

Initial PrEP product choice: results from the HPTN 084 open-label extension

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Summary



- What is your main question?
 - We assessed initial PrEP choice, reasons for choice and factors associated with choice among HPTN 084 participants in the openlabel extension
- What did you find?
 - 78% participants chose CAB for PrEP.
 - Product choice was influenced by personal preference for product attributes, participant risk behaviours and social context.
- Why is it important?
 - Results provide important insights for future implementation and serve as a reminder to ensure that health care providers support PrEP product choice aligned with user values and preferences



Background

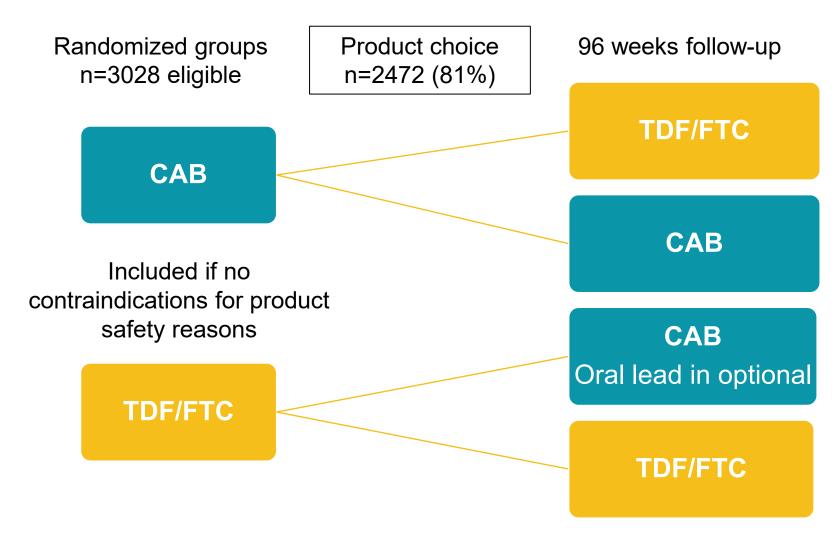


- HPTN 084 demonstrated that long-acting injectable cabotegravir (CAB) is superior to daily oral TDF/FTC for HIV prevention in individuals born female.
 - HIV incidence CAB 0.20 vs TDF/FTC 1.85 per 100 py,
 - HR 0.11; 95% CI 0.05 0.24
- In 2022, following a protocol amendment participants were offered enrolment in an open-label extension with a choice of open-label CAB or TDF/FTC as PrEP.



Study design and population







Methods



- Among participants who were eligible for and accepted OLE participation we assessed
 - initial PrEP choice
 - reasons for choice
 - Decisional Conflict Scale
 - measures perceptions of effective decision-making
 - 16 response items e.g. *I feel I have made an informed choice*
 - 5 response categories from strongly agree to strongly disagree
 - Score 0=no conflict to 100=high decisional conflict
- Compared participant demographic, behavioral and decision characteristics by initial product choice using chi-squared tests.

Decisional conflict

Informed subscale (3)

Values clarity subscale (3)

Support subscale (3)

Uncertainty subscale (3)

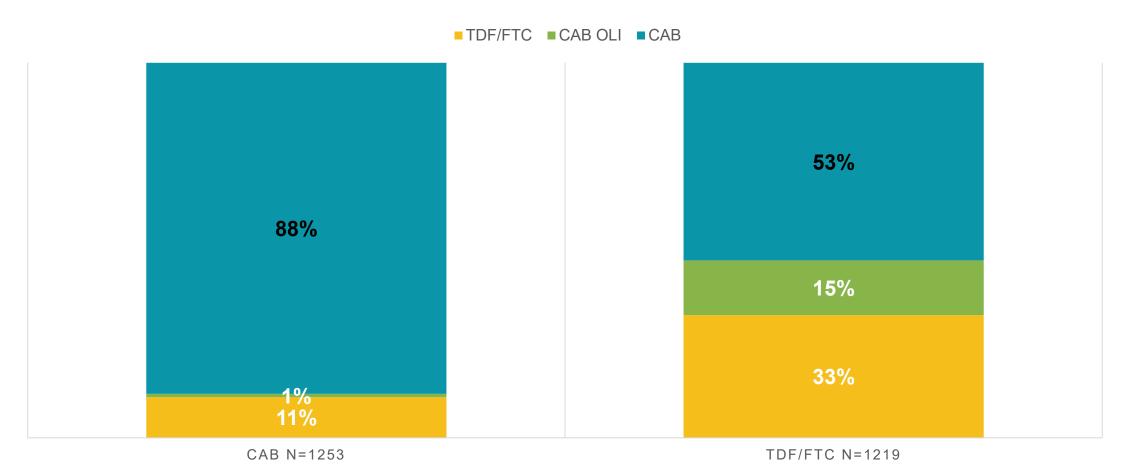
Effective decision subscale (4)



Product choice (n=2472)



78% participants chose CAB

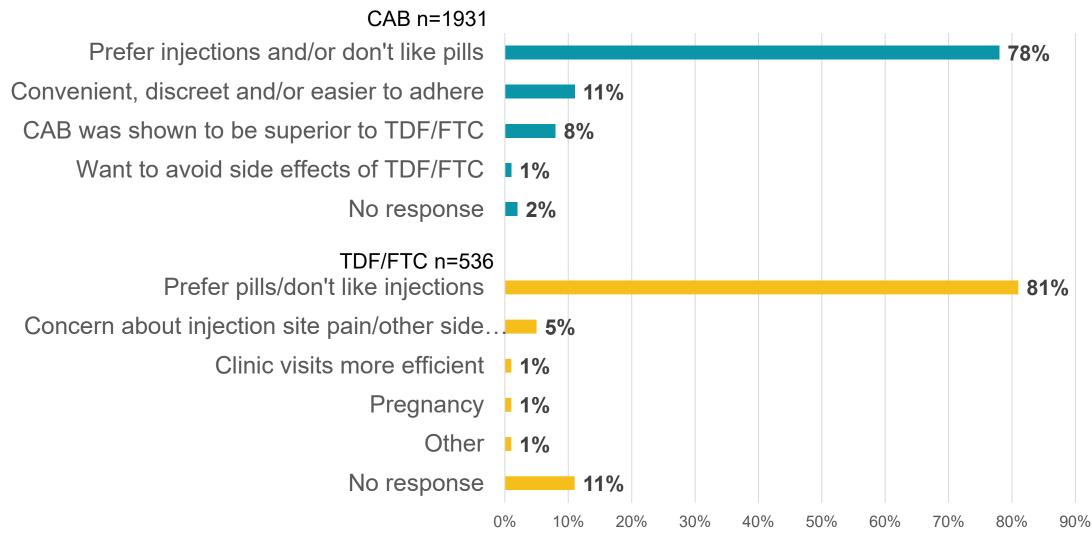




Original randomized groups

Reasons for product choice







Participant characteristics, by product choice

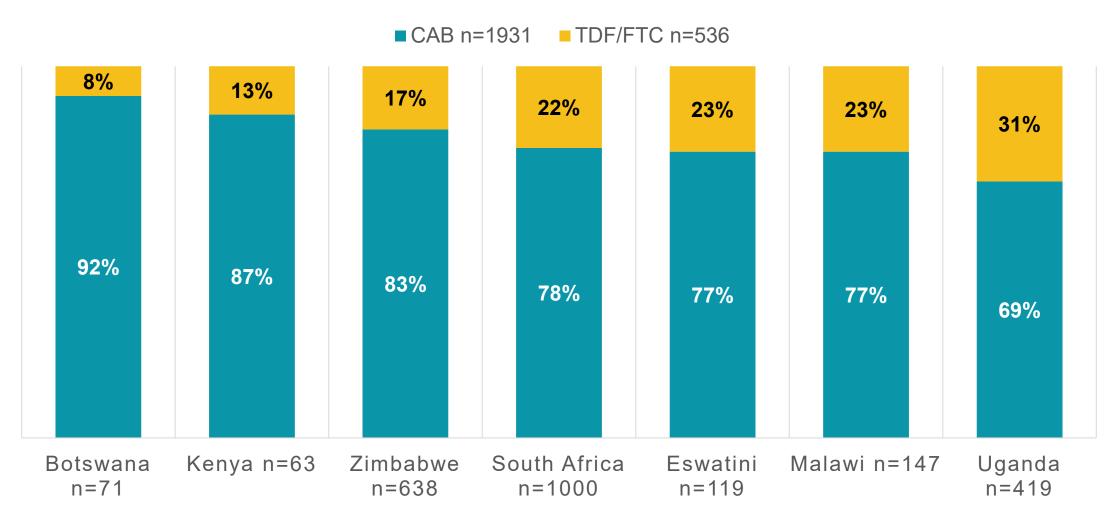


	CAB n=1931 (%)	TDF/FTC n= 536(%)	p- value
Age, median (IQR)	25 (22, 30)	24 (21, 30)	
≤ 25 years of age	54%	58%	0.430
Sexually active, not living with partner	58%	49%	0.022
Physical IPV, past 6 mo	8%	4%	0.012
Paid for sex, past mo	26%	20%	0.002
Partner living with HIV or unknown	22%	17%	0.186
Feels at high risk for HIV	27%	28%	0.197



Product choice, by country

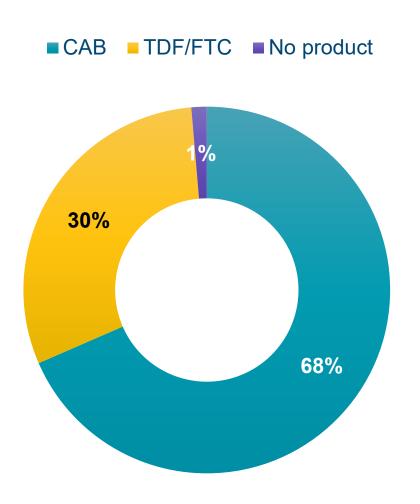






Product choice, pregnancy (n=233)



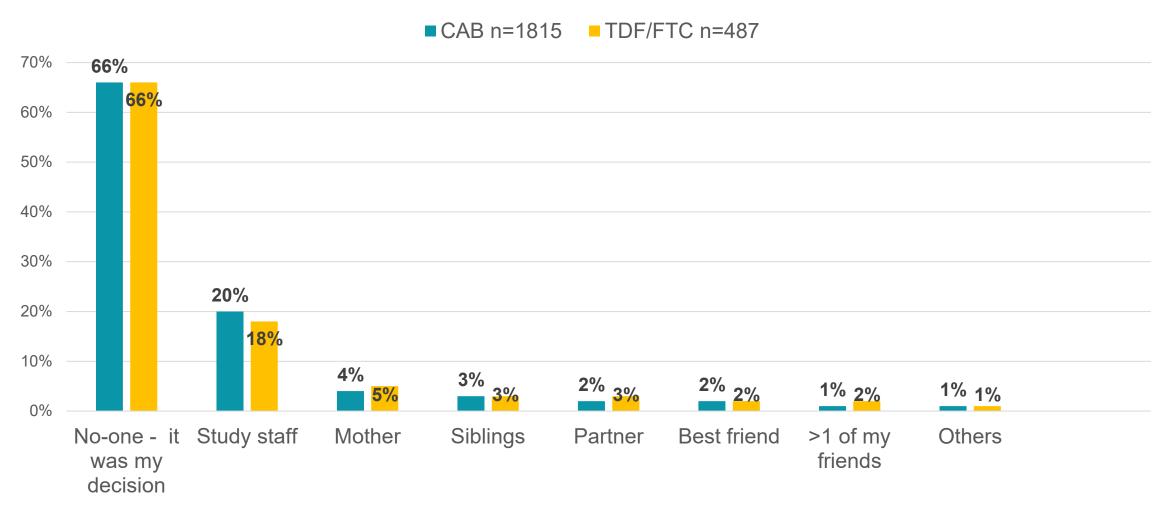






Decision-making support







Decisional conflict



	CAB n=1931 Median (IQR)	TDF/FTC n= 536 Median (IQR)	p-value
Overall score	14 (0, 25)	17 (0, 25)	0.113
Informed sub-scale e.g. I know the benefits of each options	17 (0, 25)	17 (0, 25)	0.315
Values clarity sub-scale e.g. I am clear about which benefits matter most to me	17 (0, 25)	25 (0, 25)	0.443
Support sub-scale e.g. I am choosing without pressure from others	17 (0, 25)	17 (0, 25)	0.390
Uncertainty sub-scale e.g. I feel sure about what to choose	8 (0, 25)	8 (0, 25)	0.086
Effective decision sub-scale e.g. I expect to stick with my decision	6 (0, 25)	13 (0, 25)	0.015



Conclusions



- The majority (78%) of HPTN 084 participants chose CAB for PrEP.
 - Among those starting CAB, only 15% chose the oral lead-in.
- Product choice was influenced by personal preference for product attributes, participant risk behaviours and social and geographic context.
 - Those who chose CAB appeared at higher risk for HIV and more likely to not live with partners, have experienced recent physical IPV, and to have been paid for sex
- Participants expressed very little decisional conflict
 - CAB participants perceived more strongly that they had made a good decision that they
 would stick to.
- Future PrEP programs will need to adopt approaches to support PrEP choices that align with user values and preferences to ensure effective PrEP continuation



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HIV Prevention Trials Network

- Leadership and Operations Centre, FHI360
- Laboratory Centre (Johns Hopkins)
- Statistical Center for HIV/AIDS Research and Prevention, Fred Hutchison Cancer Research Center
- HPTN Leadership

HPTN 084 Study team

- 20 sites in 7 countries in sub-Saharan Africa
- Community advisory boards and partners

... and our study participants!





