



Implementation of HIV pre-exposure prophylaxis (PrEP) in Italy (2023-2024): Results from the PrIDE cohort survey

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ABSTRACT

Objectives: Italy introduced reimbursement for oral HIV pre-exposure prophylaxis (PrEP) in 2023. We examined PrEP implementation in Italy from 2023 to 2024 to evaluate regional uptake.

Methods: A nationwide survey within the scope of the PrIDE cohort (NCT07186244) was conducted across 62 infectious diseases and community-based centers in Italy in 2023 and 2024. Data were collected on individuals who started PrEP and those in follow-up, demographics, and the people with HIV (PWH) to PrEP users ratio, as proxy for unmet prevention need. We compared metrics before and after PrEP reimbursement and analyzed regional disparities.

Results: PrEP uptake increased substantially in 2024, with a cumulative number of users increasing by 51.6% (10,697 in 2023, 16,220 in 2024). Growth was uneven across regions: Sardinia (+71.4%), Friuli (+65.4%), and Emilia-Romagna (+54.7%) experienced the most significant increases. Most PrEP users remain concentrated in certain regions (Lombardy, Lazio, and Emilia-Romagna accounting for 75.6%) and were male (95.7%). Overall, 11,785/16,220 (72.7%) individuals were retained in care through 2024. The PWH/PrEP ratio improved nationally in 2024, but remained high in some areas.

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Conclusion: The PrIDE survey shows an increase in PrEP uptake and services expansion after reimbursement in Italy. However, significant regional disparities and structural barriers endure.

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Introduction

HIV pre-exposure prophylaxis (PrEP) is a highly effective biomedical intervention for preventing HIV infection and is recognized as a key component of comprehensive HIV prevention strategies [1,2]. Widespread PrEP implementation is considered critical to achieve the goal of ending the AIDS epidemic by 2030 [2]. Since 2016, many European countries have integrated PrEP into public health programs, demonstrating substantial reductions in HIV incidence where PrEP uptake is high [3–7]. However, PrEP availability across Europe remains uneven: as of 2023, 13 countries in Europe had yet to implement national PrEP programs, and even in countries with PrEP access, specific populations are not adequately reached [3]. In particular, people who inject drugs, incarcerated individuals, undocumented migrants, and other marginalized groups often face structural barriers to PrEP and may be ineligible or underserved in many settings [3,4,8–10]. Moreover, the majority of PrEP users are currently men who have sex with men (MSM), with only a small proportion of women and transgender individuals accessing this prophylaxis [6,7,9,11]. Moreover, PrEP delivery in most European countries has been largely confined to specialized clinical settings (e.g., infectious disease or sexual health clinics), with prescriptions only by medical doctors, which can limit accessibility [1–3]. Expanding PrEP provision to more diverse healthcare and community settings is increasingly seen as necessary for improving access and uptake.

In Italy, oral PrEP with tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) was formally approved in 2017, but its use remained limited. The lack of reimbursement in the national health system meant that individuals had to pay the full cost of PrEP medication (i.e., roughly 60€ for a box of generic FTC/TDF). The cost of PrEP was a significant barrier, and many individuals purchased PrEP online at a lower cost using it without any medical supervision. Additionally, Italian regulations specify that PrEP can only be prescribed by HIV specialists [12]. This medicalized model potentially discouraged individuals who were unable or hesitant to access hospital services, thereby constraining PrEP uptake, especially outside major urban centers. By early 2023, an estimated 11,000–12,000 people in Italy had ever initiated PrEP, with a concentration in some regions [3,13]. Although civil society organizations and community clinics (e.g., “checkpoints”) played a key role by piloting PrEP programs, coverage remained far below the estimated need.

In May 2023, the Italian Medicines Agency (AIFA) approved full reimbursement for oral PrEP with FTC/TDF by the National Health Service [12]. This decision made PrEP medication free of charge through hospital-affiliated pharmacies for individuals at risk accessing the National Health Service, potentially removing the financial barrier to access. However, the centralized model of PrEP delivery in Italy could continue to limit access for those outside major cities or those uncomfortable engaging with HIV clinics. At the time of the survey, oral PrEP with FTC/TDF was the only PrEP option reimbursed by the Italian National Health Service.

Here we present findings from a survey conducted within the centers of the PrIDE cohort in 2023–2024, aiming to describe PrEP uptake, user demographics, and regional distribution in Italy during the first year after PrEP reimbursement. We also analyze changes in PrEP uptake and the rate of users in active follow-up following reimbursement and compare the number of people living

with HIV (PWH) to PrEP users as an indicator of unmet prevention needs [14].

Methods

Study design and setting: We conducted a nationwide cross-sectional survey of PrEP-providing or HIV centers in Italy. This survey represented the initial step for the establishment of the PrIDE (Prevention ICONA Dedicated Ensemble) cohort (NCT07186244), an Italian national study aimed to systematically gather data on PrEP use throughout Italy and assess the impact of the new reimbursement policy. The PrIDE cohort is a study in Italy that focuses on real-world PrEP use for HIV prevention. It is a national initiative involving 54 clinical and community centers across the country. The cohort is supported by the Fondazione ICONA (Italian Cohort Naive Antiretrovirals) and aims to provide a comprehensive understanding of how PrEP is implemented and its effects on HIV prevention in Italy.

The survey covered the calendar years 2023 and 2024, capturing the period immediately before the introduction of national PrEP reimbursement and with ongoing implementation (2023) and the year after implementation of PrEP reimbursement (2024). A total of 62 centers across Italy participated, including hospital-based infectious disease clinics and three community-based clinics, known as “Checkpoints,” that offer a package of sexual health services. All participating centers are members of the ICONA Foundation HIV research network or PrEP community centers providing PrEP care, ensuring broad geographic representation (north, center, south, and islands).

Data collection: Each center provided aggregate data via a standardized questionnaire. We collected the following primary metrics for each year considered (2023 and 2024): (1) the number of individuals who initiated PrEP in that year (“new PrEP users”); (2) the cumulative number of individuals who have ever taken PrEP at the center up to that year (“total PrEP users”); and (3) the number of PrEP users in active care, defined as individuals who continued PrEP and had at least one follow-up visit in that year. From these data, we derived measures of PrEP uptake growth between 2023 and 2024 and calculated a proxy measure for the rate of people in active PrEP follow-up (the proportion of ever-users who remained in active follow-up at the end of 2024). To assess regional coverage, centers reported the number of people living with HIV (PWH) in care at that institution. Using aggregated regional data, we computed the ratio of PWH to PrEP users for each region as an indicator of PrEP coverage relative to the local HIV epidemic size [14]. A declining PWH/PrEP ratio over time in a region was interpreted as improving PrEP coverage (assuming relatively stable PWH numbers).

Outcomes and definitions: The primary outcomes were the change in total PrEP users from 2023 to 2024 (expressed as a percentage increase nationally and by region) and the distribution of PrEP users across regions in 2024. Secondary outcomes included the percentage of cumulative users active in follow-up in 2024 and the PWH/PrEP ratio by region in 2023 and 2024. Additionally, two population-based indicators were calculated in every region, describing PrEP penetration and dynamics enabling standardized regional comparison: i) prevalence of PrEP use in 2024: number of individuals receiving PrEP in 2024, divided by the corresponding regional population aged 18–64 years, and expressed per 100,000

inhabitants; ii) incidence rate of new PrEP users in 2024: number of individuals who initiated PrEP during year 2024, divided by the regional population aged 18–64 years expressed per 100,000 inhabitants per year.

Analysis: We summarized national and regional data using descriptive statistics. Percentage changes in PrEP users from 2023 to 2024 were calculated for each region to identify differences in growth. We mapped regional data to visualize geographic disparities and changes. All data were aggregated by region and de-identified at the center level. We reported certain individual-level aggregated characteristics, such as the national gender distribution of PrEP users, which centers consistently reported. Other demographic variables (e.g., age distribution, mode of PrEP use, daily vs on-demand) were not uniformly available from all centers in this survey and thus were not included in this analysis. The numbers of PWH on active follow-up for 2023 and 2024 has also been collected by the participating centers in the survey and divided by the reported total number of PrEP users in the same year.

Two regional indicators were further calculated using aggregated data and then plotted. The adult population aged 18–64 years as of January 1, 2025, was used as the denominator, based on official ISTAT demographic data. We used the 18–64 years strata as commonly adopted as a proxy for the sexually active population. For each region, the prevalence of PrEP users in 2024 (active PrEP users at December 31, 2024 per 100,000 inhabitants) was calculated together with 95% confidence interval assuming a binomial distribution. The incidence of new PrEP users in 2024 (PrEP initiations during year 2024 per 100,000 inhabitants/year) was also calculated with corresponding 95% confidence interval assuming a Poisson distribution.

Ethics and governance: The PrIDE study was reviewed and approved by the institutional review board of the principal investigator (Ethical approval No. 105/2023, Comitato Etico Territoriale Lazio Area 4, Rome, Italy), and all participating centers complied with local ethical requirements for contributing de-identified programmatic data. The study was conducted in accordance with the

Declaration of Helsinki and the guidelines of Good Clinical Practice. Because this initial survey used aggregated retrospective data and did not collect personal identifiers, informed consent was not required from individual PrEP users.

Results

A total of 62 centers (59 hospital-based infectious disease clinics and 3 community checkpoints) were invited to the survey, 49 responded representing 79% of those invited and providing nationwide coverage. Of these, all the centers offered PrEP services by 2024, and 46 in 2023 (the service was not available only 2 centers and one center reported that they did not yet have PrEP clients). Among the PrEP-providing centers in 2024, 39 (79.6%) had a dedicated PrEP clinic or program, whereas 10 centers (20.4%) managed PrEP users within other clinical services (typically integrated into HIV clinics). National coverage was relatively high, with 16/20 Italian regions represented; Calabria, Molise, Umbria, and Aosta Valley regions were not included due to the absence of ICONA network centers or checkpoints.

By the end of 2024, a cumulative number of 16,220 individuals had initiated PrEP in Italy. This represents a 51.6% increase (+5523) from 10,697 cumulative PrEP users in 2023. Nationally, the number of new PrEP initiations in 2024 (post-reimbursement) was substantially higher than in 2023: across all participating centers, 5523 individuals initiated PrEP in 2024, compared to 4176 in 2023. Before 2023, only 6,521 people had started PrEP. The total number of people in active PrEP follow-up (regardless of start year) rose from 9001 in 2023 to 11,785 in 2024.

In 2024, more than half of all PrEP users were concentrated in the region of Lombardy, which alone accounted for 7327/16220 (45.2%) of the national total, and Lazio, which accounted for 2873/16,220 (17.7%). Overall, four regions (Lombardy, Lazio, Emilia-Romagna, and Piedmont) accounted for 13,712/16,220 (84.5%) of the users. Other regions, particularly in southern Italy, had far fewer PrEP users in absolute terms, with six regions reporting <100 PrEP users. The geographical disparity is visualized in

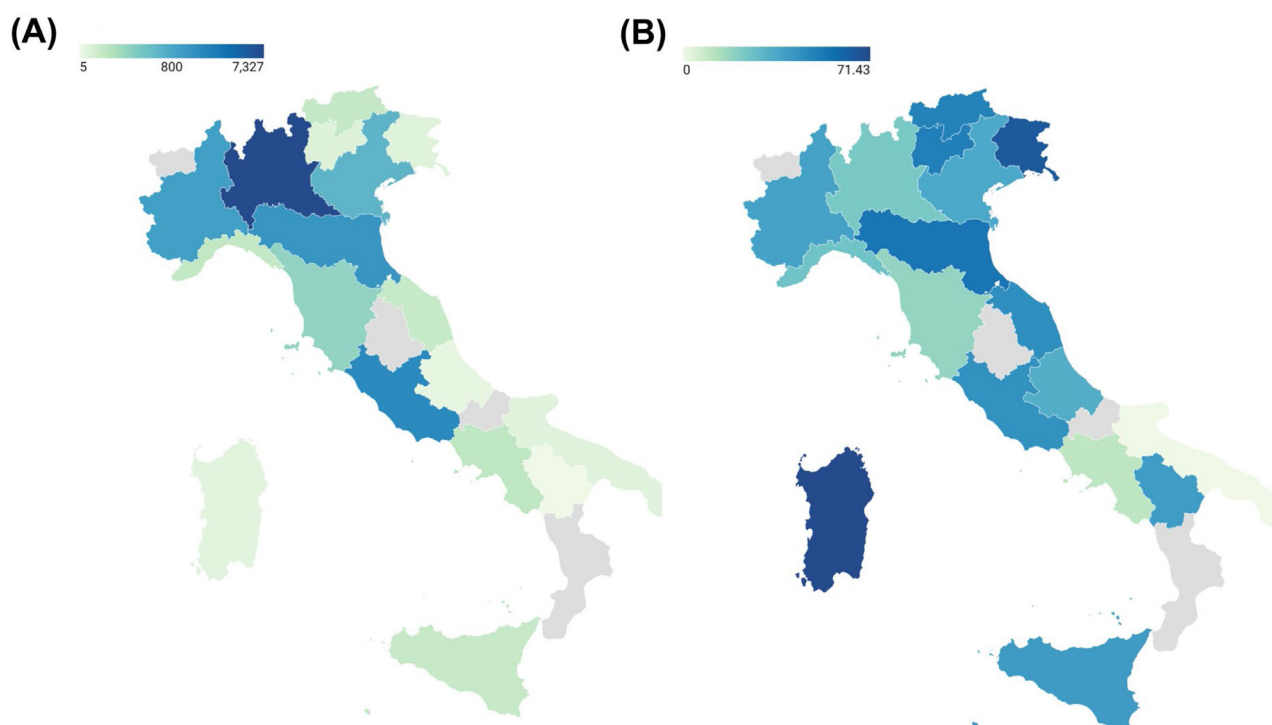


Figure 1. Overall number of PrEP users in 2024 in Italy by region (panel A) and percentage increase in PrEP users from 2023 to 2024 in Italy by region (panel B).

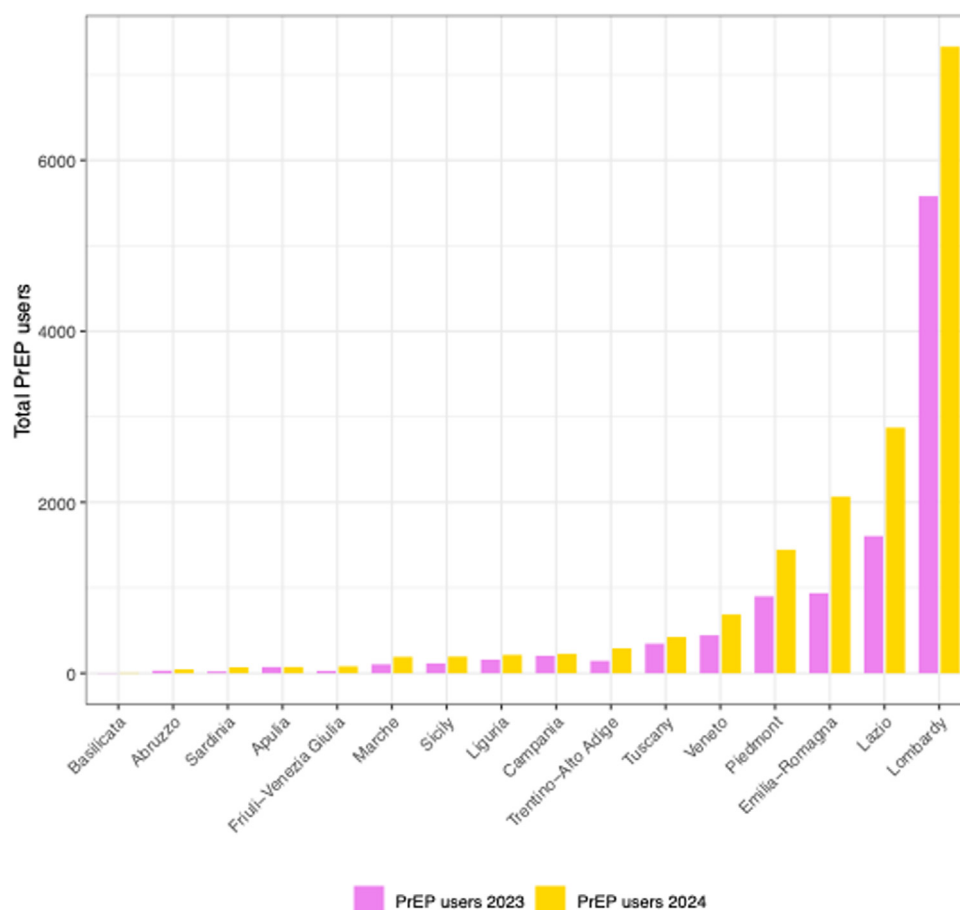


Figure 2. Overall number of PrEP users in 2023 and in 2024 by region in Italy.

Figure 1, which maps the overall number of PrEP users in 2024 (Figure 1, panel A) and the percentage increase in PrEP users from 2023 to 2024 by region (Figure 1, panel B). All regions experienced an increase in PrEP uptake in the post-reimbursement period, except Apulia, which did not demonstrate any net change. Campania showed only a modest +10% increase in PrEP users. In contrast, several regions with previously small PrEP programs experienced the largest relative growth: Sardinia saw a +71.4% increase, Friuli Venezia Giulia +65.4%, Emilia-Romagna +54.7%, and the autonomous province of Trento +51.1%, although the overall number in some of these regions still remains low (e.g. Sardinia: 70, Friuli: 81, Trento: 92). Notably, Lombardy and Lazio, which had the largest absolute numbers in 2023, also continued to grow substantially (+23.2% in Lombardy, reaching 7327 users; +44.1% in Lazio, reaching 2873 users). Growth was generally slower in many southern mainland regions (Figure 1, panel B, and Figure 2).

Despite the differential growth rates, by 2024, every surveyed region of Italy had at least some PrEP users, and most had more than the year before. The PrEP-to-population penetration, however, varied widely. Figure 3 describes the proportion of overall PrEP users (panel A) and the incidence of new PrEP users in 2024 (panel B) per 100,000 residents (age 18–64 years old).

Overall, approximately 73% of all people who had initiated PrEP at any point were reported to be active PrEP users in 2024 (i.e., attended follow-up visits and had not discontinued). This corresponds to 11,785 active users out of 16,220 ever-users, as reported nationally.

From a demographic perspective, the vast majority of PrEP users were male. In 2024, 95.8% of individuals on PrEP were identified as cisgender men. Cisgender women represented just about 2%

of PrEP users, and transgender people a further 2.3% (with transgender men <0.1% and transgender women 2.2%). This gender distribution remained essentially unchanged from 2023.

To contextualize PrEP expansion in terms of prevention impact, we analyzed the ratio of PWH to PrEP users by region. Nationally, this PWH/PrEP ratio improved markedly from 2023 to 2024, reflecting increased PrEP coverage. In 2023, many regions had far more PWH in care than PrEP users, for instance, in Veneto, there were 7.8 PWH for every PrEP user (95% CI 7.1–8.6); in Tuscany, about 13.8 PWH per PrEP user (95% CI 12.4–15.4). By 2024, these ratios declined to 4.0 (95% CI 3.7–4.3) in Veneto and 7.7 (95% CI 7.0–8.6) in Tuscany. Lombardy and Lazio regions also saw their PWH/PrEP ratios roughly halved. However, regions with historically minimal PrEP uptake still had high ratios. Basilicata, for example, improved from an extremely high ratio of 50 (95% CI 15.9–156.8) in 2023 to 30 (95% CI 12.3–73.1) in 2024, and Sicily likewise went from 40 PWH/PrEP (95% CI 33.3–48.1) down to 14.0 (95% CI 12.1–16.2). Figure 4 illustrates these changes, showing the geographical shift toward more balanced PWH-to-PrEP ratios by 2024 compared to 2023. Many northern and central regions that were moderate (yellow shades) in 2023 became lower (green shades) in 2024 as the number of PrEP users increased. Some southern regions still have higher ratios (represented by blue shades).

Discussion

This study provides a timely evaluation of PrEP implementation in Italy during a period of significant policy transformation. These findings highlight considerable progress with a marked increase in PrEP uptake and engagement in care, while also revealing

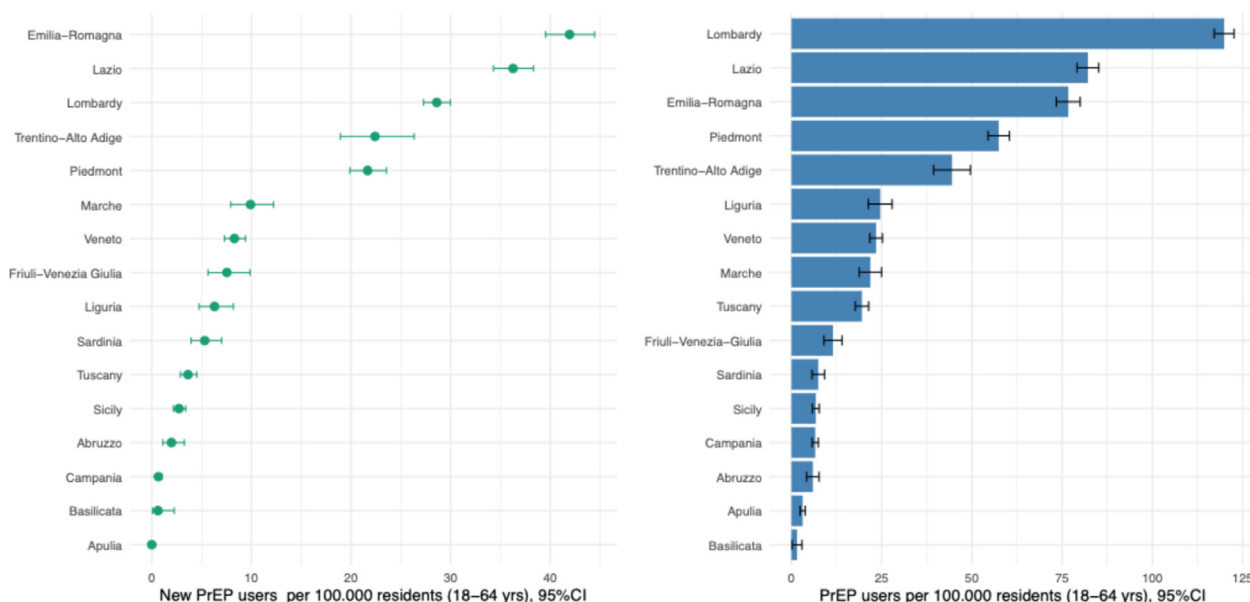


Figure 3. Proportion of overall PrEP users panel A) and incidence of new PrEP users (panel B) per 100,000 residents (age 18–64 years old) by region in Italy.

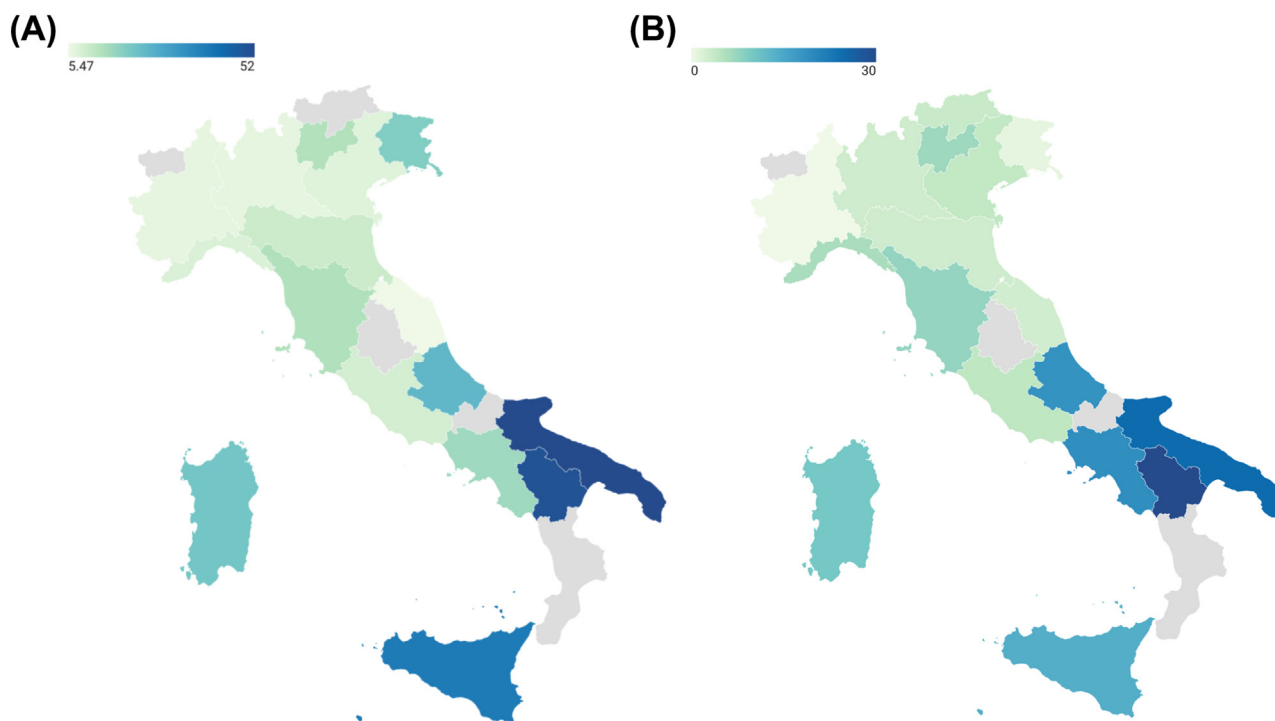


Figure 4. Ratio of people with HIV / PrEP users in 2023 (panel A) and in 2024 (panel B) in Italy by region.

critical gaps that require targeted intervention. The approximately 50% surge in the number of PrEP users between 2023 and 2024 is a strong indication of growing awareness and improved accessibility following the introduction of reimbursement. It underscores that when financial barriers are removed, demand for PrEP can rapidly expand, even in settings where uptake has been modest. Over 5500 new individuals started PrEP in the months following its free-of-charge availability, accounting for more than one-third of all those who have ever initiated PrEP in Italy. This immediate boost demonstrates the high latent demand that existed and how many people at risk were waiting for an affordable pathway to obtain PrEP. Two regions, Lombardy and Lazio, were especially instrumental, together contributing around two-thirds of the new

PrEP initiations post-reimbursement. These are areas with active HIV prevention communities, which likely facilitated a quick scale-up.

Despite these encouraging trends, the uneven distribution of PrEP uptake across the country remains a persistent concern. Regional disparities, which were present before, have in some cases widened. Conversely, in parts of southern Italy, the uptake of PrEP remains low. Cultural and social factors, such as HIV-related stigma or lower risk perception, could be dampening demand in certain communities [15]. Additionally, healthcare resource limitations in those regions mean that even with free medication, access points could be limited [16–19]. These findings mirror patterns seen in other countries, where PrEP roll-out has often been slower in spe-

cific areas compared to major urban centers [5,6,20,21]. To narrow these gaps, a coordinated implementation package is needed including standardized regional PrEP care pathways aligned with national guidance, targeted training and expanded low-threshold delivery.

Persisting in active follow-up is critical for realizing PrEP's full prevention benefit. Despite the limitations of the analysis performed, our results show a rate of around 73% of people in active follow-up measured across the 2 years of the survey. Italian data before PrEP reimbursement (ItaPrEP cohort) described a one-year probability of discontinuation from the PrEP program of around 25% [11]. Taken together, these data confirm that maintaining people engaged in PrEP programs remains a challenge [22]. Moreover, our finding that PrEP uptake among women and transgender people is extremely low indicates a need to better reach these populations [23]. Other European contexts have noted that migrants often have lower awareness of PrEP and face cultural or structural hurdles to accessing it [21]. Culturally sensitive outreach and simplifying access (for example, providing PrEP through community health centers or involving mediators) might improve engagement.

A central theme emerging from our results is the role of structural and policy barriers beyond cost. The Italian experience so far underscores that removal of cost barriers, while necessary, must be accompanied by health system adaptations, as highlighted by the slow improvement of the PWH/PrEP ratio [14,16]. One barrier is the requirement that PrEP be prescribed and monitored exclusively by HIV/infectious disease specialists, typically in hospital settings. This gatekeeping can limit PrEP's reach, especially outside of large cities, people in semi-urban or rural areas may not have easy access to an HIV clinic, or may feel discomfort going there due to confidentiality concerns. To improve accessibility, decentralization of PrEP delivery is crucial [20]. This could include empowering and training primary care physicians or other specialists to prescribe PrEP, thereby bringing services closer to individuals who might not otherwise seek out an HIV specialist [20]. There is precedent for broadening PrEP provider pools in other countries [20]. By expanding community-led PrEP initiatives with appropriate medical oversight, Italy can leverage the "Let community lead" principle advocated by UNAIDS to enhance PrEP uptake among those less likely to visit hospitals [24].

It is encouraging that the PWH/PrEP ratio moved in the right direction nationally; this suggests Italy is improving its coverage of at-risk populations. However, the ratio remains high in areas where PrEP has not been widely adopted. This metric, akin to the "PrEP-to-need ratio" used in other contexts, should continue to be monitored [14]. It provides a benchmark for identifying where prevention efforts are lagging relative to the epidemic. For instance, a ratio of 30 implies that for every 30 people living with HIV in care, there is only one person on PrEP—arguably far below the potential prevention need. Focused qualitative research in such settings could elucidate specific local issues, informing targeted interventions.

Our study also underscores the importance of data collection and surveillance in guiding PrEP implementation. We were able to assemble this national picture through collaboration among centers within the PrIDE cohort. Regular, systematic data on PrEP uptake, user characteristics, and outcomes should be integrated into Italy's public health monitoring. This will enable the timely identification of trends—for example, if the rate of users in active follow-up starts to decline or if certain subgroups begin to increase in uptake—and allow for responsive adjustments in programs. Looking ahead, several innovations and next steps merit consideration to sustain and build on the progress made, including long-acting PrEP, community and territorial pharmacy-based models, and addressing stigma and awareness.

There are some limitations to acknowledge. First, the data were collected at an aggregate level from each center; we did not have individual-level information on PrEP users (such as detailed demographics or reasons for discontinuation). Therefore, our ability to analyze factors associated with rate of people on active follow-up or uptake at the individual level is limited. Second, our analysis of regional trends assumes that the responding centers cover most PrEP users in each region (which is likely, since PrEP in Italy is mostly medicalized and we included known providers). A small number of individuals may have obtained PrEP outside participating centers (e.g., via private providers or online self-sourcing) and therefore not be captured in our estimates, or may have subsequently transitioned into NHS-based care after reimbursement and been counted as 'new' users. However, we expect this contribution to be small. Third, because this is an observational before-and-after analysis coinciding with a policy change, we cannot definitively prove causation for the uptake increase—but the temporal association and the magnitude of change strongly indicate that reimbursement was the primary driver of growth. Other concurrent factors, such as increasing public awareness of PrEP's effectiveness, may have also contributed to some extent.

Fourth, despite all major PrEP centers were included in the study, some minor or newly activated PrEP units may not have been included in the survey, potentially leading to an underestimation in some regions. Fifth, the use of the 18–64-year population as the denominator is a reasonable epidemiological approach reflecting the sexually active population. However, without individual-level data, we cannot exclude the inclusion of some PrEP users older than 64 years in the numerator. However, the number is expected to be very small and unlikely to deeply change the regional estimates. Sixth, a more accurate measure of PrEP penetration would require an estimate of the population actually at risk of HIV acquisition according to national eligibility criteria for PrEP. This represents an important area of future work in the PrIDE cohort scientific agenda, essential for characterizing PrEP coverage in Italy.

Lastly, our measure of the rate of people in active follow-up is a rough proxy and may be overestimated as time since PrEP initiation was not accounted and as people who started PrEP in 2024 who have a very short follow-up were also included. Longitudinal individual data from the PrIDE cohort will allow more nuanced measurement of PrEP persistence and adherence patterns (including cycling on and off PrEP).

Conclusion

In conclusion, Italy's first year of nationwide reimbursed PrEP has been a story of both significant success and ongoing challenges. The country managed to expand the pool of PrEP users, confirming the importance of policy action in HIV prevention. At the same time, the benefits have not been shared equally across all regions and communities. In an era where effective HIV prevention tools are available, the challenge lies in overcoming infrastructural and societal barriers to make these tools accessible to everyone who needs them. Italy's experience shows that political will, combined with targeted implementation strategies, can quickly advance HIV prevention, and that continued vigilance is necessary to close remaining gaps.

Data sharing statement

De-identified data from the PrIDE cohort survey (aggregated regional and center-level data on PrEP uptake, follow-up, and service characteristics) are available from the authors upon reasonable request. Researchers may request the data by contacting the ICONA Foundation or the corresponding author of this manuscript.

Funding

The ICONA Foundation provided logistical support for data collection and analysis.

Ethical approval

The PrIDE study was reviewed and approved by the institutional review board of the principal investigator (Ethical approval n. 105/2023, Comitato Etico Territoriale Lazio Area 4, Rome, Italy), and all participating centers complied with local ethical requirements for contributing de-identified programmatic data.

Author contributions

SN and VM conceived the study and wrote the first draft. TM and AT coordinated data collection across centers and performed the analyses. SN and VM accessed and verified the underlying data. FL, LT, DT, EC, FMF, MM, EM, DM, RR, FB, SC, MG, ARR, RE, MR and SV provided data and reviewed the manuscript. AdAM, MC, AA, and AC supervised the work. All authors interpreted the data, critically revised the manuscript for intellectual content, and approved the final version. SN and VM were responsible for the final submission.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

- [1] Gökengin D, Noori T, Alemany A, Bienkowski C, Liegon G, İnkaya A, et al. Prevention strategies for sexually transmitted infections, HIV, and viral hepatitis in Europe. *Lancet Reg Health Eur* 2023;**34**:100738.
- [2] Parczewski M, Gökengin D, Sullivan A, de Amo J, Cairns G, Bivol S, et al. Control of HIV across the WHO European region: progress and remaining challenges. *Lancet Reg Health Eur* 2025;**52**:101243.
- [3] European Centre for Disease Prevention and Control *Pre-exposure prophylaxis for HIV prevention in Europe and Central Asia—monitoring the implementation of the Dublin Declaration: 2024 progress report (2023 data)*. Stockholm: ECDC; 2024. <https://www.ecdc.europa.eu/en/publications-data/pre-exposure-prophylaxis-hiv-prevention-europe-and-central-asia-monitoring> accessed 1 October 2025.
- [4] World Health Organization *Global state of PrEP*. Geneva: WHO; 2025. <https://www.who.int/groups/global-prep-network/global-state-of-prep> accessed 1 October 2025.
- [5] Sullivan AK, Saunders J, Desai M, Cartier A, Mitchell HD, Jaffer S, et al., Impact Study Group HIV pre-exposure prophylaxis and its implementation in the PrEP IMPACT trial in England: a pragmatic health technology assessment. *Lancet HIV* 2023;**10**:e790–806.
- [6] Billioti de Gage S, Desplas D, Dray-Spira R. Roll-out of HIV pre-exposure prophylaxis use in France: a nationwide observational study from 2016 to 2021. *Lancet Reg Health Eur* 2022;**22**:100486.
- [7] Cambiano V, Miners A, Lampe FC, McCormack S, Gill ON, Hart G, et al. The effect of combination prevention strategies on HIV incidence among gay and bisexual men who have sex with men in the UK: a model-based analysis. *Lancet HIV* 2023;**10**:e713–22.
- [8] Keen P, Bavinton BR. Could disparities in PrEP uptake limit the public health benefit? *Lancet Public Health* 2020;**5**:e467–8.
- [9] Whelan I, Strachan S, Apea V, Orkin C, Paparini S. Barriers and facilitators to HIV pre-exposure prophylaxis for cisgender and transgender women in the UK. *Lancet HIV* 2023;**10**:e472–81.
- [10] Di Ciccio M, Delabre RM, Vilotitch A, Corbelli GM, Villes V, Ros Sánchez A, et al. PrEP in the context of other HIV risk reduction strategies among men who have sex with men: results from the Flash! PrEP in Europe survey. *Arch Sex Behav* 2022;**51**:2451–64.
- [11] Mazzotta V, Caruso E, Tavelli A, Esvan R, Lanini S, Micheli G, et al. HIV oral pre-exposure prophylaxis effectiveness, adherence, and discontinuation in an Italian multicentric access program: itaPrEP study. *Open Forum Infect Dis* 2025;**12**:ofaf539.
- [12] Agenzia Italiana del Farmaco (AIFA) *Delibera CdA n. 15 del 26 aprile 2023*. Rome: AIFA; 2023.
- [13] Nozza S, Mazzotta V, Masoero T, Tavelli A, Leserri F, Taramasso L, et al. *Implementation of PrEP in Italy: results of the PrIDE survey*, Rome, Italy: Presented at the Italian Conference on AIDS and Antiviral Research (ICAR 2024); 2024. Abstract OC50.
- [14] Coukan F, Sullivan A, Mitchell H, Jaffer S, Williams A, Saunders J, et al. Impact of national commissioning of pre-exposure prophylaxis (PrEP) on equity of access in England: a PrEP-to-need ratio investigation. *Sex Transm Infect* 2024;**100**:166–72.
- [15] Protiere C, Sagaon-Teyssier L, Donadille C, Sow A, Gaubert G, Girard G, et al. Perception of PrEP-related stigma in PrEP users: results from the ANRS-PREVENIR cohort. *HIV Med* 2023;**24**:938–45.
- [16] Rossotti R, Tavelli A, Calzavara D, De Bona A, Muccini C, Moschese D, et al. Do we still need eligibility criteria to recommend PrEP? Impact of national prescribing requirements on retention in care and sexually transmitted infections acquisition. *AIDS Behav* 2024;**28**:2258–63.
- [17] Rossotti R, Moiola MC, Baiguera C, Milani M, De Giorgio C, Cervi L, et al. Ongoing shortage of generic emtricitabine/tenofovir disoproxil fumarate undermines HIV prevention efforts among PrEP users in Italy. *Sex Transm Infect* 2025;**101**:549.
- [18] Menozzi M, Trapani MDD, Burastero GJ, Volpi S, Cuomo G, Mazzitelli M, et al. Four-year experience of HIV pre-exposure prophylaxis (PrEP) from an Italian multicentre cohort: incidence of sexually transmitted infections and renal toxicity. *AIDS Behav* 2025;**29**:2797–806.
- [19] Raccagni AR, Passini F, Diotallevi S, Lolatto R, Bruzzesi E, Piromalli G, et al. Brief report: gaps in HIV preexposure prophylaxis acceptance: findings from an outpatient HIV testing service in Italy. *J Acquir Immune Defic Syndr* 2025;**98**:37–40.
- [20] Bamouni S, Billioti de Gage S, Desplas D, Valbousquet J, Lamant J, Joseph JF, et al. Effect of extending PrEP initiation to primary care settings: a nationwide cohort study in France. *Lancet Public Health* 2025;**10**:e362–70.
- [21] Tiesosaparoen W, Zhang Y, Fairley CK, Hoy J, Aguirre I, Ong JJ. Improving access to oral pre-exposure prophylaxis for HIV among international migrant populations. *Lancet Public Health* 2023;**8**:e651–8.
- [22] Zhang J, Li C, Xu J, Hu Z, Rutstein SE, Tucker JD, et al. Discontinuation, suboptimal adherence, and reinstitution of oral HIV pre-exposure prophylaxis: a global systematic review and meta-analysis. *Lancet HIV* 2022;**9**:e254–68.
- [23] Fitzgerald N, Coltart H, Dominguez L, Flanagan K, Gilleece Y. PrEP for women in Europe: a systematic literature review. *HIV Med* 2023;**24**:765–76.
- [24] UNAIDS *World AIDS day report 2023*. Geneva: UNAIDS; 2023. https://www.unaids.org/sites/default/files/media_asset/2023WADreport_en.pdf accessed 1 October 2025.