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

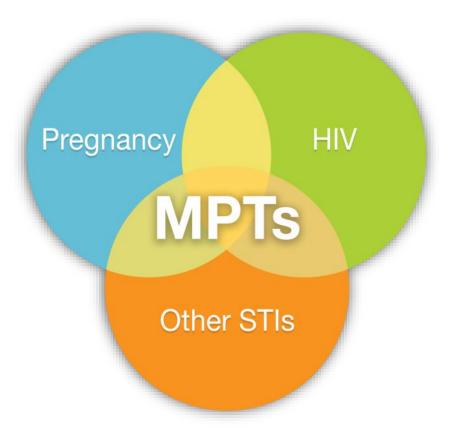
Julie Pulerwitz, ScD Director, HIV Program Population Council

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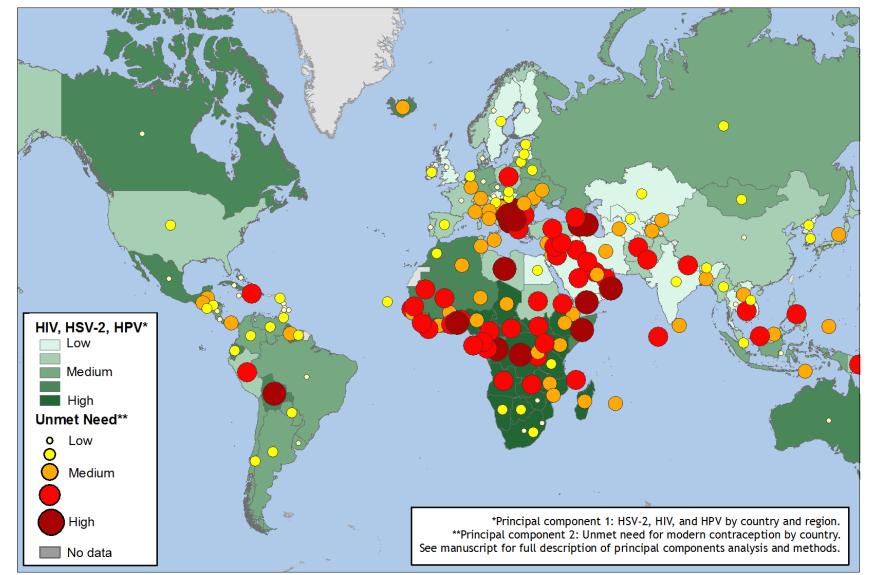
#### **Multipurpose prevention technologies**



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 <sup>1</sup><br>(95% CI) |
|--|-----------------------------------|
| Negative attitudes toward AGYW sexuality | 0.81<br>(0.66-0.99)*              |
| Behavioral disinhibition scale           | 0.89<br>(0.79-0.99)*              |

<sup>1</sup>Adjusted 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



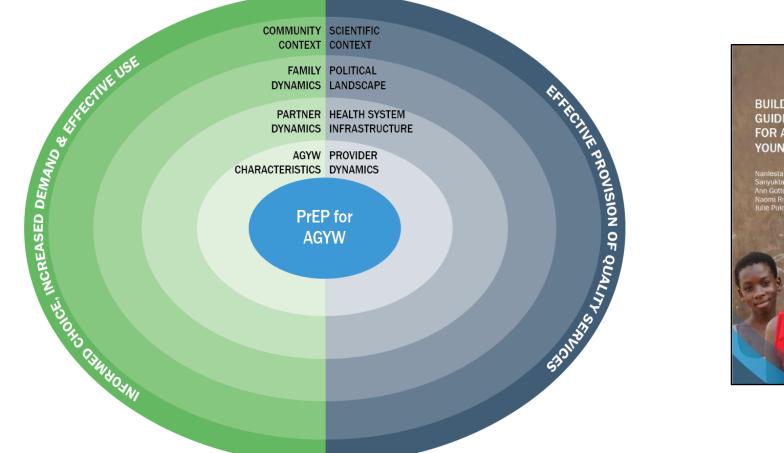
## Why MPTs? Addressing integration challenges

- 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?



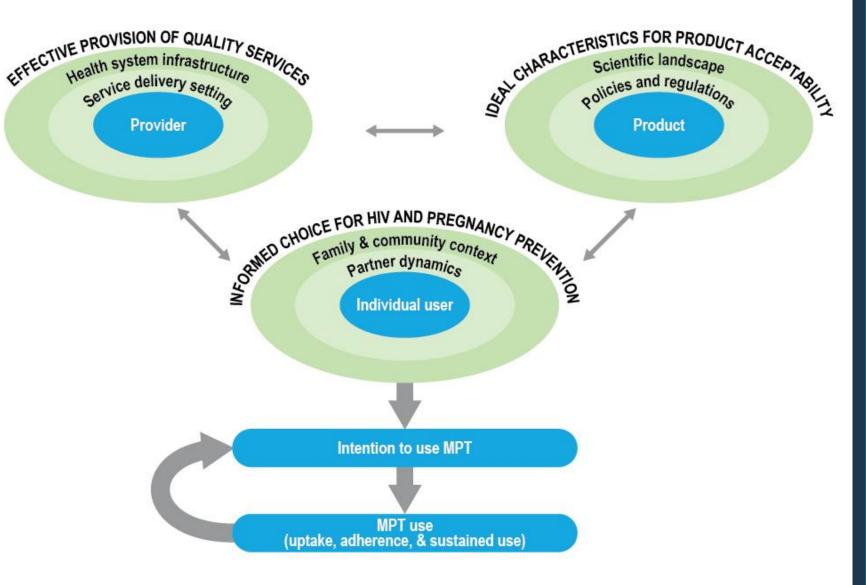
BUILDING EVIDENCE TO GUIDE PREP INTRODUCTION FOR ADOLESCENT GIRLS AND YOUNG WOMEN

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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

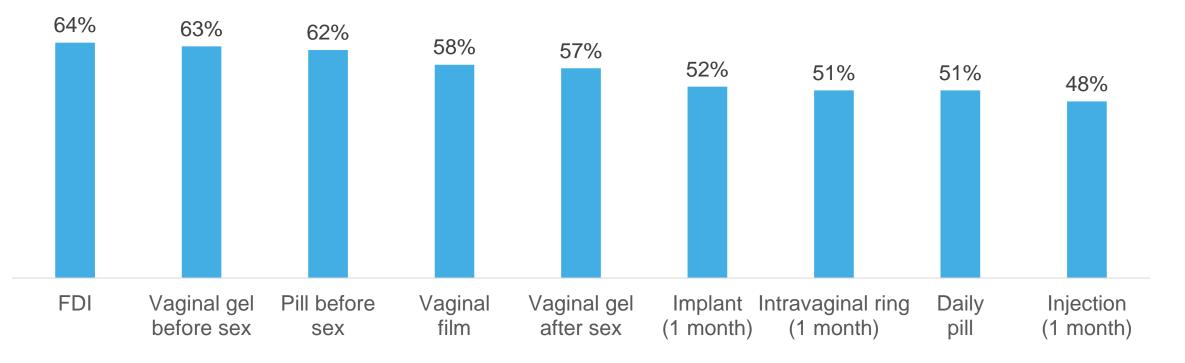
- Long-acting, short-acting, on demand
- Hormonal/non-hormonal contraceptive
- ARV vs non-ARV
- Systemic (absorbed in blood) vs topical



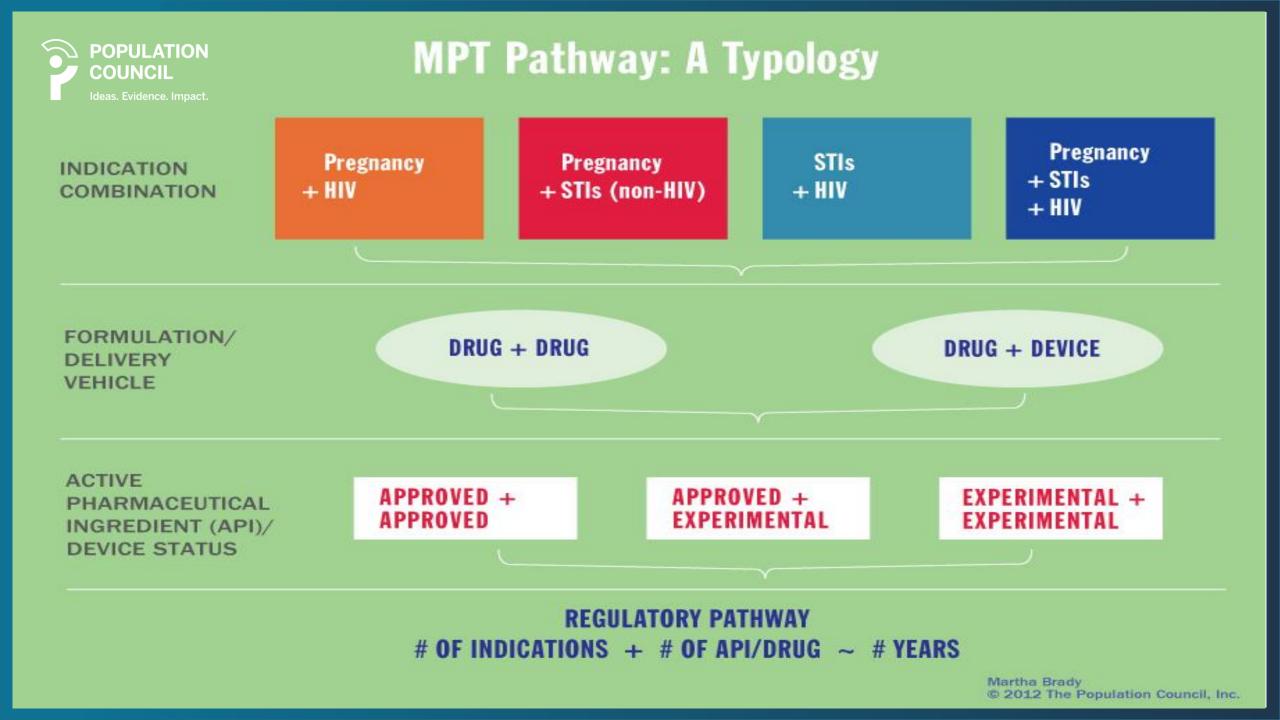


### Positive reaction to a variety of products

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



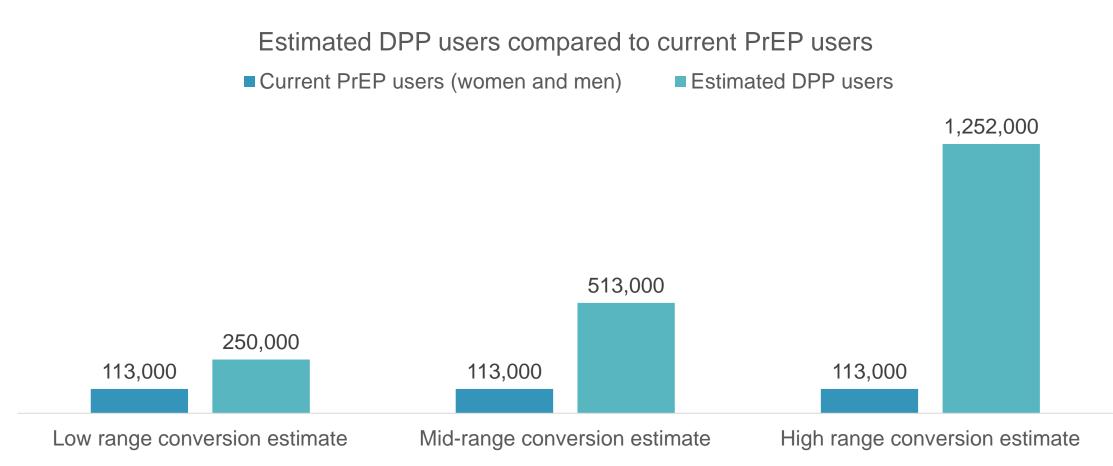
## **Emerging insights: Provider views of DPP**

- · 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!

@juliepulerwitz (Dr. Julie Pulerwitz)
@Pop\_Council (Population Council)



jpulerwitz@popcouncil.org pubinfo@popcouncil.org



popcouncil.org





#### Acknowledgments

- Population Council: Lisa Haddad, Barbara Friedland, Thomas Zydowsky, Jim Sailer, Sanyukta Mathur, Sherry Hutchinson
- CAMI / IMPT: Bethany Young Holt
- The HIV Prevention Trials Network is funded by the National Institute of Allergy and Infectious Diseases (UM1AI068619-15, UM1AI068613-15, UM1AI068617-15), with co-funding from the National Institute of Mental Health, and the National Institute on Drug Abuse, all components of the U.S. National Institutes of Health

# HPTN **ANNUAL**: MEETING 2021