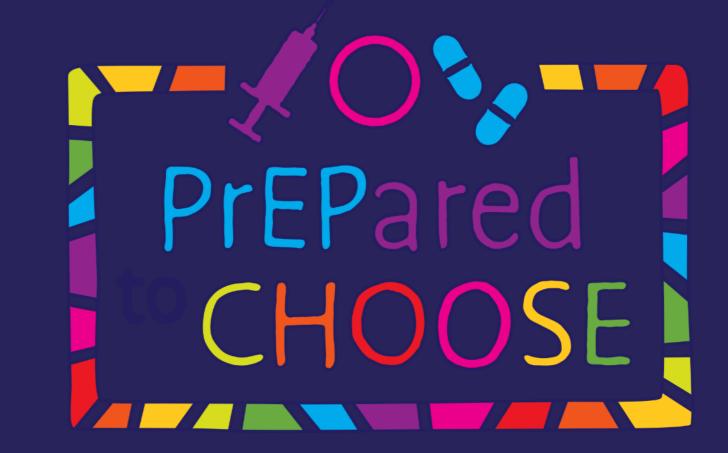
Characteristics of early non-persistors on Cabotegravir long-acting (injectable PrEP) compared to persistent users in the PrEPared to Choose study, Cape Town, South Africa.

<u>Pike C, Lebelo K, Rousseau, E. Macdonald P, Mapukata P, Vanto O, Bekker LG.</u> Desmond Tutu Health Foundation, Cape Town, South Africa.





Injectable pre-exposure prophylaxis (PrEP) products promised improved PrEP uptake and persistence compared to daily oral PrEP.

Yet – the implications of non-return may be greater for injectable Cabotegravir long-acting (CAB LA):

- CAB LA provides protection from HIV acquisition for eight weeks -> residual Cabotegravir concentrations present up to a year post-injection
- HIV seroconversion while CAB LA is circulating but not protective may result in resistance to the integrase inhibitor class of antiretrovirals → potential compromise of future HIV treatment.

METHODS

PrEPared to Choose (PtC), a phase 3B clinical trial, tracked uptake and persistence of three PrEP products

- daily oral PrEP
- monthly intra-vaginal DapiRing
- ❖ injectable PrEP 8 weekly CAB LA

amongst 1164 South African adolescents and young people (age ≥15 years) via a nurse-driven, integrated sexual and reproductive health (SRH) service from two community-based sites (mobile clinic; government clinic) in Cape Town, South Africa.



Image 1: Youth-friendly mobile clinic from which the PrEPared to Choose study is delivered, on location.

Real world simulation of PrEP choice

- Free of charge PrEP service

 no research-related reimbursement (one of the first real-world implementation studies to simulate standard of care).
- Non-randomised cohort: free, supported choice between the three PrEP products
 - Unlimited option to switch products at any future study visit.
 - Structured, comprehensive choice counselling at baseline with an HIV counsellor (30-minute session supported by a self-administered PrEP quiz and PrEP readiness assessment). Pike et al., HIVR4P 2024 poster TUPE092.
- Safety:
 - Counselling on safe cessation of CAB LA
 - Product-specific brochure with safe stopping instructions provided.
 - Dedicated study WhatsApp line to ask questions.
- Minimal retention efforts:
 - Study visit appointment card.
 - 1x automated SMS 7 days before scheduled appointment.
 - Follow up safety calls if >7 days passed.



Image 2: PrEPared to Choose study visit appointment card

Who were the PrEPared to Choose participants?

- 1164 participants enrolled between February and August 2024 (70% mobile clinic; 30% community health clinic).
- Baseline injectable PrEP uptake (74%) exceeded that of shorter-acting agents (oral PrEP 25%; DapiRing 1%).
- Participants were predominantly young women (67%,779/1164) and **PrEP inexperienced** (59%,691/1164).
- PrEP product preference was most influenced by compatibility with lifestyle. > 80% reported high product interest product and high confidence in ability to use it as intended.

Over a third (37%) of 1164 PrEP initiated participants did not return after the first visit.

26% of CAB LA initiators, **68%** of oral PrEP initiators, and 75% of DapiRing initiators did not return for subsequent PrEP visits.

The odds of CAB LA initiators ever returning was 6.06 (95% CI: 4.55; 8.06) compared to initiators on shorter acting agents (oral PrEP or DapiRing).

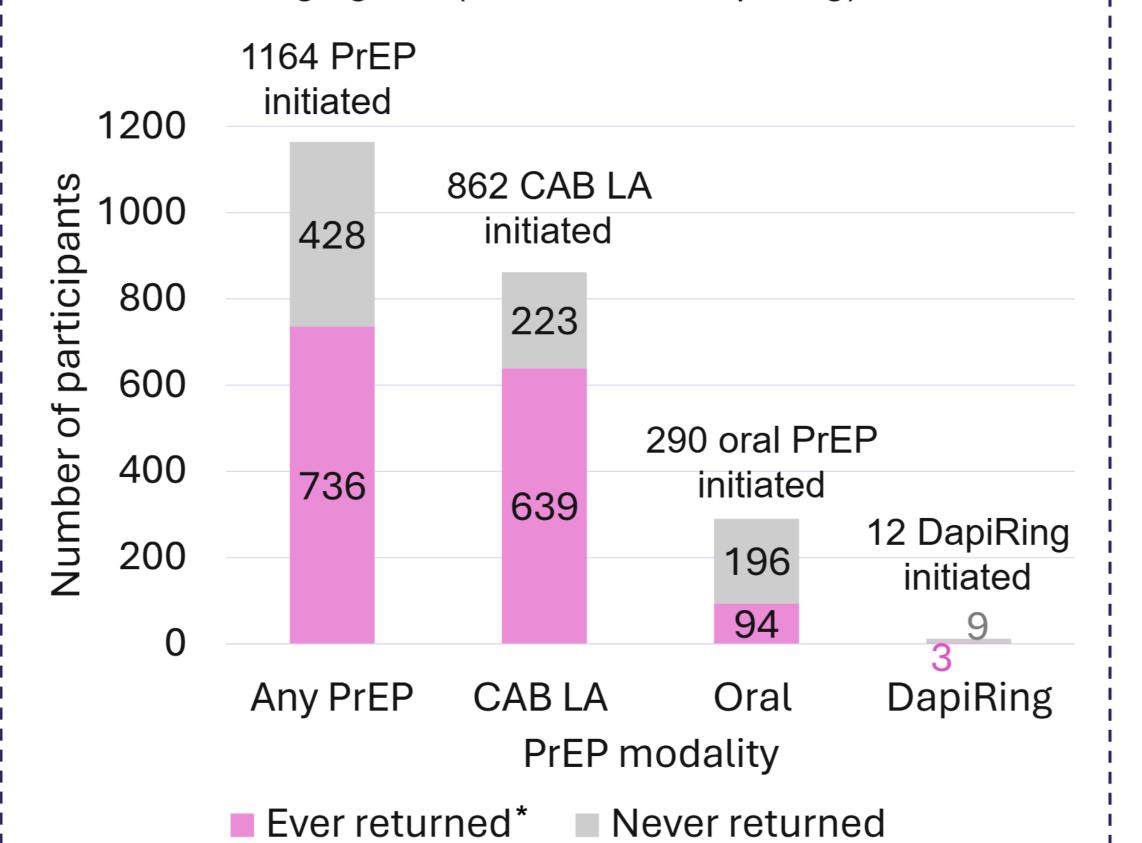


Figure 1: PrEPared to Choose participants that initiated on PrEP (overall and by modality) comparing the number that ever returned after the baseline visit (>2 study visits attended) vs those that never returned after visit 1 (baseline).

*The interval of time to return (time from baseline to visit 1) varies by participant and ranges from 28 days to several months.

11% of CAB LA initiators that ever returned, returned >28 days from their scheduled visit and were required to restart the CAB-LA regimen.

CAB LA is a two monthly intramuscular PrEP injection. At initiation or restart an additional dose after 1 month is required.

A typical injection schedule: Baseline \rightarrow month 1 \rightarrow month 3 \rightarrow month 5 \rightarrow etc.







An injection schedule with a restart: Baseline \rightarrow month 1 \rightarrow month 3 \rightarrow \rightarrow month 7 \rightarrow month 8 \rightarrow month 10 \rightarrow etc.







Restart

CAB LA user characteristics associated with an increased probability of return:

CAB LA initiating participants were more likely to ever return if they had these characteristics compared to never returned CAB LA initiators:

- Age: Older participants, >19 years were 50% more likely to ever return (OR 1.5, CI 1.09-2.30).
- PrEP experience: Participants with prior PrEP experience (OR 2.4, CI 1.53-4.09) were more likely to ever return.
- Prior PrEP disclosure: Participants that had disclosed their PrEP use (OR 2.59, CI 1.48-3.69) were more likely to ever return.
- Location of PrEP access: Participants that accessed PrEP from the mobile clinic were 42% more likely to ever return (OR 1.42, CI 1.04-1.95).

Characteristics that did not influence the likelihood of return

- **Sex**: male vs female (OR 1.12, CI 0.80-1.56)
- Employment status: similar between those employed/ in education vs. unemployed (OR 1.03 CI 0.76-1.40).
- Reason for PrEP use: as assessed during choice counselling (OR 0.86 CI 0.66-1.12)
- HIV risk perception: risk score during HIV testing and counselling (OR 0.91 CI 0.71-1.16)
- Number of sexual partners: similar between those with ≤1 partner vs >1 partner (OR 0.83 CI 0.59-1.15)
- Sexually transmitted infection diagnosis (Chlamydia, Gonorrhoea, Syphilis) (OR 1.40 CI 1.01-1.92) Mental health score: Positive vs negative PHQ 4 score
- at baseline (OR 0.79 CI 0.43-1.38)
- **Alcohol misuse**: Positive vs negative AUDIT score at baseline (OR 0.86 CI 0.68- 1.13)

Conclusion

Early results from PtC, a real-world, minimal retention implementation science trial, showed:

- Participants initiated on injectable PrEP were more likely to ever return compared to shorter acting agents (oral PrEP; DapiRing).
- Yet, a greater than expected portion of injectable PrEP users never returning after their initiation visit.
- Older, PrEP experienced CAB-LA users that accessed PrEP from community sites are more likely to return.



Acknowledgments

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- PrEPared to Choose lead: Carey Pike
- PrEPared to Choose study team & study participants
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- The Desmond Tutu Health Foundation Youth Reference Group that advises PrEP implementation studies.

Questions: Carey.Pike@hiv-research.org.za





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