Developing and Introducing a Dual Prevention Pill

Oral PrEP & oral contraceptive for HIV and pregnancy prevention

September 2021

Background

A coalition of partners is developing a novel Dual Prevention Pill (DPP) for prevention of pregnancy and HIV acquisition in high-need countries. In East and Southern Africa — where the DPP is initially planned for introduction — 65 percent of new HIV infections are amongst women aged 15 and over, and 16 percent of women of reproductive age have an unmet need for contraception.[1] As the "youth bulge" results in millions of young people entering their reproductive years,[2] it will impact efforts to end the HIV epidemic and reduce unintended pregnancies. It is critical to ensure all women have access to both contraception and HIV prevention.

The results of the Evidence for Contraceptive Options in HIV Outcomes (ECHO) Trial, released in June 2019, found that HIV incidence rates were alarming among women using widely available forms of contraception who were receiving a comprehensive HIV prevention package.[3] The findings underscore the urgent need to optimize access to HIV prevention and contraception for African women.

Contraceptive multipurpose prevention technologies (MPTs) have the potential to overcome adherence and uptake challenges seen with oral pre-exposure prophylaxis (PrEP) and stigma associated with HIV service delivery. A DPP, an MPT comprising oral PrEP and an oral contraceptive, will offer significant advantages. It will be highly effective at preventing both HIV and pregnancy when used daily, feasible to deliver in various settings, with the potential to deliver public health impact by expanding choice and method mix. Adding an MPT to the available method mix could empower users with choices that better fit their needs and lives.

In the near-term, a DPP could increase the uptake of PrEP —decreasing new infections among women in high-burden settings — and reduce the number of unintended pregnancies. A DPP could also lay the groundwork for the development and rollout of other MPTs currently in the research pipeline, such as vaginal rings, injectables, implants and films.

[1] UNFPA State of the World Population Report 2021 and UNAIDS 2020 data.

[2] UNAIDS, The Youth Bulge and HIV. https://www.unaids.org/sites/default/files/media_asset/the-youth-bulge-and-hiv_en.pdf. 2018.

[3] ECHO Trial Consortium, HIV incidence among women using intramuscular depot medroxyprogesterone

[4] Begg L, Brodsky R, Friedland B, et al Estimating the market size for a dual prevention pill: adding contraception to pre-exposure prophylaxis (PrEP) to increase uptake BMJ Sexual & Reproductive Health 2021;47:166-172.

[5] UNAIDS 2020 data.

[6] UNFPA State of the World Population Report 2021. 7 AVAC, Global PrEP Tracker, June 2021.

[7] AVAC, Global PrEP Tracker, June 2021.

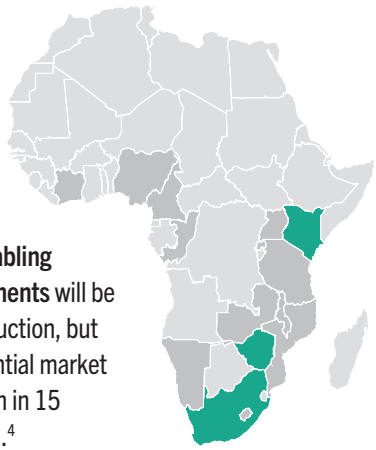
Project Goal

Rapidly and successfully introduce a daily oral pill for HIV and pregnancy prevention.

A coalition of organizations, including AVAC, the Clinton Health Access Initiative (CHAI), Mann Global Health, Viatris and the Population Council are implementing the DPP project. These efforts are supported by the Children's Investment Fund Foundation (CIFF), the Bill & Melinda Gates Foundation (BMGF), the U.S. Agency for International Development (USAID) and WCG Cares.

Geographic Scope

Settings that demonstrate **need** (high HIV incidence and high unmet need for modern contraception), **potential demand** (current oral PrEP and contraceptive use) and **enabling policy and regulatory environments** will be prioritized for early DPP introduction, but early estimates indicate a potential market of 251,000-1.25 million women in 15 countries in sub-Saharan Africa.[4]



Prioritized Countries			
Indicator	Kenya	South Africa	Zimbabwe
HIV Incidence (per 1,000 population)[5]	0.72	4.60	1.74
New HIV Infections, (# women 15+)[5]	19,000	140,000	13,000
Unmet Need for Modern Contraception (%)[6]	12	11	8
Unintended Pregnancies (#)[6]	956,000	1,060,000	298,000
Oral Contraceptive Use (% of method mix)[6]	14.1	10.5	56.5
Total PrEP Initiations (#)[7]	93,621	164,537	39,745

Key Milestones for Dual Prevention Pill Development

Product Developement

A single **co-formulated tablet containing** Truvada and combined oral contraceptive (COC) active pharmaceutical ingredients (APIs) is under development.

Conduct bioequivalence study to compare bioavailability of co-formulated tablet to Truvada and COC separately.

File dossier with stringent regulatory authority (SRA) for regulatory approval.

End-User Research

To shape product development and demand creation strategies, **conduct human-centered design research** in South Africa and Zimbabwe on perceptions, barriers, and motivators of end users, providers and influencers as they relate to the DPP.

To inform clinical cross-over acceptability studies, **conduct formative research** to understand perspectives on the DPP among women, health care providers, community members and key opinion leaders.

Conduct clinical cross-over acceptability studies with over-encapsulated tablets of two pills in South Africa and Zimbabwe to compare women's experiences using a DPP to two separate Truvada and COC pills.

Market Preparation

Establish Advisory Board with leading research entities, normative agencies, donors, implementers and advocates working on HIV and SRHR to plan for and coordinate introduction of the DPP in parallel with product development activities.

Engage with policymakers, regulators, civil society and key opinion leaders in HIV and SRH **to generate buy- in, shape introduction plans, understand potential market size and inform regulatory strategies** for DPP introduction.

Develop a comprehensive Go-To-Market Strategy with global and national stakeholders.

2021	2022	2023	2024
Go-To-Market Strategy developed	Clinical crossover acceptability studies begin	SRA dossier filing expected	US FDA regulatory decision expected
Human-centered design and formative research conducted	Bioequivalence results expected	Clinical crossover acceptability study results available	National Medicines Regulatory Authority regulatory review expected
	Implementation research designed	Implementation research conducted	Targeted introduction for prioritized countries
	Initial cost-effectiveness modeling completed	Country introduction plans developed and costed	
	Marketing strategy developed		

* Timelines are subject to modification given funding, government buy-in, development feasibility, and regulatory requirements.

For inquiries, updates and resources on the development of the DPP, please visit prepwatch.org/dpp.