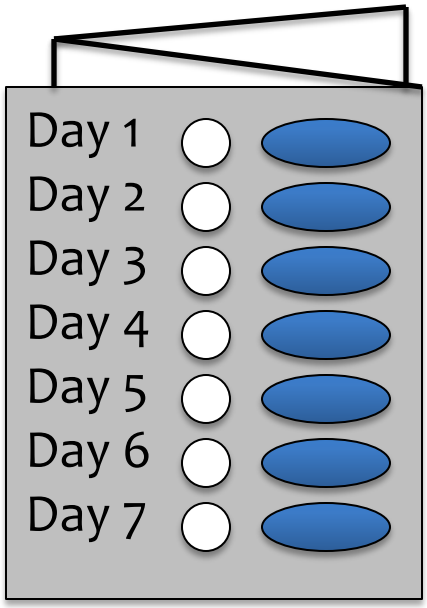
The Fastest MPT?

Co-Packaging:

Omeclamox

- Amoxicillin/ clarithromycin: Antibiotics
- Omeprazole: GERD

COC + Oral PrEP



- ✓ Regulatory Precedent
- ✓ Increased Efficacy
- ? Market Potential

Other Efforts Informing MPT Market Issues

- Trio Study: Alternative dosage form acceptability- placebo injectable, oral, IVR
- Quatro Study: 18-30 yr women with placebo film, insert, gel, IVR
- Uchoose: 16-17 yr adolescents selecting contraception from IVR, oral, injectable options
- DAP IVR OLE (HOPE, DREAM)
- MTN 034: DAP IVR, oral Truvada
- Dreams Initiative; USAID MPii programs
- Data from other trials-
- Expanded MPT modeling

Possible Barriers to Advancing an Impactful MPT

- Data-based market justification for MPT limited
- Increasing challenges with HIV prevention trials
  - Changing SOC with prevention product roll out
  - Recruitment in the context of available products
  - Trial design in the context of approved products
- Complex regulatory pathway: 2 indications
- Competitive prevention landscape
- Time

LAI | bNABs | Implants | Vaccines

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Accept Reality/Plan Accordingly

Reality:

-
-

Ne

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-
- Product down selection to a justifiable lead
- **HURRY UP!**

Proper Planning

\+ Appropriate Implementation

Successful realization of the public health impact potential of an MPT product

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THANK YOU

Questions

&

Discussion