Implementing Long-Acting Cabotegravir for HIV Preexposure Prophylaxis in a Large Urban HIV Clinic

#1108

Christian Turner[1], Gabriel A. Wagner[1], Allan Pfeil[1], Aaron Willcott[1], Tyler Lonergan[1], Lucas Hill[1], Jill Blumenthal[1]

[1]*University of California San Diego, San Diego, California, USA*

UC San Diego Health

Background

- The introduction of long-acting cabotegravir (CAB-LA) has provided a highly efficacious alternative to daily oral medication for HIV PrEP.[1]
- Provider-administered injections removes the clinical unknown of patient adherence but places increased responsibility on programs to minimize the risk for breakthrough infections.[2]
- The rate of discontinuation due to injection-site reactions (ISR's) in Phase 3 clinical trials of cisgender men/transgender women was 3% (<1% in cisgender women).[3]
- We aimed to describe the cohort of CAB-LA users and evaluate predictors of discontinuation in our initial cohort and to identify obstacles to implementation and elements critical to the success of incorporating CAB-LA
- In addition, to highlight elements unique to injectables, we describe our initial workflow for introducing CAB-LA in an existing PrEP program

Workflow

- Patient self-identifies or is identified by provider as potential candidate for CAB-LA
- PrEP navigator conducts coverage evaluation and applies for authorization if needed → PrEP navigator and/or pharmacist enroll patient in assistance programs
- Provider and/or clinical pharmacist counsels patient and screens for contraindications, schedules initial injection, orders labs as needed
- Clinical pharmacist and/or PrEP navigator orders from appropriate source
- LVN administers injection and schedules next injection according to recommended dosing window provided by clinical pharmacist
- Clinical pharmacist and PrEP navigator function as primary resource for patients to provide assistance with adverse events (AE's), scheduling, additional PrEP support; monitor for missed doses, contact patient to reschedule or counsel via phone call, text messaging, and/or EMR.
- Spreadsheet utilized and updated continuously to track planned injection dates, note patient preferences, prior authorization details, identify next injection window, product source, financial assistance programs
- Patients see clinic provider every other injection (every 4 months) – clinical pharmacist provides support for injections/labs needed between provider visits

Methods

- A retrospective cohort study was performed among adult patients receiving PrEP care at the University of California San Diego Owen Clinic.
- Inclusion criteria included patients who received at least one injection of CAB-LA between 1/1/2022-6/30/2023 (n=164).
- Demographic data were collected through EMR review and reasons for discontinuation and missed doses were documented contemporaneously and continually evaluated
- Multivariable logistic regression was performed to evaluate factors associated with discontinuation

Results

	Total (n=164)
Median age (IQR)	31.5 (27-39)
Race (%)	
White	79 (48)
Black	5 (3)
Mixed/other	80 (49)
Ethnicity (%)	
Hispanic	65 (40)
Non-Hispanic	99 (60)
SAB (%)	
Female	16 (9)
Male	148 (91)
Previous oral PrEP use (%)	126 (78)

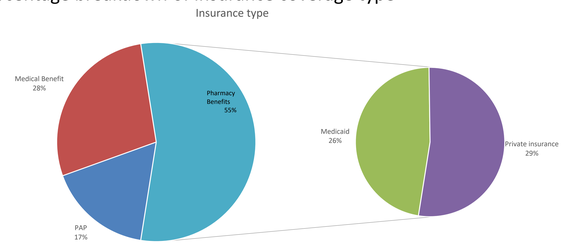
Discontinued CAB-LA	Total (n=26)
Reason (%)	
ISR	11 (6.7)
Move/transfer care	4 (2.4)
Change in HIV risk	3 (1.8)
Insurance change	3 (1.8)
Lost to follow-up	3 (1.8)
Other	2 (1.2)

IQR=interquartile range
SAB=sex assigned at birth
ISR=injection-site reaction

- No seroconversions in CAB-LA population
- Discontinuation rate of 6.7% due to ISR
- Logistic regression analysis identified 3 elements significantly associated with future discontinuation of CAB-LA
  - Younger age (OR 1.05, 95% CI 1.01-1.11, p=0.049)
  - Non-patient assistance program (PAP) coverage (OR 12.5, 95% CI 1.4-111.11, p=0.013)
  - Missed injection (OR 7.68, 95% CI 1.53-38.65, p=0.023)

Results (cont'd)

Figure 1: Percentage breakdown of insurance coverage type



- Coverage evaluation was a critical element in CAB-LA initiation and was often limiting step
- Patients w/o insurance were enrolled in California's PrEP assistance program (PrEP-AP) to cover clinic provider visits and labs
  - Medication was required to come from the PAP
- Coverage through both pharmacy and medical benefits rare at program initiation

Discussion

- Most early adopters of CAB-LA were prior oral PrEP users with a clinical need or preference for non-oral PrEP, highlighting the need for alternative choices among people who use PrEP for HIV prevention.
- Younger age, having coverage through a program other than patient assistance, and missing an injection were all associated with eventual discontinuation of CAB-LA.
- Ability to do coverage evaluation, working with different benefit types, and capacity to administer injections will be limiting resources for many potential providers.
- Robust clinical support (e.g., address AE's, administer injections, monitor missed injections) is needed in addition to traditional PrEP program service offerings.
- Workflow must adapt to accommodate increasing numbers of patients (including PrEP-naïve), include monitoring for patients who discontinue CAB-LA

References

1. Landovitz RJ, Donnell D, Clement ME, Hanscom B, Cottle L, Coelho L, et al. Cabotegravir for HIV prevention in cisgender men and transgender women. N Engl J Med. 2021;385:595–608.
2. Schmidt, H. M. A., Rodolph, M., Schaefer, R., Baggaley, R., & Doherty, M. (2022). Long-acting injectable cabotegravir: implementation science needed to advance this additional HIV prevention choice. *Journal of the International AIDS Society*, *25*(7).
3. Delany-Moretlwe S, Hughes JP, Bock P, Ouma SG, Hunidzarira P, Kalonji D, et al. Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, a phase 3, randomised clinical trial. Lancet. 2022;399(10337):1779–89.