The Population Council conducts biomedical, social science, and public health research. We deliver solutions that lead to more effective policies, programs, and technologies that improve lives around the world.
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**
In 15 countries in Sub-Saharan Africa:

- **251,000-1.25 million women per year might use DPP**
- **5.4 million HIV-negative COC users** (ages 15-49)

Market Size Estimate for the DPP

Considerations for the DPP and new biomedical technologies

DPP Acceptability Studies (2019-2023)

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

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

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

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

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

Source: n = 14 FGDs with age 16–40 from South Africa and Zimbabwe
Source: n = 29 health care providers from South Africa and Zimbabwe
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

Source: n = 14 FGDs with age 16–40 from South Africa and Zimbabwe
Source: n = 29 health care providers from South Africa and Zimbabwe
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
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