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The Promise of the Dual Prevention Pill

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Can Fantasies Become Realties? The Quest for Multi-purpose Prevention Products AIDS Foundation 13 October 2021

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



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An online women's health survey

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

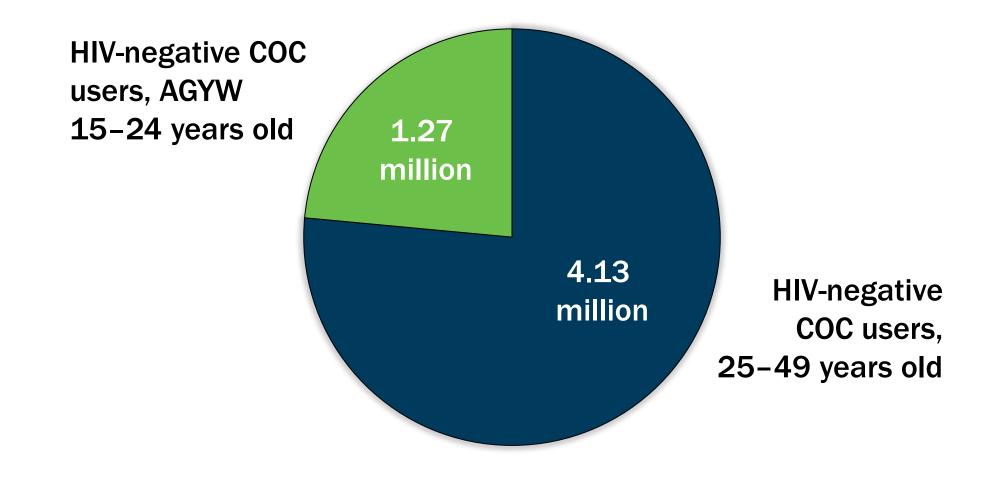
Take the survey

Dual prevention pill (DPP)



- Delivery system: oral pill
- APIs: Combines 2 approved drugs (Oral contraceptive and HIV PrEP)
- Create a single product that combines a 28-day oral contraceptive regimen with oral PrEP

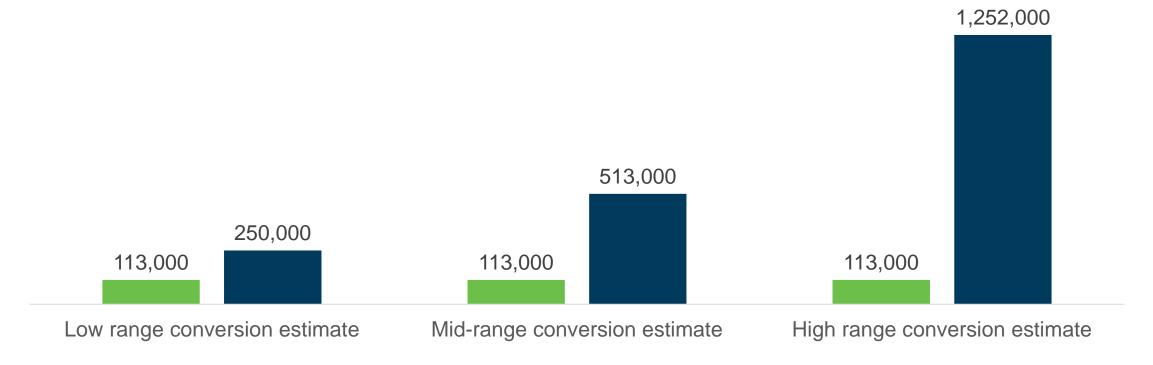
5.4 million HIV-negative COC users in 15 sub-Saharan African countries



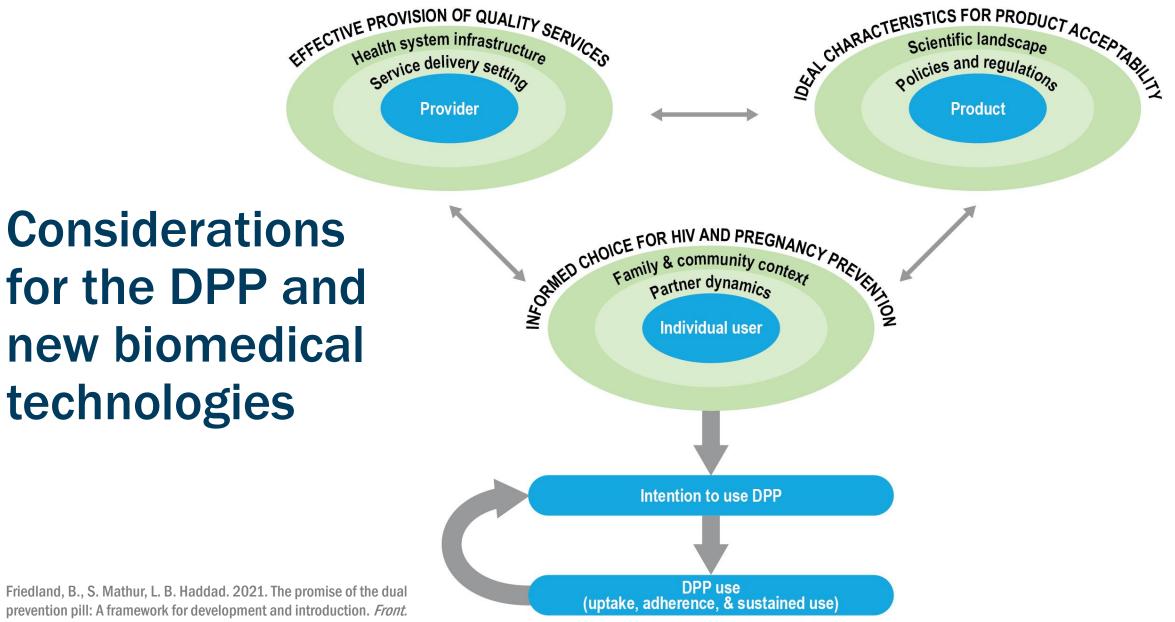
Potentially a 2- to 10-fold increase in PrEP usage

Estimated DPP users compared to current PrEP users

Current PrEP users (women and men)Estimated DPP users

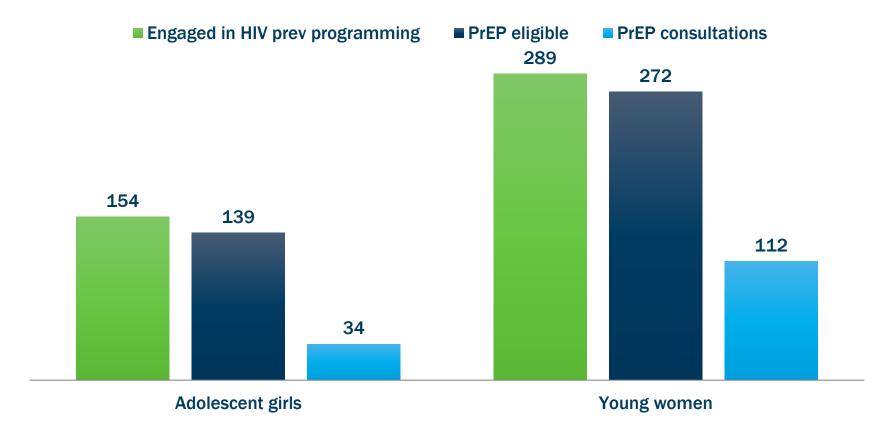


Begg, L. et al. (2021) "Estimating the market size for a dual prevention pill: adding contraception to pre-exposure prophylaxis (PrEP) to increase uptake," *BMJ Sex Reprod Health.* 47: 166–172. doi:10.1136/bmjsrh-2020-200662



prevention pill: A framework for development and introduction. Front. Reprod. Health. 3:682689 doi: 10.3389/frph.2021.682689

While nearly all AGYW were eligible for PrEP, more need access to it



Study site: Kenya

Heck, C, S. Mathur, H. Alwang'a, D. Oluoch-Madiang', R. Obanda, M. Owiti, J. Okal. Oral PrEP consultations among adolescent girls and young women in Kisumu County, Kenya: Insights from the DREAMS Program. *Under review at AIDS and Behavior*.

Health care provider perspectives & access to PrEP

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, TZ

Study site: Tanzania

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>

Partnership dynamics & influence on PrEP use

Our relationship will be affected if he is not informed...if he understands me properly, he can decide to accompany me and begin to take PrEP as well. But if I don't tell him and he finds them on his own, that is where the problem steps in.

–Young woman, Tanzania

...he [partner] came across those drugs, and he got out of control...when he found the drugs he became disturbed, furious, threw them, asked me whether a I am a commercial sex worker, whether am infected, if I had infected him. I told him the drugs are not for HIV, fearing to explain further, ...He beat me to tell him the truth.... He beat me and we seriously fought.... —Young woman, PrEP user (8mo), Uganda

Jani, N., S. Mathur, C. Kahabuka, N. Makyao, N. Pilgrim. 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: 10.1371/journal.pone.0246717

Mathur, S, G Mirembe, J. Nanyondo, W. Nansalire, D. Kibirige, J. Matheka, B. Mwesigwa, A. Tindikahwa, F. Kiweewa, M. Millard, E. Akom, H. Kibuuka. 2020. "Side effects, life transitions, and disclosure: reasons for oral pre-exposure prophylaxis (PrEP) discontinuation among young women engaged in sex work in Uganda (PEC0602)." Poster presented at AIDS 2020, San Francisco, CA, USA, 6–10 July.

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

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

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Study Participants

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Population Council, DPP Acceptability study

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