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


AIDS 2023, Brisbane, abstract 5998
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 open-label 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
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

Randomized groups
n=3028 eligible

Product choice
n=2472 (81%)

96 weeks follow-up

CAB

TDF/FTC

Included if no contraindications for product safety reasons

CAB

TDF/FTC

CAB

TDF/FTC

CAB

TDF/FTC

Relaxed LARC requirements, optional oral lead-in, CAB permitted during pregnancy
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.
Product choice (n=2472)

78% participants chose CAB

Original randomized groups

- CAB N=1253
  - CAB: 88%
  - TDF/FTC: 11%
  - CAB OLI: 1%

- TDF/FTC N=1219
  - TDF/FTC: 53%
  - CAB: 15%
  - CAB OLI: 33%
Reasons for product choice

**CAB n=1931**
- Prefer injections and/or don't like pills: 78%
- Convenient, discreet and/or easier to adhere: 11%
- CAB was shown to be superior to TDF/FTC: 8%
- Want to avoid side effects of TDF/FTC: 1%
- No response: 2%

**TDF/FTC n=536**
- Prefer pills/don't like injections: 81%
- Concern about injection site pain/other side: 5%
- Clinic visits more efficient: 1%
- Pregnancy: 1%
- Other: 1%
- No response: 11%
Participant characteristics, by product choice

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

<table>
<thead>
<tr>
<th>Country</th>
<th>CAB n=1931</th>
<th>TDF/FTC n=536</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>92%</td>
<td>8%</td>
</tr>
<tr>
<td>Kenya</td>
<td>87%</td>
<td>13%</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>83%</td>
<td>17%</td>
</tr>
<tr>
<td>South Africa</td>
<td>78%</td>
<td>22%</td>
</tr>
<tr>
<td>Eswatini</td>
<td>77%</td>
<td>23%</td>
</tr>
<tr>
<td>Malawi</td>
<td>77%</td>
<td>23%</td>
</tr>
<tr>
<td>Uganda</td>
<td>69%</td>
<td>31%</td>
</tr>
</tbody>
</table>

n values: Botswana n=71, Kenya n=63, Zimbabwe n=638, South Africa n=1000, Eswatini n=119, Malawi n=147, Uganda n=419
Product choice, pregnancy (n=233)

- CAB: 68%
- TDF/FTC: 30%
- No product: 1%

See also e-poster AS-IAS-2023-05743
Decision-making support

No-one - it was my decision: CAB 66%, TDF/FTC 66%
Study staff: CAB 18%, TDF/FTC 5%
Mother: CAB 4%, TDF/FTC 3%
Siblings: CAB 2%, TDF/FTC 3%
Partner: CAB 1%, TDF/FTC 2%
Best friend: CAB 1%, TDF/FTC 2%
>1 of my friends: CAB 1%, TDF/FTC 2%
Others: CAB 1%, TDF/FTC 1%
## Decisional conflict

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

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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!