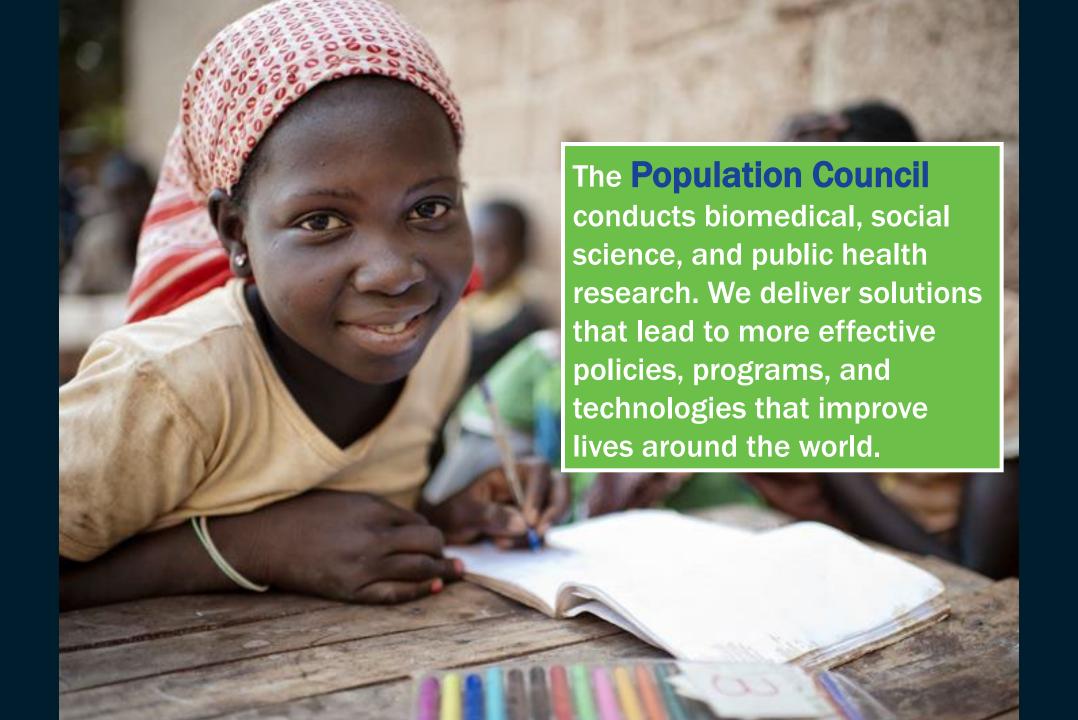
## The Promise of the Dual Prevention Pill

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HIV Prevention Technologies in Pipeline and Close to Introduction NURHT Caucus 10 May 2022



# Women want multi-purpose technologies (MPTs)

- Women worldwide face dual risks of unintended pregnancy and HIV
- Risk of unintended pregnancy often outweighs concerns about HIV
- 83% of women prefer HIV/STI prevention products with contraception vs. HIV/STI prevention alone



# The Dual Prevention Pill (DPP) is a daily oral pill for HIV and pregnancy prevention

- Viatris developing co-formulated tablet with 28-day regimen (TDF/FTC oral PrEP + LNG/EE COC)
- Different color pills for 21 vs. 7 days (dark pink = 4 APIs; peach = TDF/FTC only)
- Wallet pack with tear-off weekly sheets with instructions
- Pill color, packaging, brand names validated with women
- Branding/secondary packaging to have lifestyle feel
- Longer term, Population Council/Medicines360 to develop F/TAF-based DPP

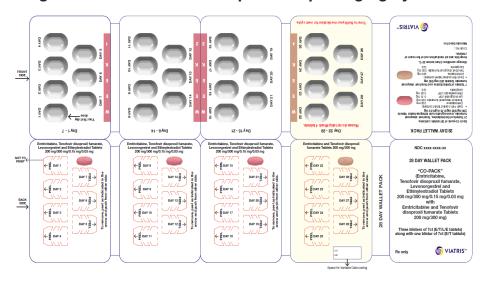
Viatris plans to file with US FDA in 2023; anticipated decision in 2024

Figure 1: Proposed DPP tablet colors



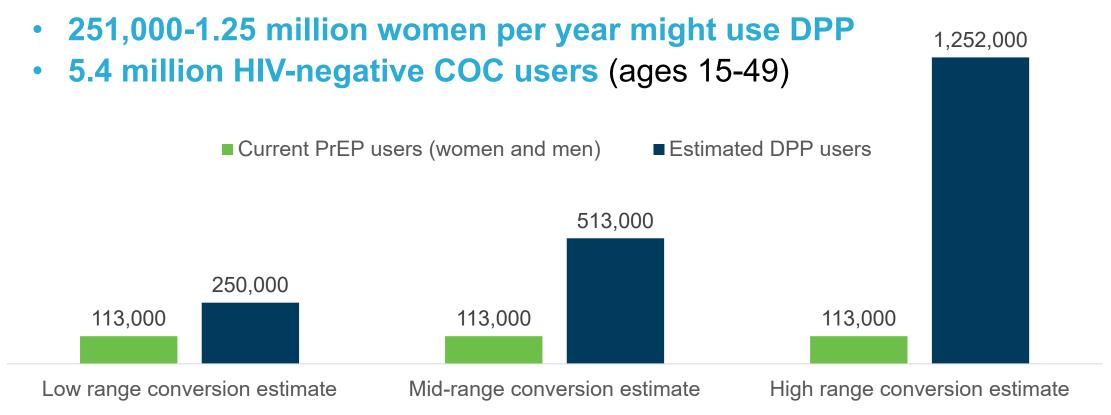


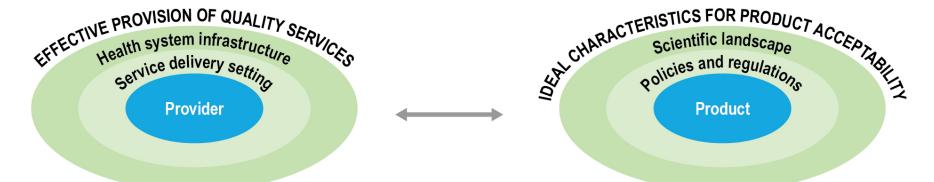
Figure 2: Illustrative mock-up of DPP packaging by Viatris



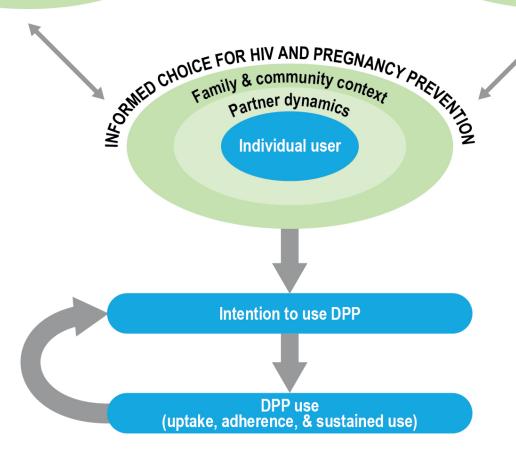
## Market Size Estimate for the DPP

#### In 15 countries in Sub-Saharan Africa:





# Considerations for the DPP and new biomedical technologies



Friedland, B., S. Mathur, L. B. Haddad. 2021. The promise of the dual prevention pill: A framework for development and introduction. *Front. Reprod. Health.* 3:682689 doi: 10.3389/frph.2021.682689

# DPP Acceptability Studies (2019-2023)

Qualitative formative research to explore acceptability of DPP to increase PrEP uptake.

Focus groups with end-users (COC and non-COC users)

In-depth interviews with different cadre of family planning and HIV health care providers

Among CURRENT COC USERS, compare preference, adherence, and acceptability of a single DPP capsule to two separate tablets (COC and PrEP).

Randomized, crossover clinical trials

- **Zimbabwe: 30 AGYW (16-24 yrs)**
- South Africa: 96 women (16-40 yrs)
  Choice period (South Africa)

In-depth interviews with women who withdraw early plus sub-set of completers

## Perceived benefits of the DPP

- Empower women to access HIV and pregnancy prevention they can control themselves
  - Prevent school dropout in young women due to unplanned pregnancies
  - Protect against stealthing (removal of condom during sex without consent)
  - Provide protection during spontaneous sexual activity (condom access limited)
  - Offer protection in the event of rape
- Reduce frequency of clinic visits for women currently using both PrEP and COCs
- Lessen the burden of taking two separate pills
- Positively impact contraception and PrEP uptake

# Potential challenges for DPP

#### **Product**

- Side effects (double the side effects?)
- Daily dosing
- Duration of use

#### **Service delivery**

- Provider attitudes
- Waiting period/testing requirements
- Provision outside the facility
- Counseling tools to encourage informed choice
- Counseling for effective use
- Cost/ability to afford DPP

#### Social

- Partner approval
- Family and community leaders unsupportive of PrEP and/or COC use
  - Myths and misconceptions around COCs
  - HIV-related stigma
- Sociocultural norms and taboos regarding adolescent sexual behavior

# **Summary**

- DPP potentially the fastest MPT to market
- May overcome uptake and adherence barriers of oral PrEP
- Potential to expand contraceptive choice
- Key to assess integration and implementation challenges early in the product development lifecycle

# **Next steps**

- Crossover clinical trials of over-encapsulated DPP poised to begin
- Protocol for larger study with co-formulated tablet in development

# Acknowledgements

#### **Study Participants**

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#### Wits RHI, Johannesburg, South Africa:

Thesla Palanee Phillips, Krishnaveni Reddy, Lebogang Maila, Onthatile Maboa, Lydia Mampuru, Siyanda Tenza, & Wits RHI team UZ-CTRC, Harare, Zimbabwe: Nyaradzo Mgodi, Petina Musara, Adlight Dandadzi, Prisca Mutero, Lucy Godo, Terrance Kufakunesu, Natasha Sedze, Caroline Murombedzi, & Zengeza CRS team

#### Funding support for the DPP studies from













This presentation is made possible by the generous support of the American people through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and U.S. Agency for International Development (USAID). The contents are the responsibility of the authors and do not necessarily reflect the views of PEPFAR, USAID, or the U.S. Government.

Research reported in this publication was also supported by the National Institute of Mental Health of the National Institutes of Health under Award Number R34MH119982. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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