Pre-Exposure Prophylaxis Product Choice in United States Participants in HPTN 083

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BACKGROUND

- In HPTN 083, a global, double-blind randomized controlled trial (RCT) conducted among 4566 cisgender men and transgender women (TGW) who have sex with men, long-acting injectable cabotegravir (CAB-LA) was superior to daily oral tenofovir disoproxil fumarate-emtricitabine (TDF/FTC) for HIV prevention. Participants were enrolled December 2016 - March 2020.
- At the first planned interim review in May 2020, an independent data and safety monitoring board recommended the study be unblinded; in April 2021, the protocol was amended as an open-label extension (OLE) in which participants were offered the choice of open-label CAB-LA or to complete study participation with daily oral TDF/FTC.
- United States (US) sites transitioned to OLE before other regions; thus this analysis is limited to US participants.

METHODS

- Product choices were compared between the following demographic subgroups: age, gender, race, ethnicity, education, and original randomized regimen using chi-squared tests.
- Reported reason for choice of regimen is also described.

RESULTS

- Total US enrollment was 1698 participants, of whom 803 (47.2%) had regimen choice data available.
- 770 (95.9%) chose CAB-LA and 33 (4.1%) chose TDF/FTC. Characteristics of participants are shown in Table 1.
- Among those initially randomized to CAB-LA (n=415), 13 (3.1%) chose TDF/FTC and 402 (96.9%) chose CAB-LA.
- Among those initially randomized to TDF/FTC (n=388), 20 (5.2%) chose TDF/FTC and 368 (94.8%) chose CAB-LA.
- Choice differences by original randomized study arm were not statistically significant, nor were there significant differences by age, cohort, race, ethnicity, or education status.

RESULTS, cont.

Table 1. Product Choice in the Open Label Extension by Demographic Subgroup

		Product Choice	
	Total n (%)	TDF/FTC n (%)	CAB-LA n (%)
Participants	803	33 (4.1)	770 (95.9)
Age			
18-24	239 (29.8)	12 (5.0)	227 (95.0)
25-29	230 (28.6)	9 (3.9)	221 (96.1)
30-39	188 (23.4)	8 (4.3)	180 (95.7)
40+	146 (18.2)	4 (2.7)	142 (97.3)
Cohort			
MSM	738 (91.9)	31 (4.2)	707 (95.8)
TGW	65 (8.1)	2 (3.1)	63 (96.9)
Race			
Black	398 (49.6)	19 (4.8)	379 (95.2)
Mixed Race, including Black	20 (2.5)	2 (10.0)	18 (90.0)
Other	385 (47.9)	12 (3.1)	373 (96.9)
Ethnicity			
Hispanic/Latinx	140 (17.4)	3 (2.1)	137 (97.9)
Not Hispanic/Latinx	663 (82.6)	30 (4.5)	633 (95.5)
Education			
College/University or Higher	613 (76.3)	26 (4.2)	587 (95.8)
Other	190 (23.7)	7 (3.7)	183 (96.3)
Original Randomization Arm			
TDF/FTC	388 (48.3)	20 (5.2)	368 (94.8)
Cabotegravir	415 (51.7)	13 (3.1)	402 (96.9)

CONCLUSIONS

- In the post-unblinding OLE of a Phase 3 multinational RCT, nearly all US participants chose CAB-LA over oral TDF/FTC.
- No specific subgroup drove this choice disparity.
- General preference for either pills or injections largely dictated participants' choice of regimen.
- Data from the non-US participants in HPTN 083 will provide important insights into regional/cultural differences in product preference.

Table 2. Reason for choosing CAB-LA or TDF/FTC

Reason for choosing CAB-LA (n=770)	N (%)
Prefer injection and/or don't like pills	541 (70.3)
CAB-LA shown to be superior to TDF/FTC for HIV prevention	112 (14.5)
CAB more convenient, discreet, or easier to adhere to	37 (4.8)
Want to avoid side effects of TDF/FTC	32 (4.2)
Contribute to research or research-dependent Issue	16 (2.1)
Curious to try something new	12 (1.6)
More than one response	5 (0.6)
Other	15 (1.9)
Reason for choosing TDF/FTC (n=33)	
Don't like injections and/or prefer pills	17 (51.5)
The potential side effects of TDF/FTC are better understood or preferable to those of CAB-LA	4 (12.1)
Concerned about resistance if injectable PrEP fails	4 (12.1)
Scheduling constraints/difficulties with visits	4 (12.1)
Undecided or not yet ready for CAB	2 (6.1)
Prior injection site reactions	1 (3.0)
Does not like long-term commitment of injections	1 (3.0)

LIMITATIONS

- This study is limited in that only half of US participants had product choice data available due in part to significant loss to follow-up. An additional limitation is that individuals preferring an oral PrEP regimen may not have chosen to enroll in HPTN 083.

Nearly all HPTN 083 participants from the US chose CAB-LA over oral TDF/FTC upon transition to the open-label extension phase of the study.

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