



# Consultation with FP/SRH Stakeholders on the Dual Prevention Pill

April 12, 2022

AVAC and FP2030 convened a consultation with family planning (FP) and sexual and reproductive health (SRH) stakeholders to understand their unique perspectives on the [Dual Prevention Pill \(DPP\)](#), a daily oral pill that prevents HIV and pregnancy. The consultation helped to elevate questions and issues to consider as DPP introduction plans are refined and that can also inform the development and delivery of future multi-purpose prevention technologies (MPTs).

Thank you to Jessica Rodrigues (AVAC), Barbara Friedland (Population Council), Danny Edwards and Dani Resar (CHAI) for presenting on the DPP, Beth Fredrick (Advance Family Planning) for facilitating an engaging discussion and FP2030 and AVAC for co-hosting. You can access the recording and slides [here](#).

## Key takeaways

- The DPP is a co-formulated bilayer tablet containing combined oral contraception (levonorgestrel and ethinyl estradiol, or COC) and oral pre-exposure prophylaxis (TDF/FTC, or oral PrEP) for simultaneous HIV and pregnancy prevention being developed by Viatrix. If approved, the DPP would be the next MPT available since male and female condoms.
- Because the DPP combines two approved products, a clinical trial is not required for regulatory approval. Instead, a bioequivalence (BE) study and strong evidence package are sufficient to support approval by the United States Food & Drug Administration (US FDA). Initial BE study results are expected in early 2022, and a US FDA regulatory decision is anticipated in 2024.
- End user preferences were incorporated into DPP product design, including pill color, packaging and brand names, and will continue to inform delivery approaches and messaging.
- Demand for the DPP is expected to be among a sub-set of women who desire both contraception and HIV prevention. Kenya, South

## Additional resources

For the latest resources on the DPP, visit the DPP [homepage](#). For more information, please see:

- [FAQs on the DPP](#) (April 2022): a compilation of frequently asked questions, co-developed with HIV prevention and SRH advocates in Kenya, Malawi, South Africa and Zimbabwe
- [Market Preparation and Introduction Strategy for the DPP](#) (August 2021): outlines activities required to build an evidence base and an approach to DPP introduction to focus efforts
- [Bringing the Dual Prevention Pill to Market: Opportunities for HIV and Pregnancy Prevention and Implications for Future MPTs](#) (July 2021): IAS satellite session on the DPP
- [Recommendations and Solutions from HCD Research on the DPP](#) and [Summary of Insights](#) (November 2020): findings from HCD research with women, providers and matriarchs in South Africa and Zimbabwe
- [Service Delivery Strategy](#) (October 2020) and [Private Sector Analysis](#) (November 2020): initial analyses of service delivery landscapes in Kenya, South Africa and Zimbabwe for the DPP; updates to these are in progress



Africa and Zimbabwe have been prioritized for early introduction due to overlapping high HIV incidence and unmet need for FP, enabling environments and moderate-to-high OC use.

- The DPP will be offered in the context of informed choice amid a range of contraceptive and HIV prevention products, recognizing that women will have different prevention needs and preferences over their life course. Counseling and delivery will aim to align with OC practice.
- Stigma and bias will need to be addressed with healthcare providers and male partners to support women to use the DPP. End user research found women do not want to have to be discreet, and fostering social acceptance of the DPP could help mitigate the need for discretion.
- Expanding delivery of oral PrEP now through multi-month dispensing (MMD), HIV self-testing, the private sector and other differentiated delivery models, as well as bridging siloes in HIV and FP programs, will promote access to the DPP. Pharmacies and social marketing organizations are particularly high-potential channels for the DPP in the private sector.
- Global procurement of the DPP will require a strong evidence package and advocacy for MPTs. PEPFAR, the largest global HIV procurer, cannot currently procure contraceptive products.
- The DPP presents an opportunity to integrate siloed HIV and FP programs and systems to pave the way for future MPTs.

## Top questions

For a comprehensive list of frequently asked questions, see [FAQs on the DPP](#).

### Who are likely to be early DPP users?

Early DPP introduction will likely focus on women ages 20-40, who tend to have higher rates of OC and oral PrEP use than younger women and girls. Early feedback from country stakeholders indicated that initially prioritizing AGYW could stigmatize the DPP, though governments could decide to include AGYW as a priority population. The product label and instructions for use will not limit use to women ages 20-40. Acceptability studies will include women ages 16-40 to understand preferences across age groups, and end-user research will develop approaches and messages for different user segments.

### Will women on longer-acting contraception, including injectable contraception, be offered the DPP?

The DPP will be offered to women as one option among other FP and HIV prevention products. Users of longer-acting contraception satisfied with their current method would not be encouraged to switch to the DPP and would be offered another HIV prevention product such as oral PrEP, the dapivirine vaginal ring (DVR) or injectable cabotegravir (CAB) for PrEP, depending on availability. If a woman is no longer satisfied with her current method or is interested in switching to the DPP (e.g., for the addition of HIV prevention or desire for a shorter-acting product), she will have the option to switch to the DPP.

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## What are the side effects of the DPP?

The World Health Organization has [affirmed](#) that there are no drug-drug interactions between oral PrEP and COC and that oral PrEP and COC can be “safely taken together.” A BE study is currently underway to better understand the side effects of the DPP and whether they are different from those experienced when taking oral PrEP and COC together. Oral PrEP and COC share similar common side effects, such as headache and nausea, while rarer side effects for each differ. In initial DPP [end-user research](#), women were concerned about potentially more intense side effects with a combined COC/oral PrEP pill. Planned research, including acceptability studies enrolling OC users, will also evaluate side effects and other clinical outcomes of DPP use.

## Will the DPP be available in other countries? There could be demand for the DPP in other markets, such as the US and in West Africa.

Viatrix plans to submit the DPP for regulatory review by the US FDA and there is a potential market for the DPP in the US, where OCP use is high and access to HIV prevention among cisgender women and women of color in particular has been limited. Other [countries](#) with higher OC use and HIV prevalence, such as Nigeria and Cote d’Ivoire, may also be countries where the DPP could have impact.

## How will delivery of the DPP balance HIV testing and prescribing requirements with the more decentralized approach to OC delivery?

In many countries, OC is available over-the-counter and is delivered by diverse cadres in a variety of settings, including through pharmacy and community-based channels. By contrast, current oral PrEP policies typically require a prescription, initiation by a trained provider and HIV testing every three months. Since the DPP contains oral PrEP, DPP users will likely need to follow oral PrEP testing and prescribing requirements.

However, recent expansion of differentiated and self-care approaches to oral PrEP delivery, including multi-month dispensing and HIV self-testing, as well as delivery of oral PrEP in FP clinics and private sector channels, show an encouraging move towards aligning oral PrEP and OC delivery. Preparing health systems for the DPP could help open up additional channels for oral PrEP, in line with where women prefer to access services, and accelerate PrEP/FP integration. The DPP Consortium will develop recommendations for provider counseling messages and a private sector delivery and financing strategy to identify how to align the DPP with OC delivery practice to the extent possible.

## What is the manufacturing capacity for the DPP and will there be enough supply to meet demand?

Viatrix will be the initial manufacturer of the DPP with sufficient manufacturing capacity to supply 250,000+ women per year with the DPP. Viatrix may be able to increase capacity further with additional packaging equipment.

## How will you engage country-level leadership to lead introduction planning?

In 2019, DPP Consortium partners conducted a series of consultations in Kenya, South Africa and Zimbabwe with Ministries of Health (MOH), implementing partners, regulatory authorities and other key stakeholders to understand perceived benefits and challenges of rolling out the DPP. Stakeholder inputs informed the development of the [Market Preparation and Introduction Strategy](#) for the DPP. Follow-on consultations with MOH in Kenya, South Africa and Zimbabwe are planned, with future plans to co-design country introduction roadmaps and implementation research.

## What challenges and opportunities do you foresee with the DPP as it paves the way for future MPTs?

The DPP could foster integration of FP and oral PrEP, which have shown higher uptake when delivered together, to deliver a dual-indication product. Linking HIV and FP programs for the DPP could strengthen regulatory, delivery, financing, M&E and supply chain systems for MPTs. Breaking down these silos will also be a major challenge, particularly to align oral PrEP with OC delivery, which is much more simplified and differentiated. Ongoing efforts indicate a trend toward expanding and diversifying PrEP delivery.