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Predictors of linkage to prevention services after HIV post-exposure prophylaxis (PEP): A single-centre retrospective analysis, years 2019-2024

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ABSTRACT

Objectives: Post-exposure prophylaxis (PEP) remains underutilised and real-world data on its role within prevention pathways are limited.
We aimed to describe PEP use following sexual exposure and to identify predictors of linkage to prevention services within three months in a real-world clinical setting.
Methods: We conducted a retrospective observational study of PEP prescriptions following sexual exposure at the HIV Voluntary Counselling and Testing site of the National Institute for Infectious Diseases in Rome. Data included demographics, exposure, prior PEP/PrEP use, and follow-up through March 31, 2025. Mixed-effect logistic regression identified predictors of linkage to prevention services within three months.
Results: A total of 1366 PEP prescriptions were issued to 1188 individuals from January 2019 - December 2024. In 85.1% of the occasions, users were assigned male at birth and in 80.5% Italian-born. The most common exposures included receptive anal intercourse (35.3%), insertive anal intercourse (26.5%), insertive vaginal intercourse (11.2%), and sexual assault (8.5%). Prior PEP and PrEP were reported in 16.7% and 4.7% of the occasions, respectively. Follow-up was recommended in all; PrEP was advised in 46.1% occasions and initiated in 17.4%. Overall, users returned for follow-up in 46.5% of the cases. Multivariable analysis (n = 871) showed that active PrEP recommendation and age ≥35 years were positively associated with reattendance, while foreign birth and prior PEP were negatively associated. Nine persons (0.7%) were tested HIV positive; two at baseline and seven after PEP, suggesting missed opportunities for timely prevention.
Conclusions: This large-scale analysis from an Italian setting highlights the role of PEP as an entry point into HIV prevention pathways, while confirming gaps in linkage to ongoing preventive care. The Italian context, characterised by a high proportion of late HIV diagnoses and ongoing PrEP implementation, underscores the importance of strengthening prevention strategies. Structured follow-up and facilitated linkage to PrEP, when appropriate, may help maximise its preventive impact.

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Introduction

Postexposure prophylaxis (PEP) is an effective and consolidated tool for preventing HIV infection following a recent high-risk exposure. Although PEP is a short-term pharmacological measure delivered in the emergency setting, it should also represent an 'educable moment' for those at ongoing HIV risk and a chance for linkage to long-term HIV/STI prevention programmes, such as frequent testing, STI vaccinations, and pre-exposure prophylaxis (PrEP) [1,2]. However, for individuals with infrequent exposures, PEP itself may represent an appropriate and sufficient prevention strategy, without the need for continuous preventive intervention.

In Italy, sexual transmission accounts for more than 85% of new HIV diagnoses, with a high proportion of late presenters: in 2023, 60% of new cases presented with a CD4 count below 350 cells/mm^3 [3].

Several observational studies have shown a particularly high incidence of new HIV infections in individuals who previously used PEP, mainly in men who have sex with men (MSM) [4–7].

These findings underscore the urgency of strengthening combined preventive interventions and highlight the need for early interception strategies for people most at risk, including in Southern European settings.

Despite its availability, PEP uptake seems to be underutilised globally, and links to other prevention services are suboptimal. Observational studies conducted in the United States and Europe have highlighted that a significant proportion of PEP users do not return to health services after the end of prophylaxis and do not have access to long-term prevention tools, such as PrEP [1,8].

A proposed strategy to overcome these missed opportunities for HIV prevention is to offer PrEP immediately after the end of PEP, where indicated, with the aim of ensuring protective continuity and facilitating maintenance in prevention pathways [9]. This approach has been described as 'PEP2PrEP' and has been associated with increased PrEP uptake [10].

Evidence on predictors of follow-up after PEP is scarce, particularly in public health services in southern Europe.

The aim of this study is to describe the characteristics of PEP recipients in a large public HIV clinical and prevention service in the metropolitan area of Rome, Italy, and explore predictors of linkage to prevention services within 3 months of PEP initiation.

Materials and methods

Study design

We conducted a retrospective observational study at the HIV Voluntary Counselling and Testing site (VCTS) of the National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS in Rome, Italy. The Institute serves as the regional reference centre for diagnosis and care of HIV/AIDS. The VCTS provides both walk-in and appointment-based services for HIV testing and counselling, STI screening, treatment and vaccinations, PEP and PrEP prescription.

The study period spanned from January 1, 2019, to December 31, 2024.

Participants

We included all individuals aged 18 years or older who voluntarily presented at the centre within the first 72 hours following a sexual exposure and were advised to start PEP during the study period.

Procedures and outcomes

PEP was prescribed in accordance with the National and European clinical guidelines available at the time of care [11,12]. Antiretroviral regimens included emtricitabine/tenofovir disoproxil fumarate (FTC/TDF), combined with either raltegravir (RAL) or dolutegravir (DTG), based on available data regarding its high efficacy, tolerability, and long-term safety.

HIV/STI screening was routinely recommended at baseline (PEP prescription) and 6-8 weeks after PEP completion [11,12].

In our setting, PrEP initiation, when indicated, was primarily performed at the post-PEP follow-up visit (6-8 weeks after completion), after confirmation of a negative HIV test. Since October 2024, an immediate transition to PrEP without interruption has been implemented for selected individuals, with initiation occurring at the follow-up visit at PEP completion. We conducted a case-note review through medical records and collected demographic and behavioural data, including self-reported sex, gender, type of exposure, previous PEP or PrEP use (either self-reported or documented), and follow-up consultations, up to March 31, 2025.

Statistical analysis

Patient baseline clinical features were analysed, and we determined predictors of linkage to prevention services within 3 months, alongside the characteristics of HIV seroconversion observed during the study.

Descriptive statistics were used to summarise patient characteristics and HIV seroconversions occurred during the observation, reporting frequencies and proportions for categorical variables, medians with interquartile ranges (IQR) for continuous variables. Univariable and multivariable mixed-effects logistic regression models with a logit link function were fitted to identify predictors of linkage to prevention services. Candidate covariates were selected a-priori according to clinical reasoning and prior literature. Random intercepts at the patient level were included to account for within-subject correlation arising from repeated visits. Observations with missing data for the included covariates were excluded from the regression analysis. Results are presented as unadjusted and adjusted odds ratios (ORs) with 95% confidence intervals (CIs), computed using the Wald method. Absence of multicollinearity between the included covariates was assessed by computing and inspecting Variance Inflation Factors (VIFs), with no factor exceeding the conventional threshold of 5.

All tests were two-tailed, and P-values <0.05 were considered significant.

Analyses were performed using R Version 4.2.1, 2022-06-24. (R Core Team, 2022).

Results

During the study period, PEP was prescribed on 1366 occasions to 1188 distinct individuals. In 1163 (85.1%) occasions, participants were assigned male at birth, and 39 (2.9%) identified as transgender. Overall, 858 (62.8%) prescriptions were to gay, bisexual, or other men who have sex with men (GBMSM), and 1099 (80.5%) to persons born in Italy.

The most frequently reported risk exposure was receptive anal intercourse (482, 35.3%), followed by insertive anal intercourse (362, 26.5%), insertive vaginal intercourse (153, 11.2%), and sexual assault (116, 8.5%). Previous PEP use was reported in 228 cases (16.7%), prior PrEP use in 64 (4.7%), and chemsex during exposure in 101 (7.4%) (Table 1).

Table 1
Characteristics of individuals receiving PEP after sexual exposure from 2019 to 2024 (N = 1366).

Variable	n (%)
Demographics	
Sex assigned at birth: male	1163 (85.1)
Gender identity: transgender	39 (2.9)
Sexual orientation GBMSM	851 (62.8)
Born in Italy	1099 (80.5)
Age, years, median (IQR)	33 (27-41)
Risk exposure	
Receptive anal sex	482 (35.3)
Insertive anal sex	362 (26.5)
Insertive vaginal sex	153 (11.2)
Receptive vaginal sex	83 (6.1)
Sexual assault	116 (8.5)
Injecting equipment sharing	2 (0.1)
ND	52 (3.8)
Behavioural data	
Chemsex use	101 (7.4)
Previous PEP	228 (16.7)
Previous PrEP use	64 (4.7)
Prevention outcomes	
PrEP recommended	630 (46.1)
Any access to prevention services within 3 months after PEP	635 (46.5)
PrEP initiation after PEP	238 (17.4)
PEP2PrEP (October-December 2024), n/N (%)	16/23 (69.6)
HIV outcomes	
HIV seroconversion, n (%)	9 (0.7)

GBMSM: gay, bisexual and other men who have sex with men. IQR: interquartile range; PEP: post-exposure prophylaxis; PrEP: pre-exposure prophylaxis; ND: not documented.

Follow-up consultation for HIV/STI screening was suggested for every PEP recipient. PrEP initiation was recommended in 630 instances (46.1%), with 238 (17.4%) resulting in PrEP initiation during follow-up. Overall, 635 individuals (46.5%) returned for HIV/STI screening and/or other prevention services (i.e., STI vaccinations) within the following 3 months.

Since October 2024, an immediate transition to PrEP has been offered following the completion of PEP. Among the 23 individuals completing PEP from October 1, 2024, to December 31, 2024, 16 (69.6%) started oral PrEP with TDF/FTC immediately after PEP without interruption (6.7% of all PrEP initiators cited above).

The number of PEP prescriptions increased over the study period, with a notable rise after 2023 (Figure 1). This upward trend was paralleled by a progressive increase in the number of users accessing prevention services within the following 3 months and initiating PrEP following PEP prescription.

Multivariable logistic regression analysis included 871 visits with complete data, corresponding to 751 individuals. Active PrEP recommendation was the strongest positive predictor of follow-up attendance (aOR 2.72, 95% CI 1.87-3.94; $P < 0.0001$). Compared to users aged 25-34 years, those aged 35-44 (aOR 1.57, 95% CI 1.06-2.32, $P = 0.024$) and over 45 years (aOR 1.95, 95% CI 1.25-3.05, $P = 0.0034$) were significantly more likely to return. Conversely, being born abroad was negatively associated with follow-up (aOR 0.38, 95% CI 0.25-0.59, $P < 0.0001$), as was previous PEP use (aOR 0.63 95% CI 0.42-0.96, $P = 0.031$) (Table 2). Unadjusted ORs are presented in table S1.

Overall, nine individuals (0.7%) were diagnosed with HIV. Two tested positive at baseline, indicating that they acquired HIV before PEP initiation, and continued antiretroviral drugs as treatment.

The remaining seven seroconversions occurred after the completion of PEP. A detailed analysis of the seven individuals who seroconverted after PEP completion is reported in Table 3. All were men at birth with no prior PrEP exposure; one individual was born in Brazil. Six out of seven had a documented negative fourth-generation HIV Ab/Ag test at least 6 weeks after completing PEP, suggesting that infection occurred after the prophylaxis period. One individual (case 1) did not attend post-PEP HIV testing, and seroconversion was documented 13 months later; in this case, the timing of infections is uncertain, and a PEP failure cannot be excluded.

The time between last HIV negative test and documented HIV seroconversion ranged from 12 to 165.29 weeks. All initiated antiretroviral therapy promptly after diagnosis, receiving regimens consistent with national and European guidelines [11,12]. Baseline viral loads varied from 1456 to 2 million copies/ml Genotyping resistance testing (GRT) was available in six cases and revealed a wild-type virus, except for one case with an isolated integrase mutation (G163K) of uncertain clinical relevance. All those with available data achieved virological suppression at 12 months.

Discussion

Despite decades of progress, HIV remains a global health priority. Our findings confirm that PEP continues to represent an effective and timely intervention to prevent HIV acquisition after high-risk exposure.

However, the study also revealed concerning missed opportunities to connect individuals to long-term prevention pathways. Identifying predictors of linkage to prevention among high-risk populations is helpful in developing new strategies that can contribute to the objective of eliminating HIV transmission by 2030 [13].

Fewer than half of PEP users returned for follow-up, and only one-third of those considered eligible started PrEP. Similar patterns have been described in Spain and the UK, with substantial proportions of PEP users not transitioning to PrEP, indicating persistent challenges in translating PEP into structured prevention engagement [8,14].

Although follow-up after PEP was routinely recommended to all users, no standardised approach was consistently applied across healthcare providers over the study period. In some cases, follow-up was only verbally encouraged, while in others, written appointments or formal referrals were provided. Similarly, not all prescribing physicians recommended PrEP even when clinical indications were present. This variability may reflect evolving national policies and PrEP eligibility criteria over time, as well as heterogeneity in clinical practice or confidence in discussing and managing PrEP.

Other user-related factors may have contributed to this low linkage rate, such as a low-risk perception, reluctance to commit to continuous long-term prevention strategies, or practical access barriers. It should also be considered that not all individuals receiving PEP require ongoing prevention strategies. For those with infrequent or episodic exposures, PEP may represent an appropriate and sufficient approach, and lack of reattendance may not necessarily reflect a gap in care but rather a prevention strategy aligned with individual risk patterns and preferences.

In the future, it will be beneficial to investigate the reasons for non-return and develop tools to enhance the role of PEP as an effective bridge.

Our findings should be interpreted in the context of national prevention policies and their evolution during the study period. In Italy, clinical PrEP eligibility guidelines were first introduced in 2017 by the Italian Society of Infectious and Tropical Diseases (SIMIT) [11]. Still, uptake remained limited for years due to the lack of reimbursement and structural barriers to access. Although oral PrEP with generic co-formulated tenofovir disoproxil fumarate 245 mg/emtricitabine 200 mg tablets was available, it was not covered by the National Health System until May 2023, when the Italian Medicines Agency (Agenzia Italiana del Farmaco, AIFA) officially approved its reimbursement for adults and adolescents at high risk of HIV [15]. However, costs related to the recommended STI testing

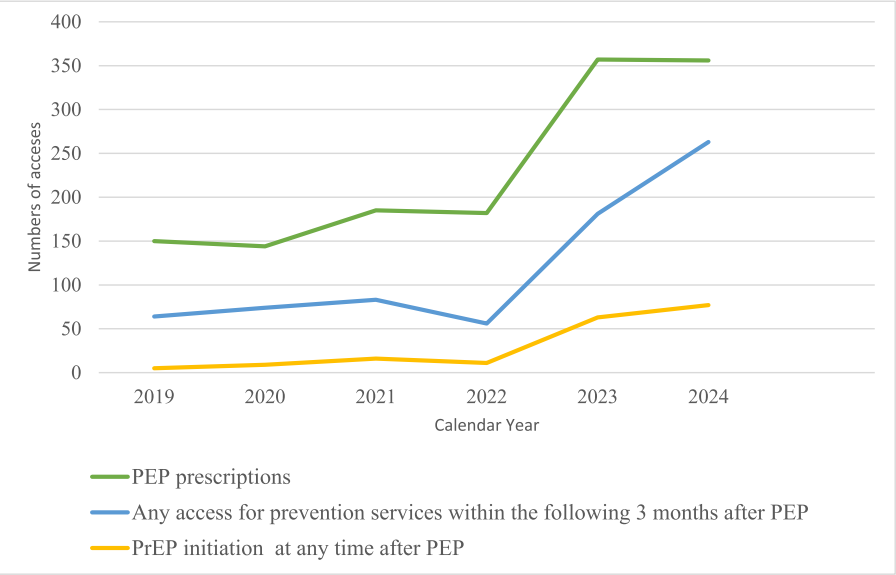

Figure 1. Number of PEP prescriptions following sexual exposure and subsequent accesses for prevention services within the following 3 months and PrEP initiation after PEP across time, 2019-2024. Note: Any access for prevention services within the following 3 months has been considered if the person attended the service for either PrEP initiation, STI screening, HIV testing, and/or vaccinations following PEP prescription, after completion, within 3 months.

Table 2
Predictors of linkage to prevention services within 3 months after PEP prescriptions for sexual exposure.

Predictors	Reference	aOR	95% CI	*P*-value
Sexual orientation: GBMSM	Heterosexual of all gender	1.09	0.76-1.57	0.63
Age group <24	Age group: 25-34 years	1.04	0.64-1.66	0.89
Age group 35-44	Age group: 25-34 years	1.57	1.06-2.32	**0.024**
Age group ≥45	Age group: 25-34 years	1.95	1.25-3.05	**0.0034**
Nationality-Born abroad	Italian born	0.38	0.25-0.59	**<0.0001**
Chemsex use	No	0.65	0.38-1.12	0.12
Previous HIV test	No	1.07	0.71-1.60	0.75
Previous PEP	No	0.63	0.42-0.96	**0.031**
Previous PrEP	No	1.75	0.87-3.52	0.11
Active PrEP recommendation	No	2.72	1.87-3.94	**<0.0001**

Observations 871
aOR: Adjusted Odds Ratio; CI: 95% Confidence Interval; GBMSM: Gay, bisexual and other men who have sex with men; PEP: post-exposure prophylaxis; PrEP: pre-exposure prophylaxis.
The values in bold are the significant values, *p*-value <0.05 have been considered significant as described in Materials and methods section.

Table 3
Characteristics of HIV seroconversions occurred after the completion of PEP.

Case	Age	Sex at birth	Country of birth	Year of last PEP prescription	Prior PrEP exposure	Time between PEP completion and last HIV negative test (days)	Time between last HIV negative test and HIV seroconversion (weeks)	VL at baseline (copies/ml)	GRT at baseline	ART regimen	VL at 12 months (copies/ml)
1	44	M	Italy	2019	No	1	56.43	27.193	G163K	3TC + DTG	<30
2	32	M	Italy	2019	No	1128	12.00	2.349.828	Wild type	TDF/FTC + DTG	<30
3	26	M	Italy	2019	No	158	50.86	42.604	Wild type	TDF/FTC + DTG	<30
4	29	M	Italy	2019	No	57	165.29	24.406	Wild type	BIC/FTC/TAF	<30
5	58	M	Italy	2020	No	161	28.43	59.133	Wild type	BIC/FTC/TAF	<30
6	31	M	Brazil	2020	No	518	31.71	1.456	Not available	RPV + TDF/FTC	Not available
7	27	M	Italy	2023	No	156	19.29	5.113	Wild type	BIC/FTC/TAF	<30

PEP: post-exposure prophylaxis; PrEP: pre-exposure prophylaxis; VL: viral load; ART: antiretroviral therapy; GRT: Genotyping resistance testing.

and renal function remained the responsibility of clients in most Italian regions, possibly contributing to limited uptake [16].

While PrEP initation showed marked increase after the introduction of national reimbursement in mid-2023, the number of PEP prescriptions also continued to rise during this period in our study. This trend suggests a persistent unmet need for PrEP among high-risk populations and reinforces the need for more proactive and tailored prevention counselling during PEP encounters.

Temporal trends should also be interpreted in light of the COVID-19 pandemic. Although our VCTS continued to offer prevention services throughout 2020, access was substantially reduced during that year due to public health restrictions.

In multivariate analysis, active counselling for PrEP initiation was the strongest predictor of re-engagement in HIV/STI prevention services among PEP users. Age also showed a significant association with follow-up: lower follow-up rates among younger

users may be attributed to a limited risk perception and low familiarity with biomedical prevention strategies. Previous studies reported poor awareness and acceptability of PEP and PrEP among adolescents and young adults in various settings, including Kenya, Brazil and Australia [17–19] highlighting the need for targeted educational programmes to improve engagement in this population.

Conversely, being born abroad and previous PEP experience were negatively associated with follow-up. These findings may reflect structural, linguistic, or cultural barriers in accessing prevention services. Addressing these disparities will require innovative integrated services that combine targeted outreach, such as peer education and collaboration with migrant community organisations, with culturally tailored approaches to strengthen engagement across the 'HIV prevention continuum' [20].

Our data underline the urgency of valorising PEP as an unmissable opportunity for people at risk of HIV transmission to enter the prevention continuum. In this context, it is necessary to implement the so-called PEP2PrEP approach, recommended by international guidelines [9,21,22] and already adopted in various settings, including a large sex clinic in UK and a nurse-led clinic in Canada [10,23].

Unexpectedly, previous PEP use was associated with a lower probability of reattendance within 3 months. This finding suggests that previous PEP experience, if not accompanied by effective counselling, may fail to establish a lasting connection to prevention services. It may also suggest a lack of risk perception by some people who choose PEP as the only pharmacological tool for HIV prevention.

Although rare, the seven seroconversions occurring after PEP suggest that individuals may continue to engage in high-risk behaviours if not effectively linked to long-term prevention tools. For those with infrequent exposures and low perceived risk, alternative strategies, such as PEP-in-pocket [24], may offer a valuable alternative.

This study has some limitations. First, it was conducted in a single centre; even though it is a regional reference centre for HIV/AIDS, our findings may not be generalizable to other settings. Second, the retrospective design has limited the availability of detailed socio-demographic data and behavioural variables, such as education level, immigration status, and reasons for non-return. Moreover, follow-up information was not systematically collected and thus not available for all individuals. Lastly, due to the lack of a centralised health data system, we could not account for individuals who may have accessed prevention services at other settings after PEP, which may lead to an underestimation of linkage rates.

Conclusions

In conclusion, our findings highlight that a substantial proportion of people receiving PEP are not linked to long-term HIV prevention services, despite being at risk for HIV infection. However, this should be interpreted in light of the fact that PEP may represent an appropriate prevention strategy for individuals with infrequent exposures. Specific barriers affect foreign-born individuals, who may require targeted interventions to provide equitable and accessible services. Standardising follow-up procedures and implementing the PEP2PrEP approach could represent effective strategies to strengthen prevention pathways and accelerate progress towards HIV elimination goals.

Ethical approval

Ethics approval was not required for this retrospective, non-interventional study, conducted in a public research hospital, as data were collected routinely during clinical practice and fully anonymised at collection.

Author contributions

VM and AA ideated the study. RE, GM, AG, AO, RS, SP, PF, EG and VB collected data from clinical records. RE and GM wrote the first draft of the manuscript. AC, GM, and AL performed the statistical analysis and were responsible for data management. All authors approved the final version of the manuscript. AC, RE, GM, AG, AL, VM, AO, RS, SP, PF, FV, and VB had full access to data, and all authors had final responsibility for the decision to submit for publication.

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Declaration of competing interest

The authors have no competing interests to declare.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ijid.2026.108679.

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