

Blazing a trail for MPT counseling: Efforts to develop recommendations for the Dual Prevention Pill and reconcile inconsistent guidance for delivering PrEP and oral contraception

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Background

A range of multipurpose prevention technologies (MPTs) to simultaneously prevent HIV and unintended pregnancy is in development. The Dual Prevention Pill (DPP), a daily pill combining oral pre-exposure prophylaxis (PrEP) and combined oral contraception (COC), is the MPT likely to enter markets next. Consolidating guidance for PrEP and COC is needed to ensure effective provision of the DPP.

In this presentation, we describe a process for future efforts to develop appropriate counseling guidance for other MPTs, based on learnings from the DPP and using missed pills as an illustrative example.

Description

In February 2021, a working group of eight clinical and implementation experts in HIV and family planning was convened to develop counseling recommendations for the DPP with the following scope of work:

- 1 **Map and categorize** counseling messages from COC/oral PrEP guidance, and relevant training materials and tools
- 2 **Identify where COC/oral PrEP guidance overlap and differ** for each topic and core elements to emphasize in DPP counseling
- 3 **Prioritize topics** based on information available
- 4 **Consult additional evidence and experts** to answer outstanding questions, and develop recommendations
- 5 **Share recommendations** to inform DPP acceptability studies in South Africa and Zimbabwe

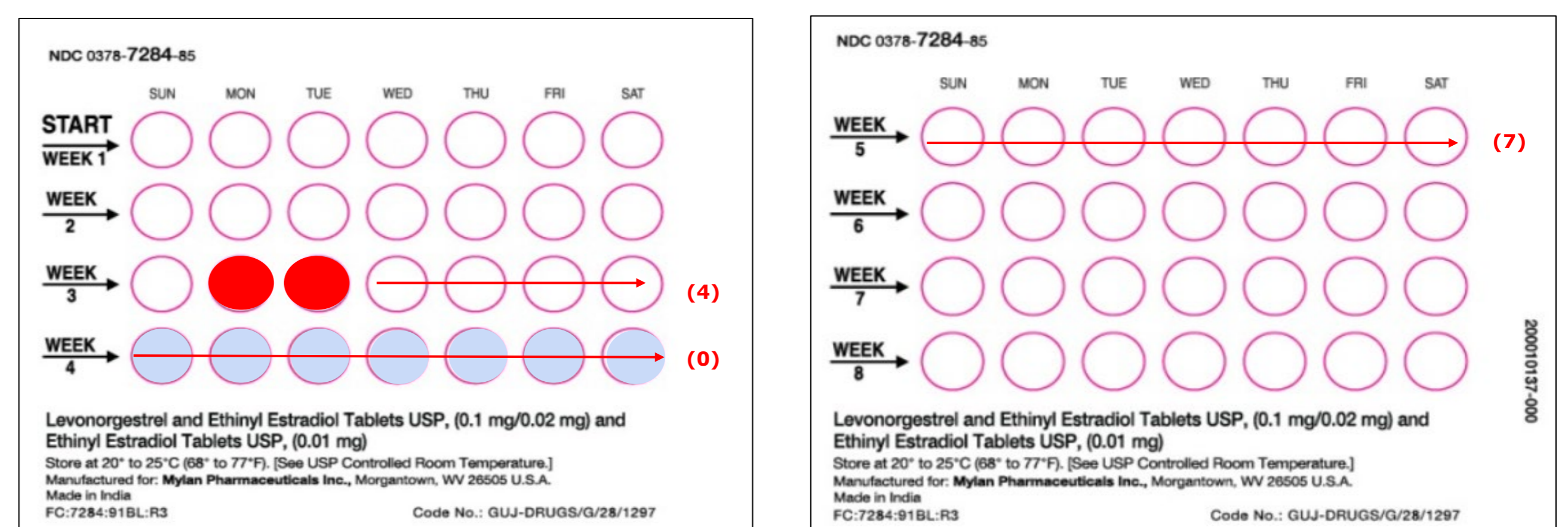
First, the working group reviewed COC/oral PrEP counseling guidance and supporting tools to identify where recommendations overlap and diverge. See Figure 1.

Lessons Learned

Reconciling PrEP and COC guidance for priority topics to develop clear messages for DPP counseling posed unique challenges, with implications for efficacy, side effects, cost, user comprehension and burden. **Missed pills** was the topic with the most complexity.

Figure 2: Considerations for DPP counseling recommendations on missed pills

- Depending on quantity and timing of missed COC pills, recouping pregnancy protection **can require use of a back-up method for up to 3 weeks.**¹
- To reduce user burden, COC users may consider skipping week 4 (i.e., monthly bleeding) to recover pregnancy protection more quickly. However, week 4 of the DPP contains oral PrEP and thus **there are supply and cost implications of tossing DPP packs early.**



- While doubling up on missed COC pills is common practice, WHO permits "occasional" doubling-up on oral PrEP.² There is **limited published evidence on toxicity of multiple PrEP doses in cisgender women.**

¹ WHO, FP Global Handbook for Providers, 2018; ² WHO, WHO Implementation Tool for PrEP of HIV Infection, 2017

The most salient considerations for other counseling topics were:

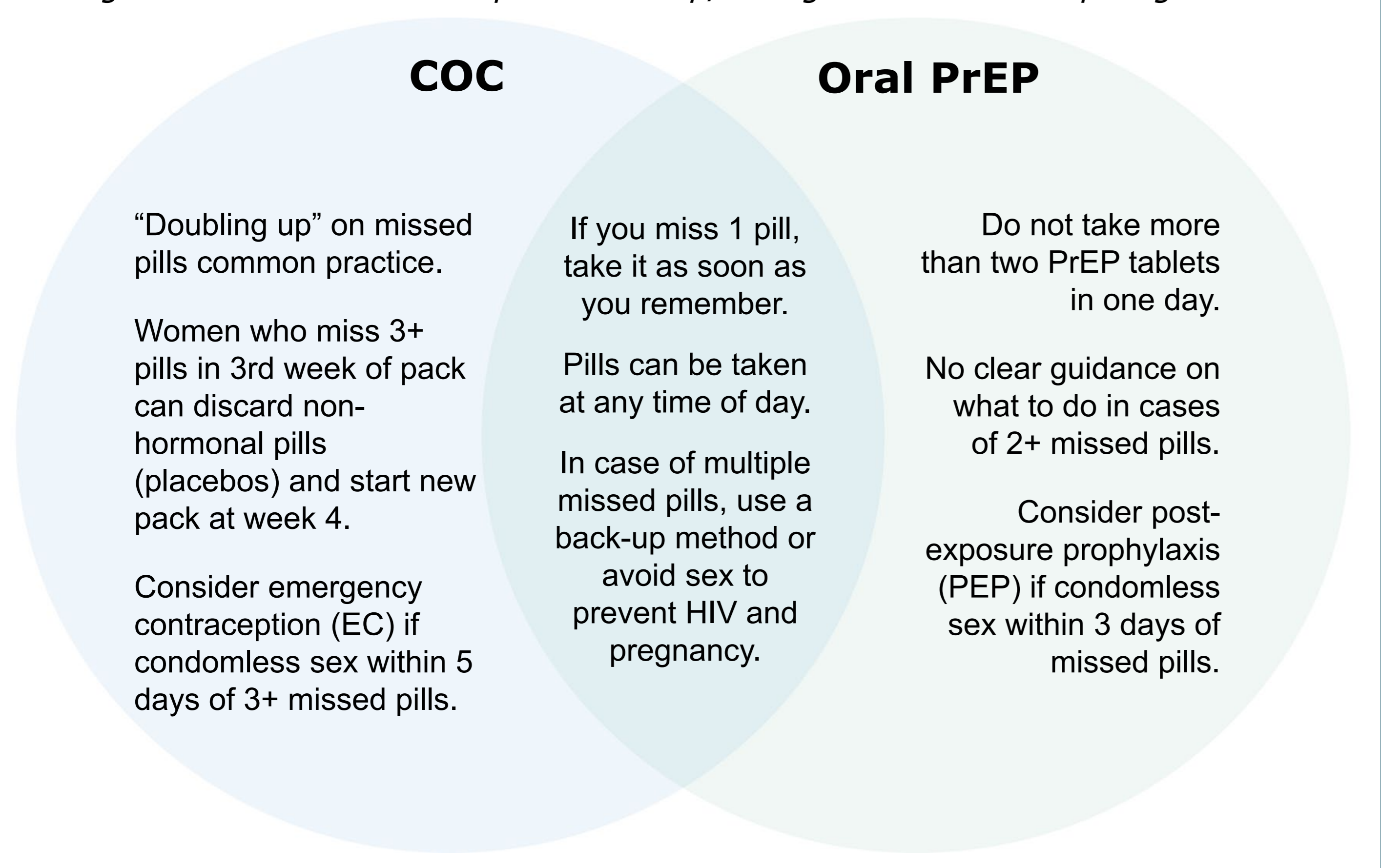
- **Uptake:** Aligning time to reach protective levels of both DPP components; ensuring daily dosing
- **Discontinuation/switching:** Managing risk of HIV and unintended pregnancy when discontinuing/switching to another HIV and/or pregnancy prevention method
- **Side effects:** Determining which side effects are common vs. serious; typical time to resolution; potential changes to monthly bleeding
- **Drug interactions:** Different contraindications for COC/PrEP
- **Monitoring:** Balancing monitoring recommendations with need and user burden, particularly for PrEP-naive users, who will be new to HIV testing requirements

Outstanding questions for all topics were resolved through additional desk research and expert consultation.

Conclusions & Next Steps

Crafting recommendations for a novel MPT like the DPP requires balancing the clinical and implementation implications of both products. Both user and provider burden must be considered to expand the prevention options on offer without compromising effectiveness or increasing client health risks. The process described in this presentation may be applied to other MPTs to accelerate the development of relevant counseling messages.

Figure 1: Illustrative example of overlap/divergence for missed pills guidance



Next, the working group selected six priority topics most important for the forthcoming acceptability studies:

- ✓ Uptake
- ✓ Missed pills
- ✓ Discontinuation/switching
- ✓ Side effects
- ✓ Drug interactions
- ✓ Monitoring

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