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Developing Analytic Strategies to Investigate Long-Acting Injectable Antiretroviral Effectiveness

UNC SCHOOL OF MEDICINE

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Background

- Use of long-acting injectable antiretroviral therapy (LAI ART) with cabotegravir/rilpivirine (CAB/RPV) for persons with HIV (PWH) is rapidly expanding in the United States
- Monitoring implementation, operational, and clinical outcomes of LAI ART is critical to inform program scale-up and modification
- Most health systems rely on manual tracking for LAI ART
- Efficiently examining LAI ART implementation and effectiveness outcomes in health systems is enhanced if data, including initiation, injection dates, and discontinuation, can be reliably ascertained from electronic health records (EHR).
- Use of EHR-based data may also facilitate real-time evaluation of program outcomes, informing quality improvement initiatives to maximize LAI ART outcome and reach

Objectives

1. Characterize LAI ART initiation and discontinuation in a single health system
2. Validate the use of EHR data compared to a referent standard of manual clinic-based records in terms of alignment of key steps of the LAI ART clinical cascade.

Methods

Study population

- PWH receiving care at University of North Carolina Infectious Diseases (UNC-ID) clinic between January 2021 and May 2024
- Enrolled into the UNC-ID Center for AIDS Research (CFAR) HIV Clinical Cohort (UCHCC)

Study data sources & definitions

- Used EHR procedure code (HCPCS cod J0741), laboratory, and encounter data to characterize frequency of injections, viral suppression (VS) (<50cp/ml), and clinic visits following LAI initiation.
- Validation of EHR data compared to manually updated clinic records
- Cabotegravir/rilpivirine use, defined as:

Variable	Clinic Records	EHR
Prescription	N/A	First medication order date
Initiation	First recorded injection date	First HCPCS procedure code J0741
Discontinuation	Last injection date in patients noted to have discontinued	Last J0741 record before a gap >90 days

Statistical analysis

- **Cumulative incidence (CI)** of initiation and discontinuation from Kaplan Meier curves
- **Sensitivity** and **specificity** of EHR procedure code versus clinic records

Results

- Among 1951 patients, 138 initiated LAI ART per clinic records.
- LAI ART initiators were 75.4% cisgender men, 64.5% non-Hispanic Black, and a median of 42 years old (**Table 1**).
- At initiation of LAI ART, 84.8% were VS.
- Median time from LAI prescription to injection was 26 days (**Fig. 1A**).
- Outpatient prescription data alone were 92.8% sensitive and 98.1% specific to identify LAI ART initiators.
- In the 6 months after first injection (N=111 with sufficient follow-up), patients had a median of 4 clinic visits (IQR 3, 5).
- Of these 111, 96.8% of those VS at initiation remained VS, and 76.5% of those virally non-suppressed (VNS) at initiation became VS.
- Per clinic records, LAI ART was discontinued in 30 (21.7%) of all 138 initiators (**Fig. 1B**).
- Among persons who discontinued per clinic records, 7.7% were VNS (median 3118 cp/mL) at next available assessment, compared to persons with >90-days between injection procedure codes, where 6.9% were VNS (median VL 2192 cp/mL) at next available assessment.
- Among those VNS at initiation, 83.3% discontinued according to clinic record while 79.1% discontinued according to J-code

Table 1. Characteristics of 1,951 PWH in care at UNC, Jan. 2021–May 2024, stratified by LAI use per clinic records.

Characteristic at LAI initiation	LAI Recipients (N = 138)	LAI Non-Recipients (N = 1,813)
Gender		
Cisgender women	28 (20%)	485 (27%)
Cisgender men	104 (75%)	1,293 (71%)
Transgender	6 (4%)	35 (2%)
Race/ethnicity		
Black, not Hispanic	89 (65%)	1,055 (58%)
Hispanic, any race	13 (9%)	159 (9%)
White, not Hispanic	33 (24%)	531 (29%)
Other group	3 (2%)	68 (4%)
HIV risk factor		
Heterosexual contact	35 (25%)	665 (37%)
Injection drug use	7 (5%)	124 (7%)
Men having sex with men	92 (67%)	934 (51%)
Other	4 (3%)	90 (5%)
Age, years	42	54
Virally suppressed[a]	117 (85%)	1767 (91%)
Viral load[b]	16,474 (78, 50,465)	1223 (50, 934528)

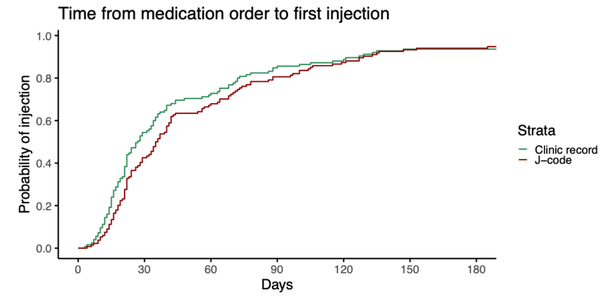
Shown are N (%) or median (IQR). [a] Defined as <50 copies/mL using the closest measurement. [b] Restricted to PWH with viral load ≥50 copies/mL at LAI initiation.

Table 2. EHR procedure code accuracy vs. clinic records.

Variable	Sensitivity	Specificity
Initiators	100%	99.9%
First injection date (+/- 7 days)	84.1%	100%
Discontinue[a]	70.0%	91.4%

[a] >90-day gap in J-code

Figure 1. Time from CAB/RPV prescription to initiation (A) and from initiation to discontinuation (B) using EHR procedure codes vs. clinic records.



Conclusions

- A nearly month-long delay between first prescription and injection receipt highlights challenges with LAI ART access and system implementation
- Most patients remained on LAI ART with favorable clinical outcomes, regardless of suppression at initiation.
- EHR data identified LAI ART initiators with high accuracy.
- Lower accuracy in identifying initiation date could affect analyses of LAI ART exposure, presumed clinical effectiveness, and implementation outcomes, and should be considered in future studies.
- Imprecision in characterizing discontinuations among persons with a 90+ day gap between injections may complicate routine assessment of program and clinical outcomes, though estimates of VNS at discontinuation was similar across these definitions

Considerations

- Characterizing missed or late visits is complicated given the mix of monthly and bimonthly injections
- J-code accuracy may improve with time and increased training of staff responsible for coding LAI ART injections

Next steps

- Examine opportunities to pair J0741 with other EHR sources documenting medication receipt to evaluate LAI ART program outcomes within and across health systems

Electronic health record data accurately identified LAI ART initiators; lower accuracy capturing initiation and discontinuation dates may compromise analyses of LAI ART exposure, clinical effectiveness, and implementation outcomes

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