Consultation on the Dual Prevention Pill (DPP) with FP/SRH Stakeholders // Consultation sur la pilule de double prévention (DPP) avec les parties prenantes de la PF/SRH

April 12th, 2022
Welcome

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• We are recording this session and the presentations and recording will be shared with you all. // Nous enregistrons cette session et les présentations et l'enregistrement seront partagés avec vous tous. y la grabación se compartirán con todos ustedes.
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<tr>
<th>Time</th>
<th>Session Description</th>
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<tr>
<td>8:30-8:35 AM</td>
<td>Welcome and Introductions</td>
<td>Mande Limbu, FP2030</td>
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<td>8:35-8:45 AM</td>
<td>Overview of the DPP in the context of MPTs</td>
<td>Jessica Rodrigues, AVAC (presenter)</td>
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<td>8:45-8:55 AM</td>
<td>The DPP in the HIV Prevention and SRH landscape</td>
<td>Barbara Friedland, Population Council (presenter)</td>
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<td>8:55-9:30 AM</td>
<td>Discussion</td>
<td>Beth Fredrick, Johns Hopkins Bloomberg School of Public Health (facilitator)</td>
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<td>9:30-9:55 AM</td>
<td>System considerations for DPP introduction</td>
<td>Danny Edwards and Dani Resar, CHAI (presenters)</td>
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<td>9:55-10:00 AM</td>
<td>Next Steps</td>
<td>Hima Patel, FP2030</td>
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Poll: What have you heard about the DPP?
// Qu'avez-vous entendu sur le DPP ?

Answer in the zoom poll on your screen! // Répondez dans le sondage sur votre écran !
Overview of the DPP in the context of MPTs

Jessica Rodrigues, AVAC
The case for MPTs

HIV prevalence and total addressable market for contraception (TAMC) data show substantial overlap of unmet need for FP and HIV prevention, indicating high potential for MPTs.

- **Kenya** has relatively lower need, though regional pockets show promise for MPTs and DPP, given higher OC use, % non-FP users.
- **South Africa** has moderate-to-high need for FP and HIV prevention, with certain provinces exhibiting higher % OC use.
- **Zimbabwe** has high OC use and HIV prevalence rates across the country, with higher overlap in the Matabeleland South province.

The case for MPTs

Discreet choice experiments suggest **higher demand for MPTs** among women interested in HIV prevention compared to single-indication products

**Tablets, Ring, Injections as Options (TRIO) study** *(Kenya, South Africa)*

- Most women **prefer an oral pill that has dual protection over a single-indication product**, including an injection, and in general “overwhelmingly” prefer MPTs for HIV and pregnancy prevention to separate products

**CUPID study** *(Uganda, Zimbabwe)*

- 91% heterosexual couples preferred MPTs over separate HIV prevention and FP products
- Male partners strongly contribute to women’s product preference decisions

**Divergent Preferences for HIV Prevention** *(South Africa)*

- MPTs that prevent HIV and pregnancy would **quadruple demand among adolescent girls** compared to products offering just HIV prevention
- HIV protection is most important attribute of MPTs across populations (AGYW, adult women, FSW)

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, combined oral contraception (COC))

- **Different color pills** for 21 vs. 7 days (dark pink and light peach, respectively)

- **Packaging will be wallet pack** with tear-off weekly sheets with instructions on them

- Pill color, packaging, brand names **validated with women**

- **Branding/secondary packaging** will have women’s 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**
Where does the DPP fit among other products?

### Introduced
- OCP
- Oral PrEP

### Not Yet Introduced
- Dapivirine vaginal ring (DVR)
- Cabotegravir long-acting injectable (CAB-LA)

### Key:
- Contraception
- HIV prevention

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The DPP can generate lessons for future MPTs

- **Evidence generation**: Future MPTs are likely to build on the health system adaptations, regulatory, delivery and financing lessons generated from DPP introduction and scale-up.

- **Attract new funders**: Funding HIV and SRH innovations would benefit other MPTs in the pipeline. Investment in the DPP could signal to governments that MPTs are a priority.

- **Potential catalyst for HIV/SRH integration**: Foster integration of HIV prevention and sexual and reproductive health (SRH) services to deliver a dual-indication product.

- **Increased user acceptance/familiarity with MPTs**: A user-controlled, co-formulated pill supports convenience and may motivate increased knowledge, use and adherence. Women and couples prefer a dual-purpose product, even as an oral formulation.
**Potential DPP users**

**Recommended focus population for introduction is women ages 20-40, based on initial cross-country analyses**

- **Early adopters** may be urban women with higher incomes and OC and/or oral PrEP experience or no OC/oral PrEP experience.
- Other populations to consider with tailored outreach: adolescent girls, female sex workers, post-partum women.
- Governments will ultimately determine prioritized populations.
- **Women on LARCs who are satisfied with their current method** will not be a focus population for the DPP.

*Figure 3: DPP Initial Focus User Profiles*
Market preparation and early introduction

Because DPP combines two approved products, clinical trial not required. Bioequivalence (BE) study is being conducted along with compiling a package of evidence to support US FDA approval.

<table>
<thead>
<tr>
<th>PRE-REGULATORY/REGULATORY</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
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<tbody>
<tr>
<td>Implementation research designed in Kenya, South Africa, Zimbabwe</td>
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<tr>
<td>Country introduction roadmaps developed</td>
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<tr>
<th>EARLY INTRODUCTION</th>
<th>2024</th>
<th>2025</th>
<th>2026</th>
<th>2027</th>
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<tr>
<td>Implementation research conducted</td>
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<tr>
<td>DPP registered with NMRAs</td>
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<tr>
<td>Country introduction plans refined and costed</td>
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<tr>
<td>DPP scaled in Kenya, South Africa, Zimbabwe</td>
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<tr>
<td>Funded introduction plans in 5 countries</td>
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<tr>
<td>DPP approved in additional LMICs</td>
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<tr>
<td>Demand forecast refined</td>
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DPP CONSULTATION WITH FP/SRH STAKEHOLDERS
Key milestones for DPP development

**Product Development**
- Pilot bioequivalence (BE) study in progress; to inform pivotal BE study
- Pill color, packaging, brand names validated with women
- Branding and secondary packaging validation; pivotal BE study

**End-User Research**
- Formative research in South Africa, Zimbabwe conducted; to inform acceptability studies
- HCD research in South Africa, Zimbabwe conducted
- Acceptability studies with over-encapsulated and co-formulated DPP; and additional HCD research with women, partners, providers

**Market Preparation**
- Market Preparation and Introduction Strategy developed
- Advisory Board and Civil Society Advisory Group formed
- Comprehensive demand generation strategy; country intro roadmaps
What we’ve heard

Common questions from FP/SRH stakeholders about the DPP

• Will there be sufficient demand for the DPP?

• Could the DPP jeopardize progress on long-acting reversible contraceptives (LARCs)?

• Will counseling on the DPP confuse providers and negatively impact FP programs?
There is a market for an oral pill MPT

- **OC use has been stable over time** in East and Southern Africa (ESA), even as LARC use increased

- **Oral PrEP uptake has grown rapidly** in sub-Saharan Africa (SSA), especially from 2020-2021

- **Some women prefer flexibility of shorter-acting methods** and may be compelled by a novel, user-controlled product with dual health benefits

Adding it up: market size estimate for the DPP

- In 15 countries in Sub-Saharan Africa:
  - Initial estimate of 251,000-1.25 million women per year might use DPP
  - 5.4 million HIV-negative COC users (ages 15-49)

Method switching is common over the life course

- In the context of informed choice, women will be offered the DPP alongside other available contraceptive methods.

- Contraceptive use is greater when more methods are available to more women.

- HIV prevention counseling for women who are satisfied using a LARC will likely differ from counseling for women who are not on LARCs.

Enhancing provider skills and addressing provider motivation to provide MPTs like the DPP is crucial

- FP providers are familiar with counseling on informed choice

- DPP counseling recommendations will need to align OC and PrEP requirements (e.g., on missed pills)
  - DPP provider counseling sub-group, comprised of FP and HIV clinical and implementation experts, developing initial recommendations for DPP counseling
  - Acceptability studies will generate evidence on counseling for the DPP compared to separate OC/oral PrEP

- Need to understand provider attitudes/motivations toward providing DPP (and MPTs) and support needed to ensure quality service provision for an expanded method mix
Thank you!

Consultation on the DPP
with FP/SRH Stakeholders
Moderated Discussion:

**Moderator:** Beth Fredrick, Johns Hopkins Bloomberg School of Public Health

- **Barbara Friedland**, Population Council
- **Jessica Rodrigues**, AVAC
HEALTH SYSTEM CONSIDERATIONS FOR DPP INTRODUCTION:
EARLY INSIGHTS FOR PREPARING M&E SYSTEMS AND IDENTIFYING PROCUREMENT OPPORTUNITIES AND CHALLENGES

DPP Consultation
April 2022
Advanced planning to prepare health systems for DPP introduction is critical; supporting effective M&E systems and efficient procurement pathways will play an important role in implementation.

Adapting and strengthening M&E for the DPP will enable ongoing data-driven decision-making.

Advanced planning for DPP procurement is essential to secure timely, predictable sufficient supply in LMIC markets.

As a dual-indication product crossing both HIV prevention and family planning, the DPP brings novel system challenges. Early alignment and problem solving will be critical for smooth product introduction.
1. M&E Planning

2. Procurement Considerations

3. Discussion
M&E planning for novel MPTs must consider different phases of implementation, from evidence generation in early introduction to routine monitoring in scale-up, as well as diverse stakeholder priorities.

M&E needs will vary by time period and stakeholders involved:

**Early Implementation Evidence Generation**
Building an initial evidence base to inform introduction and scale-up will require intensive monitoring.

**Early Adoption and Introduction**
Remaining evidence gaps, related to evaluating real-life delivery models and their ability to meet the needs of communities often requires enhanced monitoring.

**Wider Delivery and Scale-Up**
As countries move towards higher volume delivery, streamlining M&E processes to avoid burdening providers and data collectors is critical.
This analysis gathers learnings from decades of family planning experience and PrEP programs to inform recommendations.

### Family Planning Programs

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>1950</td>
<td>Contraceptive pill approved by US FDA</td>
</tr>
<tr>
<td>&gt;150 million</td>
<td>Women using oral contraceptives globally as of 2020</td>
</tr>
</tbody>
</table>

- Highest contraceptive coverage rates in **Eastern and SE Asia** and **Europe and N America**; highest OC coverage in Europe and N America
- **Diverse method mix:** condoms as the most common contraceptive method globally followed by IUDs, pills, and injectables
- **Significant unmet need remains.** Highest unmet need and unintended pregnancy rates in sub-Saharan Africa

### PrEP Programs

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>2012</td>
<td>TDF/FTC approved by US FDA</td>
</tr>
<tr>
<td>1.9 million</td>
<td>Cumulative oral PrEP initiations globally as of the end of 2021</td>
</tr>
</tbody>
</table>

- **Largest share of cumulative oral PrEP initiations in Eastern and Southern Africa**
- **Limited range of options currently widely available;** new products in development or early introduction (injectables, implants, vaginal rings)
- New infections have decreased since 2010 but progress has stagnated with 1.5 million new infections in 2020. Highest rates of new infection among women in sub-Saharan Africa.

Sources: [Ledbetter, 1984]; USAID Family Planning Timeline; Guttmacher, 2021; UN, 2020;
We reviewed country guidelines, program reports, and published literature to identify strengths and weaknesses of family planning and HIV prevention M&E systems across 6 focal areas. Notes: [1] 6 focal areas are adapted from: O’Fallon et al. 2016. Monitoring and Evaluation in Family Planning: Strengths, Weaknesses, and Future Directions. USAID/MEASURE. LINK. While this literature review includes a range of country-level resources and guidelines, findings will need to be validated in country to inform prioritization of next steps.
### Overview of Findings: Preliminary insights and considerations for M&E planning for MPTs

<table>
<thead>
<tr>
<th>Data availability</th>
<th>Evidence generation needed in key areas (e.g., adherence and continuation) where there may be limited data availability in routine M&amp;E.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>While implementation projects may leverage resource-intensive M&amp;E methods, ongoing sensitization to align on expectations for routine monitoring is critical.</td>
</tr>
<tr>
<td>Indicators &amp; Measures</td>
<td>Indicators used in early implementation projects should be informed by national evidence needs and priorities.</td>
</tr>
<tr>
<td>Data utilization &amp; knowledge management</td>
<td>Knowledge management plans and platforms should prioritize continuous information sharing with governments and co-ownership of project outcomes.</td>
</tr>
<tr>
<td>Personnel &amp; Training</td>
<td>Early implementation projects should focus on sustainable capacitation, supporting personnel and M&amp;E training through national systems.</td>
</tr>
<tr>
<td>Sustainability</td>
<td>Early collaboration on M&amp;E planning and knowledge sharing between partner-led implementation projects and governments will support sustainability.</td>
</tr>
</tbody>
</table>

During Implementation Projects

- Evidence generation needed in key areas (e.g., adherence and continuation) where there may be limited data availability in routine M&E.
- Advanced planning and clear mapping of requirements and processes to include indicators in national health information systems needed to ensure ongoing data availability.
- Leveraging demographic health surveys will be crucial for ongoing evaluation of MPTs over time and understanding the role of MPTs in the broader contraceptive method mix.
- During the earliest phases of introduction planning, stakeholders should align on a minimum set of indicators for integration into national M&E systems.
- Clear ownership and responsibility over data utilization and knowledge management processes, considering both HIV prevention and family planning stakeholder needs, is critical.
- Coordination between HIV prevention and FP programs will be crucial for updating curricula and tools. MPT pre-service training will provide an efficient pathway for rapid scale-up.
- With a growing MPT portfolio, establishing efficient processes for integrating new products into M&E systems is critical for long-term sustainability.
1. M&E Planning

2. Procurement Considerations

3. Discussion
CHAI is analyzing procurement needs and challenges for the DPP and future MPTs across a range of global HIV and FP procurers.

**Approach**

1. Desk research and analysis
2. Validation with CHAI internal expertise
3. External engagement

**Scope**

- Social Marketing Organizations

**Insights are presented across the following categories**

- **Cross-cutting**
  - Coordination and Integration
  - Packaging & efficiency trends
  - Supply security
  - Evidence needs
  - Legal/policy
  - Regulatory
  - Process
  - Treatment guidelines

- **Procurer-specific analyses**

**Today’s discussion will focus on**

- **Cross-cutting issues for global DPP procurement:** Supply security and Evidence needs
- **Advantages and challenges for DPP procurement from social marketing organizations**

Based on estimates on initial DPP costs and limited market volumes, stakeholders have posited that procurement may be more likely to be supported initially by HIV donors like PEPFAR and The Global Fund.* The needs of these orgs form part of a broader analysis.

Today’s discussion focuses on strengthening understanding of challenges and opportunities for FP procurement of the DPP, with a spotlight on social marketing organizations.
Crosscutting issues related to procurement of the DPP

**Supply security**

- A single manufacturer for the DPP (Viatris) is anticipated for at least the initial years of DPP supply.
- DPP supply security and affordability may be a concern of governments and procurers, who may favor the security of separate products with multiple suppliers.
- Viatris has stated their capacity is sufficient for at least the initial years. This period should be leveraged as a learning opportunity to demonstrate a market to attract future suppliers.
- As DPP demand further clarifies, manufacturing capacity will need to be adjusted with sufficient lead-time to enable additional suppliers to enter the market.

**Evidence needs**

- Large procurers can set a high bar on evidence of impact. For new interventions to gain traction those seeking to secure procurement will need to be prepared.
  - Clinical trial effectiveness
  - Cost-effectiveness
  - Potential market size
  - Evidence of demand (e.g., preference elicitation studies)
- Women aged 20-40, already on COCs or PrEP, or not currently on OCCs or PrEP are more likely to be early-adopters of the DPP. This positions the DPP as a niche product during early introduction.*
- Understanding the perspective of procurers about potentially lower volumes and – initial - limited potential for economies of scale compared to other FP commodities will need to be secured.
- Partners engaged in securing DPP procurement will need to ensure they understand procurer needs and have robust evidence of efficacy, cost-effectiveness, market size, and user demand.

*Dual Prevention Pill Market Preparation and Introduction Strategy. August 2021. [Link](#).
Social marketing organizations (SMOs) can be nimble and responsive and support diversity in what, when, how, and from whom clients can obtain RH commodities.

SMOs can also address issues related to driving demand and reaching challenging geographic locations and are positioned to deploy differentiated approaches to address the needs of different population segments.

Young women in DPP target introduction countries often meet their family planning needs - including OCPs - through private sector channels (e.g., pharmacies).* Early DPP analysis concluded that SMOs should form part of introduction, particularly when considering private sector DPP introduction.

Social marketing organizations may be an important mechanism to target population segments who may desire (and benefit from) the DPP. In some cases, they may be more flexible than larger procurers with considerations of volume and macro-level cost-effectiveness when compared to existing options.

*Private Sector Analysis for the DPP (Kenya and RSA) 2020. [Link](#).
1. M&E Planning

2. Procurement Considerations

3. Discussion
Next Steps & Thank you! // Prochaines étapes et merci !

Hima Patel, FP2030
What do you want to learn more about regarding the DPP? // Sur quoi voulez-vous en savoir plus concernant le DPP ?

Go to menti.com and enter code 3253 4053

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