Rates and predictors of HIV pre-exposure prophylaxis discontinuation by administration schedule in the Italian PrIDE cohort (EPI-PrEP Study)

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Epi-PrEP Study

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Background

Long-term persistence on HIV pre-exposure prophylaxis (PrEP) is essential to maximise its preventive benefits. In Italy, PrEP uptake has increased following the reimbursement of oral PrEP, and recently, long-acting injectable (LAI) PrEP has become available. However, data on PrEP discontinuation remain limited. We aimed to estimate the incidence and predictors of PrEP discontinuation by administration schedule in the Italian PrIDE cohort.

Methods

Epi-PrEP is a retrospective epidemiological analysis including PrEP users enrolled in the Italian multicenter observational PriDE cohort between 2024 and 2025 with at least one follow-up visit after initiation.

PrEP discontinuation was defined as a definitive stop or loss to follow-up during the observation period. Incidence rates of discontinuation (IRD) were calculated per 100 person-years of follow-up (PYFU). Cumulative discontinuation probabilities were estimated using the Kaplan–Meier method. Factors associated with discontinuation were explored using a Cox regression model including time-varying covariates for PrEP schedule and behavioural characteristics.

Results

The 1,298 PrEP users included were mostly Italian (87.6%) cisgender (96.8%) males with a median age of 39 (IQR 33-47) years. 24.7% were PrEP-naïve. Details are summarised in **Table 1**.

Median follow-up was 147.5 (111-197) days. IRD was 25.18 (21.22-29.67) per 100 PYFU.

According to the PrEP schedule, IRD was 33.84 (26.92-42) for daily PrEP, 24.53 (16.43-35.23) for on-demand PrEP, 29.83 (19.11-43.39) for the switching schedule, and 6.31 (2.72-12.43) for long-acting injectable PrEP.

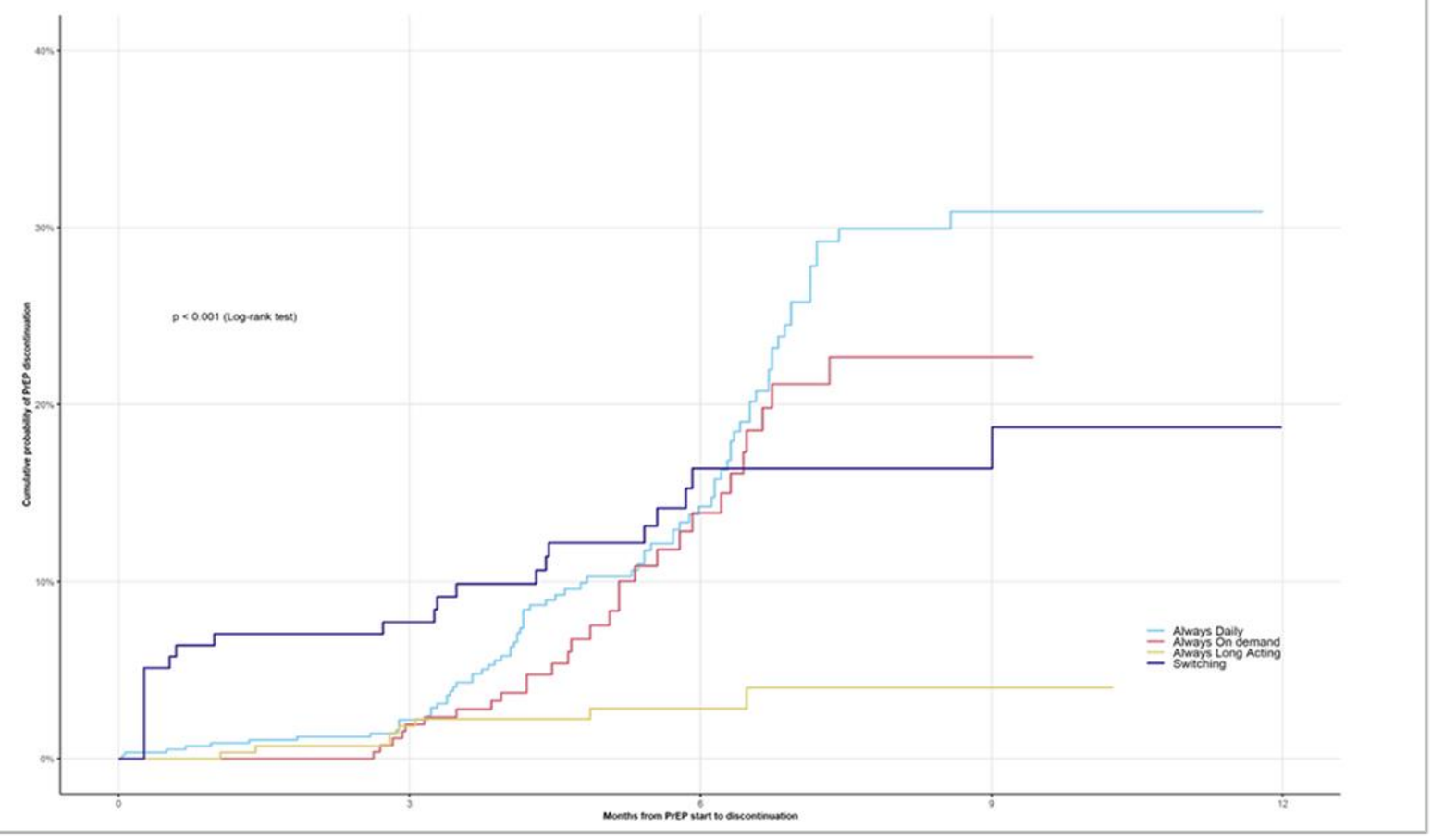
The 1-year cumulative probability of discontinuation was 22.61% (18.22-26.77), lower for LAI PrEP users (4.01%; 0.85-7.07) (**Fig. 1**).

In multivariable analyses, transgender and non-binary people (HR 5.46; 95%CI: 1.06-15.19, p=0.001) and those enrolled in central-south Italy (8.85; 5.43-14.44, p<0.001) showed higher risks of discontinuation. Conversely, sex workers (0.16; 0.03-0.76, p=0.022), people taking PrEP in community-based centres (vs. hospital-based: 0.16; 0.04-0.69, p=0.014) or taking LAI PrEP (vs. daily: 0.3; 0.17-0.54, p<0.001) showed lower discontinuation risks.

Table 1. Characteristics of study population

Variable	Overall n= 1298 (100%)[1]		Overall n= 1298 (100%)[1]
Sex at birth		**Sex-worker**	
Male	1278 (98.5%)	No	1211 (93.3%)
Female	20 (1.5%)	Yes	39 (3.0%)
		Unknown	48 (3.7%)
Age (years)	39.0 (33.0, 47.0)		
Age group		**Gender Identity**	
18-24	40 (3.1%)	Cisgender	1257 (96.8%)
25-39	655 (50.5%)	Transgender	10 (0.8%)
40-64	583 (44.9%)	Non-binary	31 (2.4%)
65+	20 (1.5%)		
Place of birth		**Setting**	
Italy	1137 (87.6%)	Hospital based	1219 (93.9%)
Abroad	161 (12.4%)	Community-based	79 (6.1%)
Education level		**Sexual orientation**	
Middle school or less	50 (3.9%)	GBMSM	1268 (97.7%)
High school	407 (31.4%)	Bisexual Female	10 (0.8%)
University	818 (63.0%)	Heterosexual	20 (1.5%)
Unknown	23 (1.8%)		
Employment status		**Geographic area**	
Employed	1197 (92.2%)	North	720 (55.5%)
Student	63 (4.9%)	Centre	570 (43.9%)
Retired	17 (1.3%)	South and Islands	8 (0.6%)
Unemployed	0 (0.0%)		
Unknown	21 (1.6%)		
PrEP Schedule		**Previous PrEP use**	
Always Daily	570 (43.9%)	No	320 (24.7%)
Always On demand	273 (21.0%)	Yes, ongoing	930 (71.6%)
Always Long Acting		Yes, interrupted	47 (3.6%)
Switching	299 (23.0%)	Unknown	1 (0.1%)
	156 (12.0%)		
[1] n (%); Median (Q1, Q3)			

Figure 1. Kaplan-Meier curve for the one-year cumulative discontinuation according to the administration schedule



Conclusions

Discontinuation remains common in real-world PrEP use and varies substantially by administration schedule, service delivery model, and population subgroups. Differentiated, person-centred PrEP pathways and targeted retention strategies are needed to improve long-term PrEP continuity and maximise prevention.

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