Pre-Exposure Prophylaxis Product Choice of Participants in HPTN 083

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BACKGROUND

- HPTN 083 demonstrated superiority of long-acting injectable cabotegravir (CAB-LA) compared to daily oral tenofovir disoproxil fumarate-emtricitabine (TDF/FTC) for HIV pre-exposure prophylaxis (PrEP) in cisgender men and transgender women who have sex with men. In the study's open-label extension (OLE), participants were offered choice of CAB-LA or to complete study participation with TDF/FTC.
- This analysis reports OLE product choice for all participants by region to investigate presence of any geographic differences in product preference or rationale for product choice.
- In an analysis of product choice in the United States only, participants predominantly chose CAB-LA; these data have been previously presented.

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

METHODS

- Product choice among participants overall and within four regions globally is described, along with reported reasons for regimen choice.
- Participants' reasons for declining OLE participation and for study termination are also reported.

RESULTS

- Among 4566 participants enrolled, 533 (11.7%) were ineligible for the OLE, 547 (12.0%) were lost-to-follow-up, and 431 (9.4%) terminated study participation.
- Additionally, 337 (7.4%) declined OLE participation and 126 (2.8%) remain OLE-eligible as of August 2023.
- Of the remaining 2592 participants entering the OLE, 2488 (96.0%) chose CAB-LA and 104 (4.0%) chose TDF/FTC.
- Among regions, the proportion choosing CAB-LA was similar: 1142/1193 (95.7%) in Latin America, 501/515 (97.3%) in Asia, 75/81 (92.6%) in Africa, and 770/803 (95.9%) in the United States.

Table. Reported reasons for choosing an HIV PrEP regimen at the time of HPTN Open Label Extension Entry

	Overall (n=2592)	United States* (n=803)	Latin America (n= 1193)	Asia (n=515)	Africa (n=81)
Reason for choosing CAB-LA	**n=2488 (%)**	**n=770 (%)**	**n=1142 (%)**	**n=501 (%)**	**n=75 (%)**
Prefer injection and/or don't like pills	1774 (71.3)	541 (70.3)	784 (68.7)	405 (80.8)	44 (58.7)
CAB-LA shown to be superior to TDF/FTC for HIV prevention	431 (17.3)	112 (14.5)	237 (20.8)	78 (15.6)	4 (5.3)
CAB more convenient, discreet, or easier to adhere to	115 (4.6)	37 (4.8)	52 (4.6)	8 (1.6)	18 (24.0)
Other	168 (6.8)	80 (10.4)	69 (6.0)	10 (2.0)	9 (12.0)
Reason for choosing TDF/FTC	**n=104 (%)**	**n=33 (%)**	**n=51 (%)**	**n=14 (%)**	**n=6 (%)**
Don't like injections and/or prefer pills	63 (60.6)	17 (51.5)	30 (58.8)	12 (85.7)	4 (66.7)
The potential side effects of TDF/FTC are better understood or preferable to those of CAB-LA	10 (9.6)	4 (12.1)	4 (7.8)	1 (7.1)	1 (1.7)
Concerned about resistance if injectable PrEP fails	8 (7.7)	4 (12.1)	4 (7.8)	1 (7.1)	1 (1.7)
Other	23 (22.1)	8 (24.2)	13 (25.5)	0 (0.0)	0 (0.0)

*Includes previously reported United States Open Label Extension Product Choice Data

- Reported reasons for choosing CAB-LA or TDF/FTC are listed in the Table.
- Among those who declined the OLE, the most common reasons were lack of continued study interest (168/337, 49.9%), followed by participant having plans for relocation (71/337, 21.1%), preferring TDF/FTC but not eligible for study-provided TDF/FTC (33/337, 9.8%), or already accessing TDF/FTC through another mechanism (21/337, 6.2%).
- Only 8 (2.4%) declined due to injection site reactions.
- Among those who terminated prior to the OLE, the most common reasons were also lack of continued study interest (186/431, 43.2%), followed by scheduled exit visit (103/431, 23.9%), investigator decision (94/431, 21.8%), and participant having plans for relocation (43/431, 10.0%).

CONCLUSIONS

- In the HPTN 083 OLE, nearly all participants globally chose CAB-LA over TDF/FTC.
- Participants' regimen choice was largely driven by general preference for injections or pills.
- Study visit fatigue was a large contributor to declined OLE participation and to premature study termination.
- Ensuring PrEP choices will be critical to continued optimization of PrEP uptake/persistence.

LIMITATIONS

These results should be interpreted with the lens that individuals preferring an oral PrEP regimen may have opted not to participate in HPTN 083.

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