

Acceptability of injectable cabotegravir versus daily oral TDF/FTC for PrEP: Lesson from HPTN 084

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Introduction

- HPTN 084, a multisite, double-blind, randomized Phase 3 trial, compared the safety and efficacy of injectable cabotegravir (CAB) administered 8-weekly to daily oral TDF/FTC for prevention of HIV-1 in uninfected African women. Initiated in November 2017, the study enrolled >3,200 sexually active women aged 18-45 who were randomized to receive one active (CAB or TDF/FTC) and one placebo product and participated in a 5-week oral run-in before moving into an injection phase.
- We examine qualitative data from the initial phase of a four-country sub-study nested within HPTN 084 to better understand acceptability of these two PrEP methods and considerations for CAB access among African women at risk of HIV.

- Sub study to enroll a maximum of 104 women from 4 sites; Lilongwe, Malawi; Johannesburg, South Africa; Kampala, Uganda; Harare, Zimbabwe.
- Up to 3 in-depth interviews (IDIs), spanning participation in the blinded trial, the unblinded phase and transition to the open-label extension are planned to assess the acceptability of and preferences for various PrEP options, as well as PrEP access considerations for women.
- This analysis focuses on the first IDI, conducted during the blinded clinical trial, during which participants described their household and partner contexts, reasons for trial participation, and initial experiences using study products.
- **Sample** 10-16 continuing participants (CP) per site selected from randomly generated lists of participants by period of enrollment (2018, 2019 and 2020) for repeated IDIs.
- In addition, up to 10 special cases (SP) who became pregnant, experienced product holds or sero-converted were also invited to participate.

The research teams followed a four-step process to;

- 1) read transcripts for emerging themes (e.g., Sexual History, Product-related Acceptability, Adherence, Pregnancy, PrEP Use, and Clinical Trial Experiences)
- 2) develop a codebook and apply codes in NVivo to transcripts with intermittent interrater reliability checks;
- 3) develop memos identifying sub-themes and illustrative contexts for main codes; and
- 4) summarize information in Excel matrices to explore differences across risk categories related to product acceptability and other themes. Numbers reported in findings represent spontaneous reports during IDIs.

Results – PrEP perceptions

By far, women liked the ease and convenience of a long-acting formulation (40 of 63). Injectable PrEP did not require daily remembering and fit better into women's lifestyles, especially for women who traveled or had unpredictable work

The **main disadvantage of injectable PrEP** was pain. The majority of women described some level of pain (48 of 63)

About 1/3 of participants found oral PrEP easy to take and mentioned low side effects. But, more than half worried about forgetting to take oral pills.

I joined this study because when my marriage ended, I was promiscuous and when I heard that there is a study where there is a product that prevents HIV, I decided to join. During that time, with the nature of my work, I thought I was being protected because I was having unprotected sex with multiple sexual partners. Sure. So, there was a certain month when I was reckless because I went away for a long time, and I stopped taking my pills.... I had more confidence in the injection and although I missed the oral pills, I had the feeling that the injection would protect me because it is long acting. (Malawi, 29 divorced sex worker)

I had just started participating, I would forget. HOW MANY DAYS DID YOU FORGET? I won't lie to you, they were a bit many. I think about a week but of course not consecutively, you would forget today but you take it the following day, like that. (Uganda, 22-year-old, single participant, monogamous)

The Depo injection is more painful... Aah as for this one, it is not painful. I would not know if it is the one which is not painful (e.g., placebo), or it's the people who make it painless. (Zimbabwe, 24-year-old divorced sex worker)

Results- PrEP Preference

- Most women preferred 8-weekly injections to daily pills (40 of 63), with strongest preferences appearing to be related to risk category.

“The injection is painful, but I will choose it. MAY YOU TELL ME WHY? [Be]cause it’s a one-time thing. You just have to remember the date, but after that it’s over. AND IF MAYBE WE FOUND THAT THE PILL WORKS BETTER, WOULD YOU STILL PICK THE INJECTION? No, I’ll go for the pill. A pill is not bad, hey, the part of having to remember every day. (South Africa, 28-year-old single participant, transactional sex)”

- Women’s desire for privacy and ease of use outweighed other injectable concerns, resulting in a strong preference for Injectable PrEP. Concerns about cost and accessibility will need to be addressed by implementation programs.

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