

erica hamilton, MPH, FHI 360; Doreen Kemigisha; Hlukelo Chauke, MA;
Miria Chitukuta, MSc; Kudzai Matambanadzo; Juliane Etima; Nomhle Khoza,
PhD; Lynda Stranix-Chibanda, MBChB, MMed; Sybil Hosek, PhD; and the
HPTN 084-01 study team

Track C late-breaker



Acceptability of CAB LA in cisgender female adolescents in South Africa, Uganda, and Zimbabwe (HPTN 084-01)



 **IAS 2023**



Summary



Research question

- What barriers and facilitators to acceptability of long-acting injectable cabotegravir (CAB LA) do HPTN 084-01 participants report?

Findings

- CAB LA is generally acceptable to this population, but barriers still exist.

Importance

- Barriers and facilitators should be discussed with future clients as part of the decision-making process around HIV prevention product choice.
- These findings are highly relevant for current roll-out and implementation of CAB LA in sub-Saharan Africa.

- I have no relevant financial relationships with ineligible companies to disclose.
- Product for this study (CAB LA) was provided by ViiV Healthcare.

To the young participants and their parents/guardians who agreed to join this study and made it such a success...

THANK YOU!



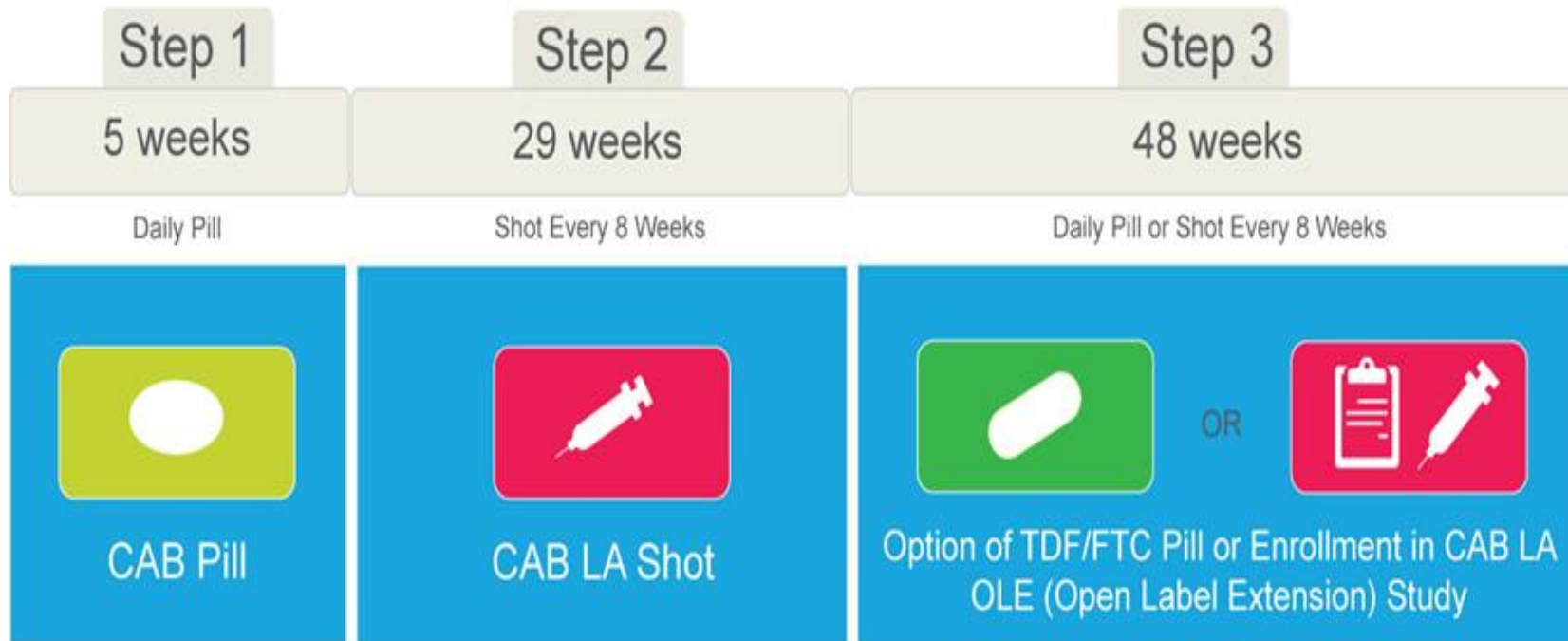
Study Context

- Adherence to daily oral HIV pre-exposure prophylaxis (PrEP) has been low among African adolescent girls and young women (AGYW).
 - This population is critical to curbing the HIV epidemic.
- Along with other sociocultural factors, PrEP uptake and adherence are a function of product acceptability.
- Understanding the acceptability barriers and facilitators faced by AGYW in regard to long-acting HIV prevention products is critical for successful implementation.



- Single arm, open label, Phase 2b safety, tolerability, and acceptability study
- N = 55 cisgender adolescents assigned female at birth (<18 years of age)
- ~19 months on trial
- 3 high burden countries in Africa (South Africa, Uganda, Zimbabwe)

Study Flow



*In step 2, the first two shots are four weeks apart and 8 weeks apart after that

Study Product

- Step 1: Oral CAB 30 mg once daily
- Step 2: Intramuscular injections of 3 mL (600mg) administered in the gluteal muscle
- Step 3: Oral TDF/FTC (300mg/200mg) once daily or move to 084 OLE for CAB LA

As presented at CROI (Feb 2023):

- CAB LA was found to be safe and tolerable, with no discontinuations of product due to adverse events.
- Participants found CAB LA to be acceptable and expressed interest in future use.
 - Results from CASI at Week 17 (3 injections) presented.
- Most participants (92%) chose to continue CAB LA over TDF/FTC when given a choice.
- We present additional acceptability results gleaned through the HPTN 084-01 qualitative interviews.

Methods

- In-depth interviews
 - Purposive sampling
 - 15 participants (5 ea. site)
 - 15 parent/guardians (5 ea. site)
 - Sites followed Qualitative Manual (SSP)
 - Oct 2021-July 2022
 - Coding completed Jan-March 2023
 - Analysis March-June 2023
- Team of 5 coders
 - NVivo 12
 - Group consensus on codebook development and code meaning
- Thematic analysis
 - Focused on acceptability code
 - Coding queries
 - 9 memos used in this analysis



Emergent Themes - Barriers

- ISRs (injection site reactions)
 - injection site pain
- Fear of the injection
- Side effects

(Barriers: injection pain)

So there are times where you feel less painful and there are times where you feel painful?

“It’s always painful. It depends on which doctor gives me the injection.”

~ Ward 21 ppt

(Barriers: fear of the injection, side effects)

“The injection is scary.”

“Aah on the day I had the injection I felt anxious and when I saw it being held, I was afraid. And as for the pills you just take one and there is no way that when you take the pill, maybe because I have never vomited because of the pill.”

~ Spilhaus ppt



Emergent Themes - Facilitators

- Lack of adherence challenges
- Discretion (vs. daily oral tablets)
- Knowledge of efficacy
- Administration mode
 - Needle size (1½ inch)
 - Site of administration (gluteal muscle)
 - Familiarity due to use of injectable contraceptives
- Parent/guardian buy-in

(Facilitator: lack of adherence challenges)

“The injection is better because if you chose the PrEP pills, you would sometimes forget them and the injection is unforgettable because you get injected for maybe a month and the pain last for two days, the injection is better.” ~Ward 21 ppt



(Facilitator: no worry about contracting HIV)

“I have not worried about it.”

“Because I had started using CAB and I rely on it.”

~ Spilhaus ppt

(Facilitator: parent/guardian buy-in)

When this study has ended, what are the chances that you will encourage your daughter to use an HIV prevention method?

“There is a huge chance...100 percent.”

What would you like her to use?

“To use the injection.”

~ Spilhaus p/g

Conclusions

- Findings
 - Barriers include ISRs (injection site pain), fear of the injection, and side effects.
 - Facilitators include lack of adherence challenges, discretion, knowledge of efficacy, administration mode, familiarity due to use of injectable contraceptives, and parent/guardian buy-in.
- CAB LA is generally acceptable in this population
 - Most (92%) chose to stay on CAB LA by joining the HPTN 084 OLE when given the choice.
 - Benefits generally outweighed the pain of the injection.
- Choice matters
 - HIV prevention product is not “one size fits all”.
 - Some participants still preferred oral tablets for various reasons.
 - We need multiple options in our HIV prevention toolkit.
- These barriers and facilitators should be discussed with future clients as part of the decision-making process around HIV prevention product choice.



Thank you

ehamilton@fhi360.org

+1 919-321-3493



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Acknowledgments



A BIG THANK YOU to all of the HPTN 084-01 participants, their families, and the communities that support them for their commitment to the study and to the site staff for their dedication to study implementation!

- Gratitude to the HPTN 084 Qualitative Team for use of their codebook as a basis for our team's codebook.
- Overall support for the HIV Prevention Trials Network (HPTN) is provided by the National Institute of Allergy and Infectious Diseases (NIAID), Office of the Director (OD), National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), and the National Institute of Mental Health (NIMH) and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) under Award Numbers UM1AI068619-15 (HPTN Leadership and Operations Center), UM1AI068617-15 (HPTN Statistical and Data Management Center), and UM1AI068613-15 (HPTN Laboratory Center).
- HPTN 084-01 is also co-funded by the Bill & Melinda Gates Foundation (BMGF) and support is provided by ViiV Healthcare.
- The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.