

Implementation of a provincial PrEP clinic: analysis by public refundability and new HIV infection diagnoses in Latina

A. Carraro^{1,2}, L. Cimino¹, G. Mancarella^{1,2}, R. Marocco², S. De Maria^{1,2}, S. Corazza¹, A. Grimaldi¹, A. Gasperin¹, M. D'Achille², V. Rossi², A. Carlesso², M. Renzelli², L. De Angelis², O. D'Onofrio², P. Addio³, G. Bonanni³, C. Del Borgo², A. Carnevale⁴, M. Lichtner⁵

1 Department of Public Health and Infectious Disease, Sapienza University of Rome, Rome, Italy 2 Infectious diseases Unit, SM Goretti Hospital, Sapienza University of Rome, Latina, Italy 3 Pharmacy Unit, SM Goretti Hospital, Latina, Italy 4 Arcigay Latina SeiComeSei 5 Department of NESMOS, Sapienza University of Rome, Rome, Italy

Introduction

- The incidence of new HIV infections in Italy is 3.2 new cases per 100.000 habitants (EU incidence 5.1).
- UNAIDS goal is getting to zero in 2030; this objective is achievable through various strategies (TasP, PEP, PrEP,...).
- PrEP (with TDF/FTC) effectiveness is about 100%.
- The refundability of the drug makes treatment more accessible. In Italy TDF/FTC as PrEP is free of charge since 2023.

Methods

- Retrospective observational study** (median follow up 48 weeks).
- Centre of care:** Infectious Diseases Unit, S.M. Goretti Hospital, Sapienza University of Rome, Latina.
- Investigation performed:** as indicated national treatment plan.
- Main population:** PrEP users since December 2019 to December 2023.
- Control population:** People living with HIV (PLWH) with a new HIV diagnosis (2017-2018 and 2022-2023).
- PrEP free of charge was available in our outpatient clinic since **October 2023**.
- PrEP clinic activity has been advertised on official Regione Lazio, ASL Latina and Checkpoint Latina **website** and on relative social media.
- A flyer was available for all PrEP users.



Results

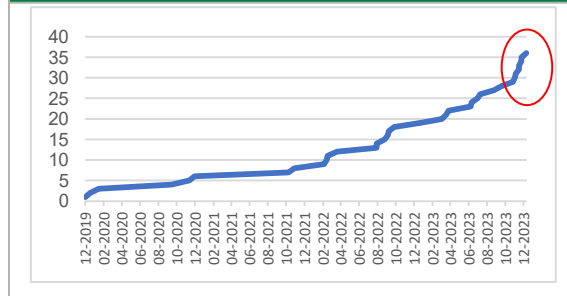
PrEP users population

- PrEP users: 45; population characteristics in (Table 1). No seroconversion was observed (efficacy 100%); none major adverse effects.
- A constant access of new subjects, but a more rapid increase of users in last months (after October 2023) was seen (Graph 1).
- After refundability, daily intake increases compared to on-demand (16,6% vs 33,3% (p=0,05)).

Table 1. PrEP population characteristics

Characteristic	n (%)
Sex	
Male	44 (97.7%)
Age	
Median (Min-Max)	36 (22-65)
Nationality	
Italian	43 (95.5%)
Sexual Relations	
Omosex (MSM)	43 (95.5%)
Pre-enlistment STI	
Positivity for IST	20 (44.4%)
Risk Factors	
Occasional use of condoms	28 (62.2%)
No condom use	15 (33.3%)
Intravenous drugs	1 (2.2%)
Chemsex	1 (2.2%)
Previous uses of PEP	
no	41 (91.1%)
Adverse Effects	
no	45 (100%)

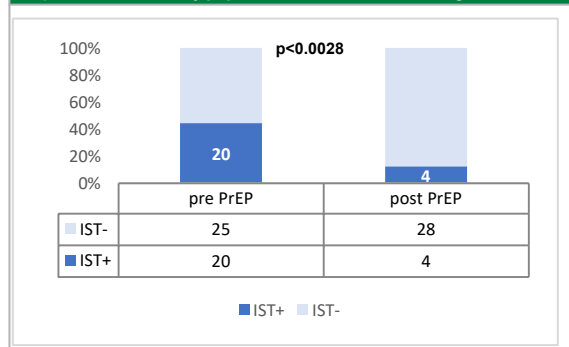
Graph 1. PrEP users in Infectious Diseases Unit, S.M. Goretti Hospital



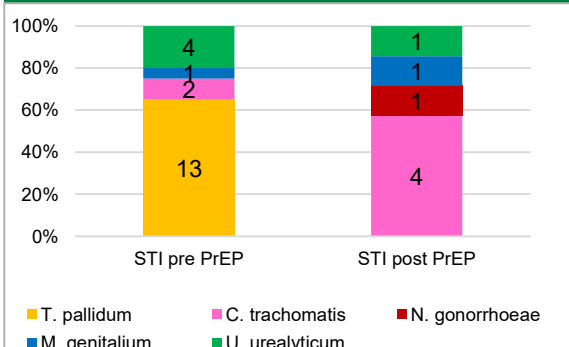
STI pre and post PrEP

- During PrEP users, there was an unexpectedly decrease of STI (Graph 2 and 3).

Graph 2. STI in the study population before and after taking PrEP



Graph 3. Sexually Transmitted Infections, for etiology



Impact of PrEP on new diagnoses

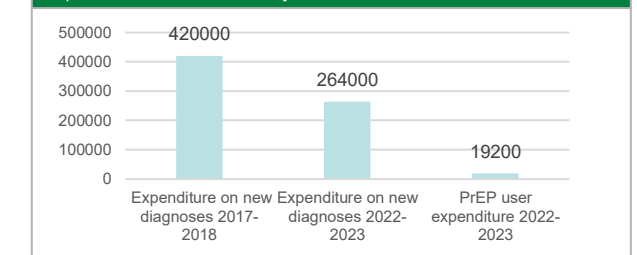
- New PLWH biennium 2017-2018 are more than in biennium 2022-2023; main reduction is observed among men who have sex with men (MSM) that are the major PrEP users (table 2).

Table 2. PrEP and PLWH population characteristics

Characteristic	2017 - 2018	2022 - 2023	PrEP users
Sex			
Male	30 (66.6%)	28 (77.7%)	44 (97.7%)
Female	15 (33.3%)	8 (22.2%)	1 (2.2%)
Età			
Min-Max	26-73	21-67	22-65
Average	46,7	41	38
Median	46	38	36
Nationality			
Italian	27 (60%)	19 (52.7%)	43 (95.5%)
Foreign	18 (40%)	17 (47.2%)	2 (4.4%)
Risk Factors			
Eterosex	25 (55.5%)	18 (50%)	2 (4.4%)
Omosex (MSM)	20 (66.6%)	13 (46.4%)	43 (97.7%)
TD	0	5 (13.8%)	0

- The public expenditure only for ART for PLWH with new diagnosis for biennium 2017-2018 was € 420.000, and for biennium 2022-2023 was € 264.000. The expenditure for PrEP in biennium 2022-2023, assuming that everyone takes drugs daily (overestimating their consumption), was €19.200 (graph 4)

Graph 4. Estimated Public Expenditure for ART and PrEP



Conclusions

- In our experience, PrEP has an extremely high efficacy and without consequent side effects.
- After PrEP start, a lower rate of STI was registered than before.
- The refundability has impact on PrEP adherence and on frequency of intake.
- The inversion of MSM rate in new HIV diagnosis could be associated to PrEP access, even if a deeper analysis and longer follow-up should be done.
- Public expenditure for PrEP is much lower than for ART. In terms of pharmacoeconomics, it is convenient to invest on PrEP.

References

Devarajan, S., Sales, J. M., Hunt, M., & Comeau, D. L. (2020). PrEP and sexual well-being: a qualitative study on PrEP, sexuality of MSM, and patient-provider relationships. *AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV*, 32(3), 386-393. <https://doi.org/10.1080/09540121.2019.1695734>

Orser, L., & O'Byrne, P. (2019). The role of public health units in the delivery of HIV pre-exposure prophylaxis (PrEP). *Canadian Journal of Public Health* (Vol. 110, Issue 1, pp. 72-75). Springer International Publishing. <https://doi.org/10.17269/541997-018-0141-7>

Reyniers, T., Nöstlinger, C., Laga, M., De Baetselier, I., Crucitti, T., Wouters, K., Smekens, B., Buyze, J., & Vuylsteke, B. (2018). *Choosing Between Daily and Event-Driven Pre-exposure Prophylaxis: Results of a Belgian PrEP Demonstration Project*. <https://journals.lww.com/ajids>

Schumacher, C., Wu, L., Chandran, A., Fields, E., Price, A., Greenbaum, A., Jennings, J. M., Page, K., Davis, M., Ryscavage, P., Jones, J. L., Farley, J., Arrington-Sanders, R., Tepper, V., & Demissew, M. (2020). Sexually transmitted infection screening among gay, bisexual, and other men who have sex with men prescribed pre-exposure prophylaxis in Baltimore City, Maryland. *Clinical Infectious Diseases*, 71(10), 2637-2644. <https://doi.org/10.1093/cid/ciz1145>