Multipurpose prevention technologies: the vision, the approaches, the challenges

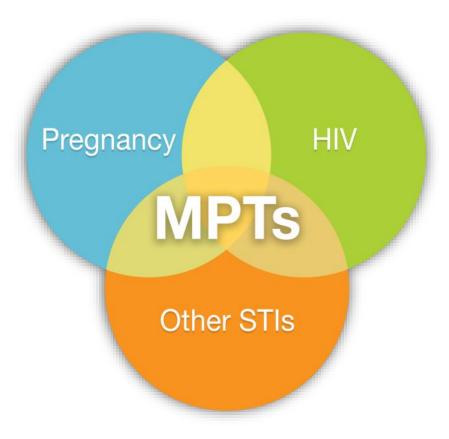
Julie Pulerwitz, ScD Director, HIV Program Population Council

HPTN ANNUAL: MEETING 2021:





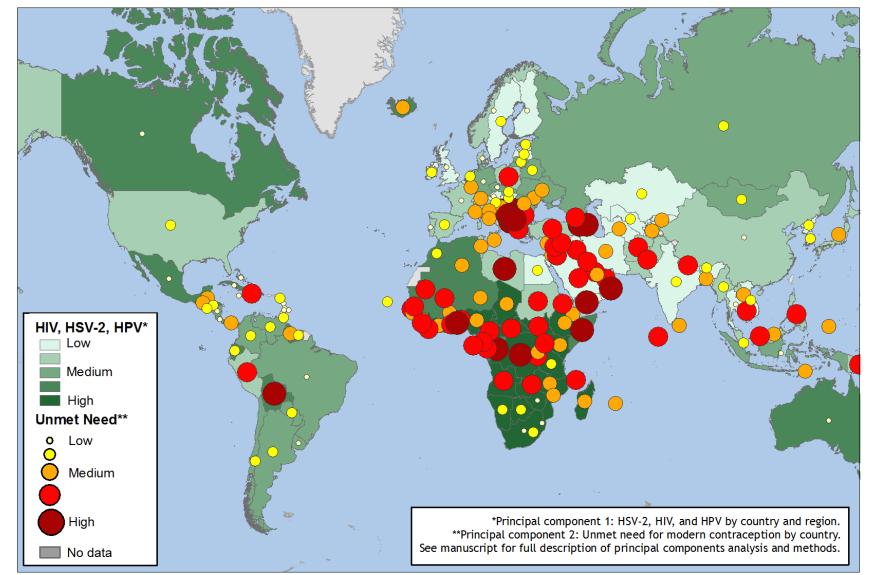
Multipurpose prevention technologies



Source: Adapted from Initiative for Multipurpose Prevention Technologies



Interlinked **HIV/STI** risk and unmet need for modern contraception among women



Names and boundary representation are not necessarily authoritative

GIS guidance and Principle Component Analysis provided by the GEOCENTER



Women want MPTs

83% of women prefer HIV/STI prevention products with contraception vs. HIV/STI prevention alone



Share your wisdom Learn about women's health Shape our future



Share.Learn.Shape.

An online women's health survey

Your answers can have a direct impact on new ways to prevent sexually transmitted diseases (STDs), including HIV.

Take the survey



Source: Plagianos et al. (2018) Abstract PO.93, HIV R4P Conference, Madrid, Spain, 21–25 October



Why MPTs?: Addressing stigma challenges

Factors associated with providers' willingness to prescribe PrEP (n=316)

	Adj. IRR ¹ (95% CI)
Negative attitudes toward AGYW sexuality	0.81 (0.66-0.99)*
Behavioral disinhibition scale	0.89 (0.79-0.99)*

¹Adjusted for provider demographics, prior PrEP knowledge, other facility factors (e.g., stockouts) *p<0.05 Some of us are very critical and judgmental. We just judge someone, 'Ooh you came again? Last time you had gonorrhea, did you do it again?'

—Service provider, age 32

Pilgrim N, Jani N, Mathur S, Kahabuka C, Saria V, Makyao N, Apicella L, Pulerwitz J. (2018) "Provider perspectives on PrEP for adolescent girls and young women in Tanzania: The role of provider biases and quality of care," *PLoS ONE* 13(4): e0196280. doi: <u>10.1371/journal.pone.0196280</u>



When the peers of my age see a person taking PrEP, they will think that the person has AIDS or they are very unfaithful hanging out with many partners...I will be considered as a bad person in the community. —Young woman, age 22, Tanzania

> ...Personally, I cannot go and tell my father that I am going for PrEP services. He will stop me and ask, 'who said that you are sick?'

> > -Young woman, age 20, Tanzania

Jani, N. et al. (2021) "Relationship dynamics and anticipated stigma: Key considerations for PrEP use among Tanzanian adolescent girls and young women and male partners," *PLoS ONE* 16(2): e0246717. doi: <u>10.1371/journal.pone.0246717</u>



Why MPTs? Addressing adherence/uptake challenges

• Major concerns emerging from early PrEP studies



Participants with detectable tenofovir (TDF) in plasma in the FEM-PrEP trial



- Many women more concerned about pregnancy than HIV
- Condoms currently the only dual protection



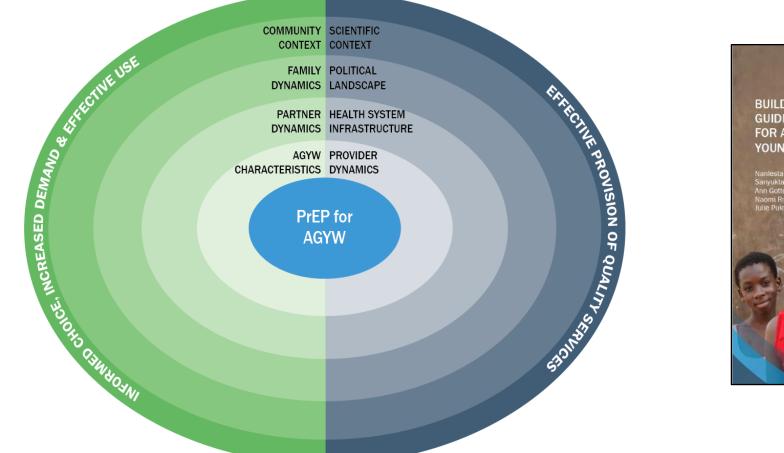
Why MPTs? Addressing integration challenges

- For the individual, integrated option will be easier and preferred for many
 - Choice/ options essential to address the changing needs along lifespan
- Will require integrated services at the provider level
 - Appropriate recommendations taking into account multiple indications.
- Facility level integration as well





Framework for PrEP introduction: a model?



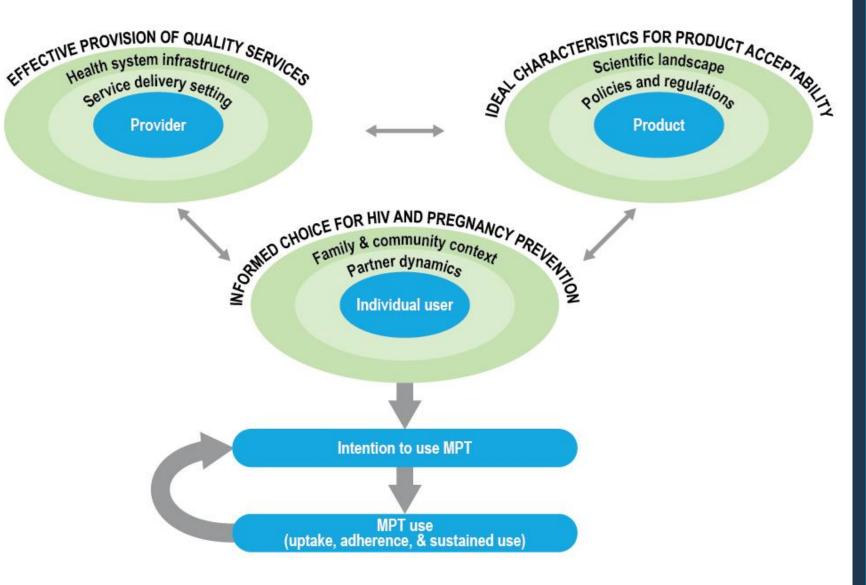
BUILDING EVIDENCE TO GUIDE PREP INTRODUCTION FOR ADOLESCENT GIRLS AND YOUNG WOMEN

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Mathur S, Pilgrim N, and Pulerwitz J. 2016. "PrEP introduction for adolescent girls & young women," The Lancet HIV 3(9): e406-e408.



MPT development/ introduction framework



Source: Adapted from Friedland, B.; Mathur, S.; Haddad, L. B. "The promise of the dual prevention pill: A framework for development and introduction," *Under review Front. Reprod. Health.*



Product development: A focus on choice, convenience and control

Provider administered Implants, IUDs User controlled Daily oral tablets Intravaginal rings Patch Films, gels, and inserts

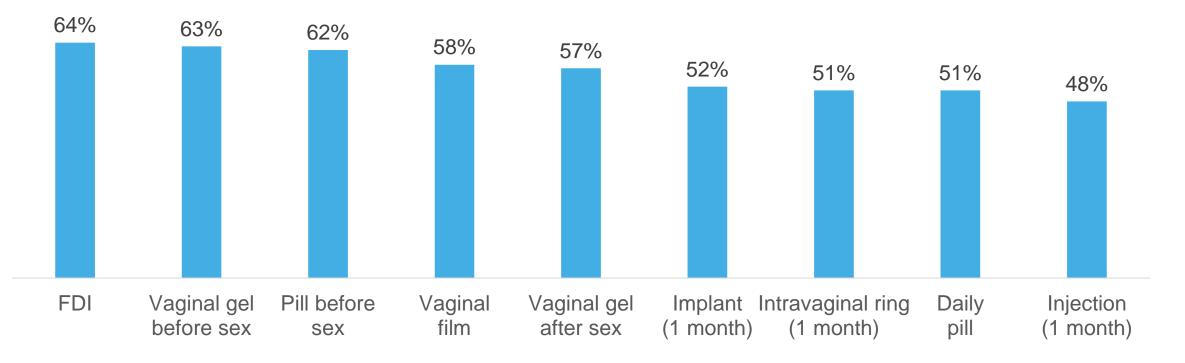
- Long-acting, short-acting, on demand
- Hormonal/non-hormonal contraceptive
- ARV vs non-ARV
- Systemic (absorbed in blood) vs topical



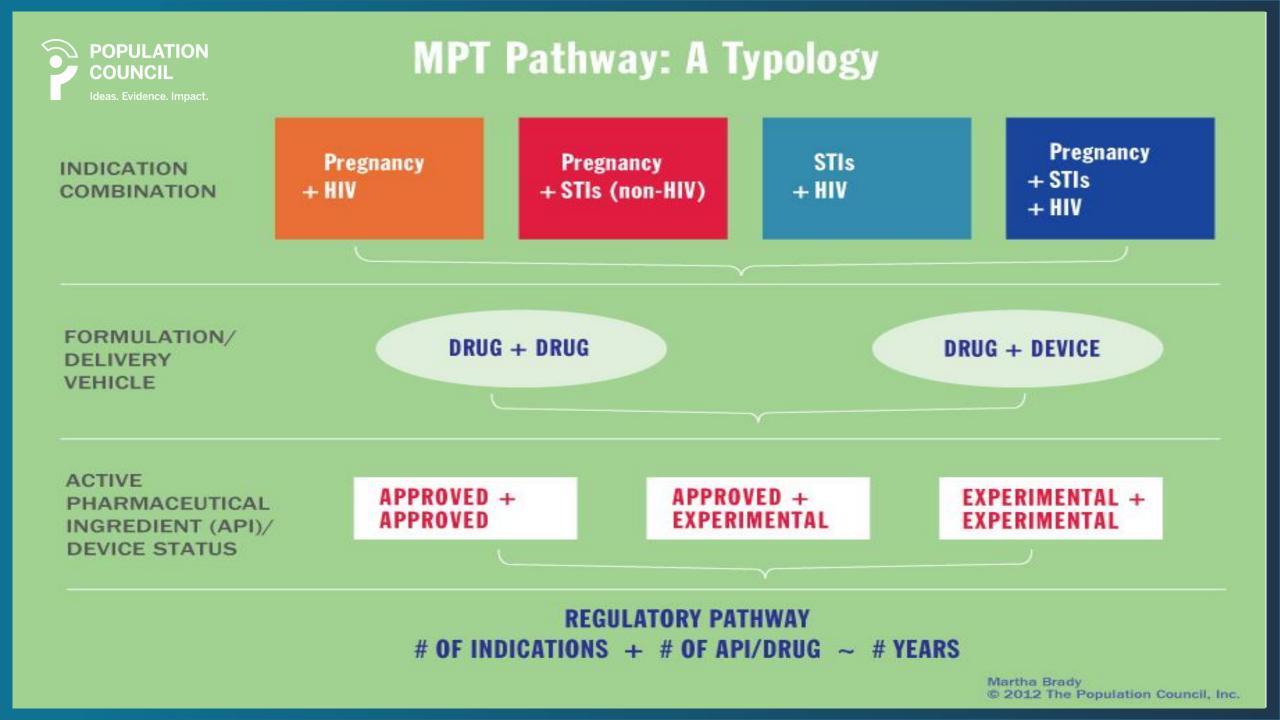


Positive reaction to a variety of products

Interest in using 9 different HIV/STI prevention products (n=558)



Source: Plagianos et al. (2018) Abstract PO.93, HIV R4P Conference, Madrid, Spain, 21–25 October







Learn more about The IMPT

MPT Product Development Database

Multipurpose Prevention Technologies (MPTs) are an innovative class of products that deliver varied combinations of HIV prevention, other STI prevention, and contraception and will improve the lives of women and families worldwide.

This database includes MPT products that are currently in active development. The database outlines detailed product information and can be searched to display products by desired criteria as selected from the drop-down boxes or by entering a keyword in the search box. Click on the product name to access detailed information on each product. Please note there are other MPT candidates not listed that may move forward pending funding. Click here to learn more about the inclusion criteria and information update methodology.



MPT Database Feedback

Know of an MPT product not included in this database or have updated information for listed products? Let us know here!

Hormonal/Non-Hormonal		Delivery Route		Delivery Method		Development Stage	
Show All Hormonal Types	~	Show All Delivery Routes	\sim	Show All Delivery Methods	~	Show All Stages	\sim
Indication		Product Developer		Product Sponsor/Funding		Active Ingredient	
Show All Indications	\sim	Show All Developers	\sim	Show All Sponsors	~	Show All Active Ingredients	\sim



Dual prevention pill (DPP)

Delivery system: oral pill

APIs: Combines 2 approved drugs (Oral contraceptive and HIV PrEP)

Opportunities:

- Streamlined regulatory pathway: no efficacy trials required, only bioequivalence
- WHO/CDC guidelines recommend PrEP and combined oral contraceptives prescribed together

Considerations:

- Packaging
- Clinical guidance, e.g., missed pills



Oral PrEP

Combined Oral Contraceptive Pills

Dual Prevention Pill (contraceptives + PrEP)



Emerging insights: Women's views on DPP

Women perceived the DPP favorably

- Convenience (1 pill for 2 needs, go to only 1 clinic)
- Easy to use (other methods involve pain)
- Condoms not ideal (discomfort, partners do not like, and sex often unplanned)

Concerned about:

- Side effects (physical appearance, depression, and kidney function)
- Stigma/negative treatment from health care providers
- Need to visit clinic to collect pills
- Relationship conflict/lack of support from partner
- Parental approval/support

Source: n = 3 FGDs with 18 women age 16-40 in South Africa



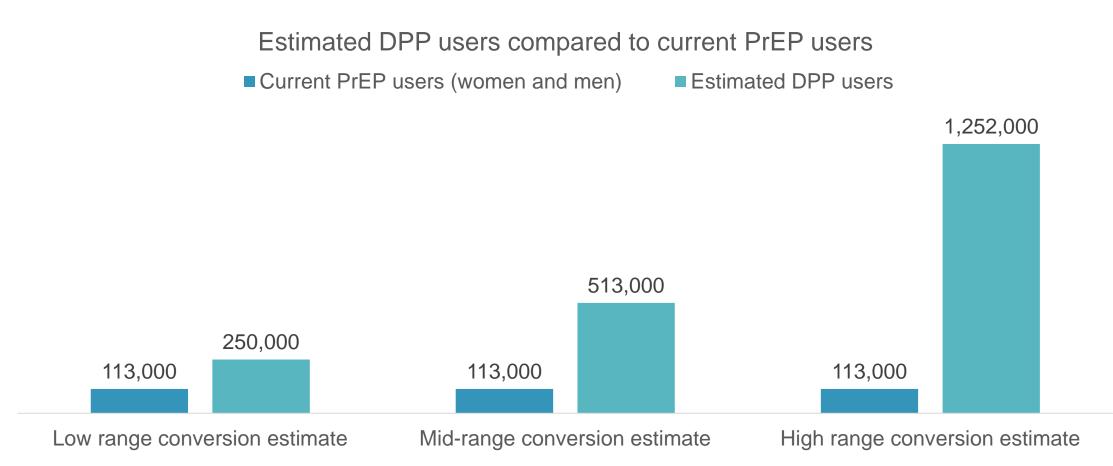
Emerging insights: Provider views of DPP

- · See this as an important option for women
- Concerned about reactions from partners/ intimate partner violence
- Recommendations for successful roll-out:
 - Women will need counseling as they initiate and to help adhere to the dosing regimen
 - Providers need training and support to manage workload
 - Offer through clinics, but consider getting it out of the health facility to reach more women





Potentially a 2- to 10-fold increase in PrEP usage



Begg, L. et al. (2020) "Estimating the market size for a dual prevention pill: adding contraception to pre-exposure prophylaxis (PrEP) to increase uptake," *BMJ Sex Reprod Health*. OAP. doi:<u>10.1136/bmjsrh-2020-200662</u>



EEQ IVR

Delivery system: intravaginal ring (IVR)

APIs: Combines etonogestrel [ETG] and ethinyl estradiol [EE]) with Q-Griffithsin (Q-GRFT)

Opportunities:

- NuvaRing (for ETG / EE) is approved & 20 years on market
- GRFT is a highly potent plant-based HIV inhibitor—non-ARV so less potential for resistance

Considerations:

- GRFT in early stages of clinical development
- Optimizing physical characteristics (e.g., to maximize comfort)
- Medical guidance for taking them out





Vaginal insert: GRFT/CG FDI

Delivery system: fast-dissolving film/insert (FDI) **APIs**: Combines Griffithsin (GRFT)—anti-HIV—plus carrageenan (CG) anti-HSV, HPV

Opportunities:

- FDIs are on-demand, portable, inexpensive
- Both plant-based vs ARV

Considerations:

- GRFT in early clinical development (1 Phase 1 trial)
- Since on demand, developing with optimal

window of effectiveness



Key questions for MPT introduction

- How do we ensure access to a range of products, including MPTs, for people with changing lifetime needs for both HIV / STI prevention and around pregnancy?
- What is the best way to integrate MPTs into different clinical settings? (Implementation science research)
- As products are introduced, how do key socioecological factors (e.g., stigma; partner communications/negotiations) affect their uptake and success?
- What will a cost analysis of MPT delivery vs separate products tell us?
- What will be the most compelling way to market MPTs (e.g., contraception + HIV or HIV + contraception?)





Thank you!

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