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Implementing twice-yearly lenacapavir (LEN) within public health PrEP services in Brazil: the ImPrEP LEN-Brasil study

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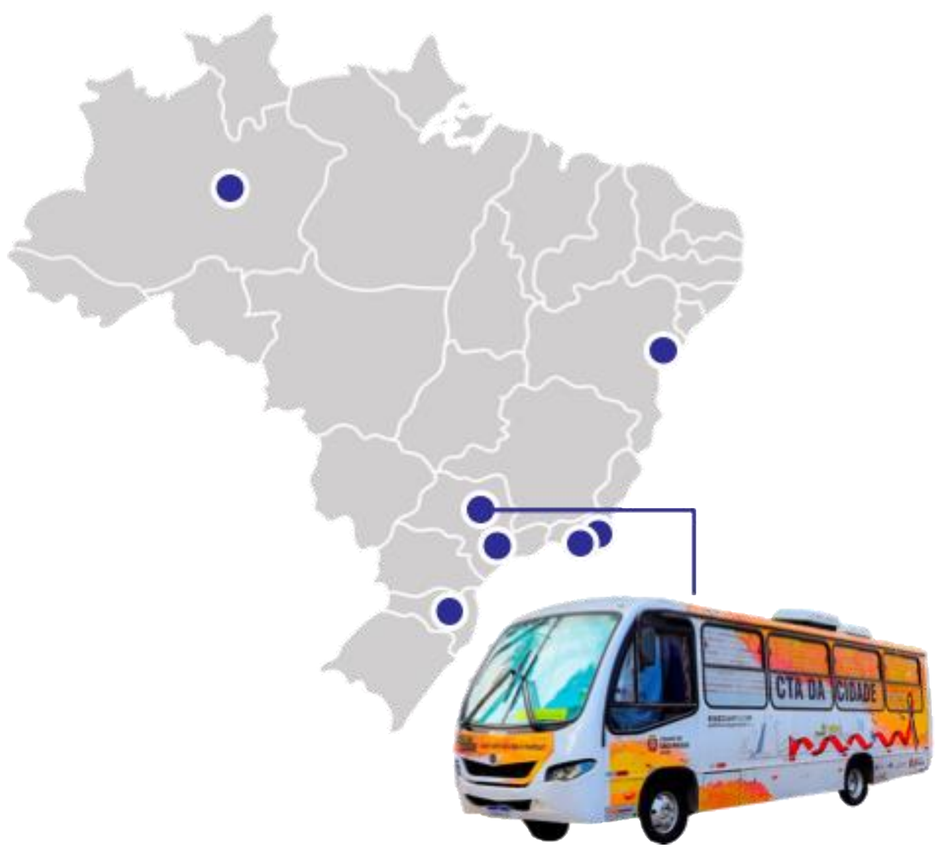
Background

- Twice-yearly subcutaneous lenacapavir (LEN) for PrEP has shown high protective efficacy[1,2] and may be impactful for people experiencing barriers to daily oral PrEP.
- ImPrEP LEN-Brasil study is the first LEN implementation initiative in Latin America and aims to generate evidence for national policies regarding LEN integration into public health PrEP services in Brazil.
- We describe study design, operational procedures, and preliminary findings on PrEP choice and injection sites at baseline.

Methods

- Multicenter, hybrid type-2 implementation-effectiveness, open-label study conducted across nine PrEP services in six cities, including a mobile unit (**Figure 1**).

Figure 1. Location of study sites, ImPrEP LEN Brasil.



- We plan a mixed methods study (in-depth interviews, focus groups and community engagement activities) approach guided by the EPIS-framework to contextualize findings.[3]
- Eligible participants are cis-men, transgender, and non-binary persons who have sex with men, aged 16–30y and testing HIV-negative.
- The study is offered to persons seeking PrEP services and through network-based approach using peer-distributed vouchers to enhance reach among highly vulnerable subgroups.
- Study intervention offers a person-centered model in which participants choose between same-day initiation of LEN or oral-PrEP, supported by an mHealth educational tool designed to facilitate informed, preference-sensitive decision-making.[4-6]
- Participants choosing LEN will be followed for at least 18 months; enrollment will conclude once 1,500 LEN initiations are reached.
- Automated WhatsApp messages integrated with the national antiretroviral logistics system (SICLOM) support oral loading doses and injection reminders.
- Primary outcome is LEN persistence (≤28 weeks between injections) at multiple timepoints (months 12, 18, 24 and 30). Secondary outcomes include HIV incidence, PrEP modality choice, retention, and safety.

Results

- From 03-Feb-2026 to 15-Jul-2026, 695 participants were screened.
- Among eligible persons (N=668), **651 (97%) chose LEN for PrEP**.
- Among participants initiating LEN, most were cis-men (83%) and Black/Pardo (61%). Nearly half were aged 18-24 years (41%) and completed secondary education or lower (41%) (**Table 1**).

Table 1. Characteristics of participants initiating LEN, ImPrEP LEN Brasil.

	n	%
Referral		
Voucher	61	9.4
Other	560	90.6
Previous use of PrEP		
No	510	78.3
Yes	141	21.7
Age (years)		
18-20	59	9.1
21-24	208	32.0
25-30	384	59.0
Gender		
Travesti/Trans woman	73	11.2
Trans man	13	2.0
Non-binary	24	3.7
Cis man	541	83.1
Race		
White	241	37.0
Black	168	25.8
Pardo	227	34.9
Asian	4	0.6
Indigenous	11	1.7
Schooling		
Elementary	13	2.0
Secondary	256	39.3
Superior	382	58.7

- Almost half of LEN injection sites for initial LEN dose were administered on the abdomen (**Table 2**).

Table 2. LEN Injection sites for initial LEN dose, ImPrEP LEN Brasil.

	First Injection		Second Injection	
Left Upper Abdomen	22	3.4%	81	12.4%
Right Upper Abdomen	52	8.0%	84	12.9%
Left Lower Abdomen	95	14.6%	108	16.6%
Right Lower Abdomen	167	25.7%	63	9.7%
Left Thigh	7	1.1%	26	4.0%
Right Thigh	26	4.0%	7	1.1%
Left Arm	84	12.9%	159	24.4%
Right Arm	161	24.7%	84	12.9%
Left Gluteus	20	3.1%	18	2.8%
Right Gluteus	17	2.6%	21	3.2%

Conclusions

- ImPrEP LEN-Brasil implements a person-centered, system-integrated model for LEN delivery.
- Preliminary findings indicate strong demand for LEN among young populations.
- Our results will generate critical implementation evidence to guide equitable scale-up within large-scale public health systems.

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