Impact of Italian Medicines Agency (AIFA) reimbursement on the PrEP-naive population characteristics and incidence of sexually transmitted infections

U-09

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BACKGROUND

Pre-exposure prophylaxis (PrEP) is a cornerstone of HIV prevention worldwide**. In Italy, a decisive policy shift occurred in May 2023 with the introduction of reimbursement by the Italian Medicines Agency (AIFA)**, making users exempt from paying for TDF/FTC supplies via the national healthcare system. Until then, PrEP was only available out-of-pocket, representing a significant barrier to uptake.

We conducted a retrospective study to evaluate the impact of PrEP reimbursement on STI incidence and to explore demographic differences between individuals initiating PrEP before and after reimbursement

METHODS

Monocentric observational cohort study at the Infectious Diseases Unit of IRCCS Policlinico of Milan, a tertiary public research facility comprising a sexual health clinic. We analyzed all PrEP-naive individuals initiating PrEP from January 1, 2022 to December 31, 2023 enrolled in two different groups:

- Group 1, who started PrEP (T0 before AIFA reimbursement (T0–T1) and was observed during the reimbursed phase (T1–T2);
- Group 2, who initiated PrEP (T0) after reimbursement (T0 - T1).

Demographic, behavioral data, prior STIs and PEP use, PrEP regimen, retention, and vaccination status (HAV, HBV, HPV, Mpox) were collected. STI incidence was expressed as rates per 100 person-years (py). Chi-squared, Fisher's exact and Student's t-test were used for categorical and continuous variables, respectively.

The study was approved from the local ethics committee with code 0039795 - U

The results of *Free-PrEP Study* show that **national PrEP reimbursement significantly improved access to PrEP**, vaccination prevention, and the integration of sexual health services in Italy, **without leading to an increase in overall STI incidence**.

PrEP is confirmed not only as a pharmacological intervention, but as a **comprehensive model of integrated prevention**, capable of improving public health and meaningfully contributing to the global goal of ending HIV transmission.

RESULTS

During the study period, 97 participants met inclusion criteria out of 350 screened: 35 in Group 1 and 62 in Group 2. Median age was 34 years. Participants were predominantly men who have sex with men (MSM, 97.9%), with a small proportion of transgender women (TGW); most resided in the Milan metropolitan area. More than 60% of participants reported ≥1 prior STI, most commonly gonorrhea and syphilis. 27.8% had previous PEP use and approximately 13% reported chemsex. On-demand PrEP was the most frequently used regimen. During follow-up, STI incidence was 47.5 per 100 person-years, consistent with major European PrEP cohorts. Approximately 25% of participants were lost to follow-up. **Vaccination coverage increased substantially during follow-up**.

Table 1. Incidence rates (expressed as incidence per 100 persons/year) and rate ratios of sexually transmitted infections among subjects included in the study

	Overall (N=97)	Group 1 (N= 35)					Group 2 (N=62)		
	T0 - T1, (95% CI)	T0 - T1, (95% CI)	T0 - T2, (95% CI)	T1-T2, (95% CI)	IRR° (95% CI)	p	T0 - T1 (95% CI)	IRR* (95% CI)	p
At least 1 STI	47.49 (34.01-66.15)	49.77 (28.9-85.7)	27.23 (16.12-45.97)	49.84 (30.53-81.35)	0.58 (0.32-1.06)	0.076	45.68 (29.14-71.62)	0.92 (0.54-1.56)	0.76
Syphilis	15.56 (8.84-27.40)	22.97 (10.32-51.13)	16.9 (7.59-37.61)	0	0.00 (0.00-0.00)[1]	**<0.001**	14.43 (6.48-32.11)	0.63 (0.22-1.76)	0.380
Gonorrhea	23.75 (14.96-37.69)	22.97 (10.32-51.12)	49.51 (18.58-131.91)	29.24 (15.73-54.34)	0.56 (0.15-2.06)	0.380	19.24 (9.62-38.46)	0.84 (0.32-2.19)	0.718
Chlamydia	16.79 (9.75-28.92)	15.31 (5.75-40.80)	19.54 (9.32-40.99)	30.92 (9.97-95.86)	0.83 (0.25-2.83)	0.770	14.43 (6.48-32.11)	0.94 (0.22-2.99)	0.920
Mpox	3.80 (1.23-11.79)	0	2.68 (0.38-19.02)	8.93 (1.26-63.38)	0.00 (0.00-0.00)[1]	**<0.001**	4.81 (1.20-19.23)	0.00 (0.00-0.00)[2]	**<0.001**

° Rate ratio between T0-T1/T1-T2 for Group 1
*Rate ratio between Group 1 and Group 2 during T0-T1
[1]No cases observed in Group 1 during T1-T2; the IRR is estimated near zero.
[2]No cases observed in Group 1; the IRR is estimated near zero.

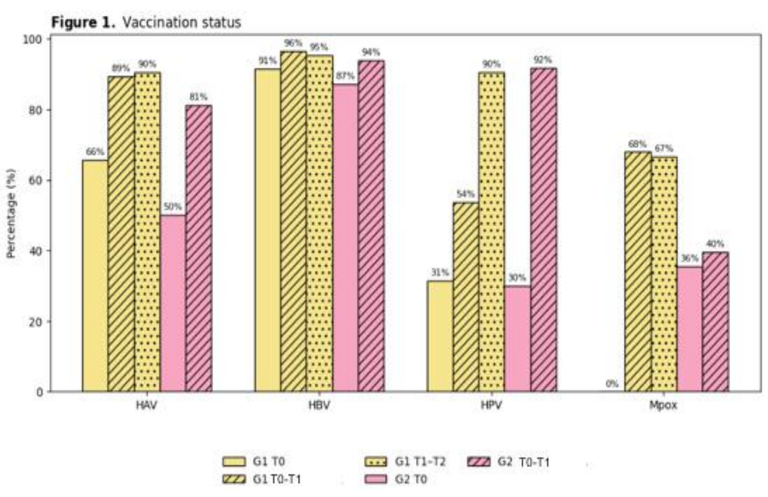
CONCLUSIONS

National "Agenzia Italiana del Farmaco" (AIFA) reimbursement was associated with improved PrEP access and greater engagement in integrated prevention services. **By removing financial barriers, reimbursement facilitated new user enrolment and increased vaccination uptake**.

Despite persistently high rates of gonorrhea and chlamydia, syphilis incidence declined markedly during the reimbursement phase in Group 1, supporting the role of regular screening and early treatment within PrEP programs.

Overall, national reimbursement strengthened PrEP as a platform for comprehensive sexual health prevention in Italy. However, loss to follow-up remained high, highlighting the need for retention strategies to maximize long-term public health impact.

Figure 1. Vaccination status



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