Willingness to use Long-Acting Injectable Cabotegravir (CAB-LA) or Oral TDF/FTC for Pre-Exposure Prophylaxis (PrEP) During Pregnancy in Africa: Findings from the HPTN-084 Qualitative Sub-study

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BACKGROUND

HPTN 084 demonstrated that long-acting injectable cabotegravir (CAB-LA) was superior to daily oral TDF/FTC for HIV prevention in women. During the blinded part of the trial, participants were required to use long-acting reversible contraception in response to a safety signal concerning peri-conception use of dolutegravir and to switch to open-label TDF/FTC at the first positive pregnancy test. Given this context, we explored pregnant participants' PrEP preferences, motivations, and concerns.

Table 1: Socio-demographic characteristics of pregnant participants

	Pregnant participants (n=16)
Mean age (range)	25 (21-30)
Marital Status	
Married/Cohabiting	13 (82%)
Divorced/Separated	1 (6%)
Single	2 (12%)
Pregnancy Situation	
Not Intentional	9 (56%)
Intentional	7 (44%)
Unemployed in past 12 Months	14%

Pregnant participants desired to protect themselves and their baby from HIV infection, motivating their willingness to use PrEP during this period. Many women preferred CAB-LA to oral TDF/FTC but wanted assurance that safety was demonstrated; ongoing studies will address this.

METHODS

As part of a four-country (Malawi, South Africa, Uganda, and Zimbabwe) qualitative sub-study nested within HPTN 084, we conducted in-depth interviews (IDIs) with 16 pregnant participants whose pregnancies occurred primarily in the period after unblinding of participants when CAB-LA efficacy was known (October 2020-March 2022). The IDIs explored pregnancy circumstances, HIV risk perception, experiences using oral TDF/FTC, and perceptions and/or preferences for CAB-LA during the pregnancy period.

All IDIs were audio-recorded and transcribed. Qualitative thematic analysis was used for data analysis following a four-step process which included: reading transcripts for emerging themes (e.g., Sexual History, Product-related Acceptability, Adherence, Pregnancy, PrEP Use, and Clinical Trial Experiences), developing a codebook and applying codes in NVivo to transcripts with intermittent interrater reliability checks; developing memos identifying sub-themes and illustrative contexts for main codes; and summarizing information in Excel matrices to explore differences across risk categories related to product acceptability and other themes.

RESULTS

Of the 16 pregnant participants, about half had planned their pregnancies while the other half were unintended. Most participants (6 of 7) who intended to get pregnant did so due to partner pressure. Many unintended pregnancies resulted from challenges with long-acting contraception, including stopping or switching from implants (4 of 9) due to menstrual side effects, possible misiming of injections (3 of 9) or expulsion of an IUD (2 of 9) during heavy menses.

"When we were getting married, I told him that I am taking study pills. So, I told him that for one to take part in the study, she is supposed to be using long term contraceptives. At the beginning my partner understood but later he said that he wants a child. [My friends] advised me that I need to do what he wants because those are some of the things that make men start having other sexual partners. That was when I decided to come to the clinic and tell them that my partner wants me to become pregnant, so I would like to stop using contraceptive method and they accepted it." (IDI Participant from Malawi)

Most women perceived on-going risk of HIV due to their partner's behaviors or his HIV status. All accepted to use oral TDF/FTC during pregnancy due to its known efficacy and safety; a few acknowledged that CAB-LA safety was unknown. Some said that taking oral TDF/FTC became a routine since they had been taking study pills daily. However, others reported challenges with daily pill adherence, including difficulty swallowing pills and high pill burden as participants also took pregnancy supplements.

Table 2: Facilitators/challenges with taking daily oral TDF/FTC while pregnant

Facilitators of taking oral TDF/FTC	Challenges with taking oral TDF/FTC
Perceive oral TDF/FTC as safe and effective, protecting them from HIV injection while they are pregnant.	Adhering to daily pill taking as some forgot to take them every day.
Taking oral TDF/FTC became a routine since they had been taking study pills daily while in the trial.	For a small number of participants who did not like taking any kind of pills, they had a harder time taking the pills.
Like that one can set a time that is convenient to take the pill by setting an alarm.	Some experienced side effects initially but these side effects went away later.
Pills can be taken anywhere and easily carried around when a person is out and about.	High pill burden as participants also took pregnancy supplements.
	Fear of HIV stigma as some might think that she is taking ARVs instead of PrEP.
	Lack of privacy in taking pills

Half of the women said that they would have preferred using CAB-LA if proven safe during pregnancy because use was more discreet and had a longer duration of action. Other factors influencing PrEP preferences during pregnancy included fear of side effects for self and baby, fertility desires, product-related attributes, and partner approval.

CONCLUSIONS

Pregnant participants desired to protect themselves and their baby from HIV infection, motivating their willingness to use PrEP during this period. Many women preferred CAB-LA to oral TDF/FTC but wanted assurance that safety was demonstrated; ongoing studies will address this. Understanding pregnant participants' values, preferences and informational needs regarding PrEP use in pregnancy is essential for future trials and product introduction

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