

# Differentiated and simplified PrEP delivery in Italy: alignment with WHO guidance is needed

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## BACKGROUND

High PrEP coverage among people at substantial risk for HIV is essential to drastically reduce new HIV infections and end AIDS as a public health threat by 2030. The World Health Organization (WHO) encourages countries to **scale-up PrEP coverage**, **simplify and demedicalize PrEP initiations**, and **implement differentiated service delivery approaches** in order to reach these goals (1-5). Since first recommending oral PrEP in 2015, WHO has been regularly updating its technical guidance, based on emerging implementation evidence, which may result in gaps in national guidelines incorporating those updates.

In Italy, PrEP reimbursement within the national health system was approved only in 2023, together with the respective prescription guidance. The national HIV guidelines and the national HIV/AIDS strategic plan were last updated in 2017, both including also guidance for PrEP prescription and delivery. The 2023 prescription guidance, the 2017 strategic plan and HIV guidelines constitute the current Italian national PrEP guidance.

## METHODS

A **policy analysis** was conducted to assess inclusion of the WHO recommendations on PrEP adopted since 2017 into the current Italian national PrEP guidance.

A list of **recommended practices** was extracted from the latest WHO PrEP guidance (1-5) and their inclusion into the Italian guidance was checked.

## RESULTS

24 practices recommended by WHO since 2017 were identified and grouped into three thematic areas (Table 1). The analysis showed that only 9 of the 24 WHO-recommended practices are included in the Italian guidance, with 7 of them regarding accessory services integrated into PrEP delivery.

**Several gaps** emerged from the analysis, including:

- **Disclosure of personal details** on sexual behaviour or drug use is mandatory.
- **Restricted event-driven PrEP eligibility**, limited to men who have sex with men.
- **Restricted prescription and dispensation**. PrEP is reimbursed within the national health system only when dispensed at HIV clinics, can be prescribed exclusively by HIV specialists, and **community-based delivery** is not considered.
- For those not eligible for event-driven PrEP, the 2023 Italian prescription guidance recommends an **outdated dosing schedule**, stopping PrEP 4 weeks after the last possible exposure, instead of 7 days as recommended by WHO (3).

## CONCLUSIONS

The findings highlight **several critical barriers to PrEP access** in Italy.

- **Medicalization and centralization**: PrEP delivery in HIV clinics is undesirable for some members of key populations, and is not accessible to members of marginalised and underserved groups already facing barriers with the national health system.
- **Lack of adoption of evidence-based recommendations** that do not entail additional costs and increase the accessibility and acceptability of PrEP. These include evidence-based simplification of prescription requirements and of clinical monitoring, that would allow **same-day PrEP prescription** and increase cost-effectiveness. The gaps regarding dosing schedules and eligibility criteria create barriers that specifically affect cisgender women and all transgender people who could benefit from PrEP.
- The integration of **community-based delivery** into the national health system, along **task-sharing** with peer navigators and community health workers, with a modest investment, would increase PrEP accessibility, acceptability and cost-effectiveness.
- Not dispensing PrEP outside of HIV clinics makes community-based PrEP services less convenient and less desirable, affecting PrEP coverage.

**The current PrEP delivery model in Italy has to be reformed following WHO guidance, in order to make PrEP accessible to all those who can benefit from it, increase coverage, and drastically reduce new HIV infections in the coming years.**

## REFERENCES

1. WHO (2022), *Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022-2030*. <https://iris.who.int/handle/10665/360348>.
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Table 1. Inclusion of WHO-recommended practices on PrEP delivery into the current Italian national PrEP guidance (March 2024)

WHO-recommended practices	Italy
<b>Eligibility criteria</b>	
PrEP included in the packages of interventions for key populations (4)	YES
PrEP available to all individuals at substantial risk of HIV upon request (1-4)	NO
All individuals assigned male at birth who have sexual exposure and are not taking exogenous estradiol-based hormones eligible for event-driven PrEP (3)	NO
People with HBV infection eligible for event-driven PrEP (3)	NO
Mature adolescents aged ≥15 years eligible for PrEP (2)	NO
Individuals with parenteral exposure eligible for PrEP (3)	NO
<b>Differentiated and simplified service delivery</b>	
Kidney function testing not required for PrEP prescription (3)	NO
Kidney function testing offered based on age and comorbidities (3)	NO
HBsAg testing not required for PrEP prescription (3)	NO
PrEP prescription not limited to HIV specialists (1-3)	NO
PrEP prescription also outside of clinical facilities (1-3) <sup>a</sup>	YES
PrEP dispensation also outside of clinical facilities (1-3)	NO
Peer navigators involved in service delivery (1,3,4)	NO
Use of telehealth solutions and digital technologies (1,3,4)	NO
Use of HIV rapid diagnostic tests (2,3)	NO
Use of HIV self-tests (3)	NO
<b>Integration with sexual and reproductive health services</b>	
HBV screening offered (2,3)	YES
HBV vaccination offered (2,3)	YES
HCV screening offered (2,3)	YES
Screening for syphilis, CT and NG offered (5)	YES
Etiological management of STIs (5)	YES
HAV vaccination offered (5)	YES
HPV vaccination offered (5)	YES
Pregnancy testing offered (2)	NO

<sup>a</sup>In this case PrEP is paid out-of-pocket by the client.

**YES**=recommended practice is included in the current Italian national PrEP guidance.

**NO**=recommended practice is not included in the current Italian national PrEP guidance.

**CT**=Chlamydia trachomatis.

**NG**=Neisseria gonorrhoeae.