



Infermieri di  
Malattie Infettive  
Ente del Terzo Settore

1° CONGRESSO NAZIONALE IM24 NETWORK ETS

**1° Congresso Nazionale**  
Firenze  
25-26 Febbraio  
2025

Centro Congressi  
Hotel Albani

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**HEADING FOR THE FUTURE**

Sistema Socio Sanitario



Regione  
Lombardia

ASST Fatebenefratelli Sacco



Ospedale Luigi Sacco

AZIENDA OSPEDALIERA - POLO UNIVERSITARIO

I setting del PNP 2020-2025 per la promozione della salute:  
Progetti di interazione tra scuola, ambiente di lavoro, comunità,  
servizi sanitari, territorio.

# PREVENZIONE DI HIV E IST

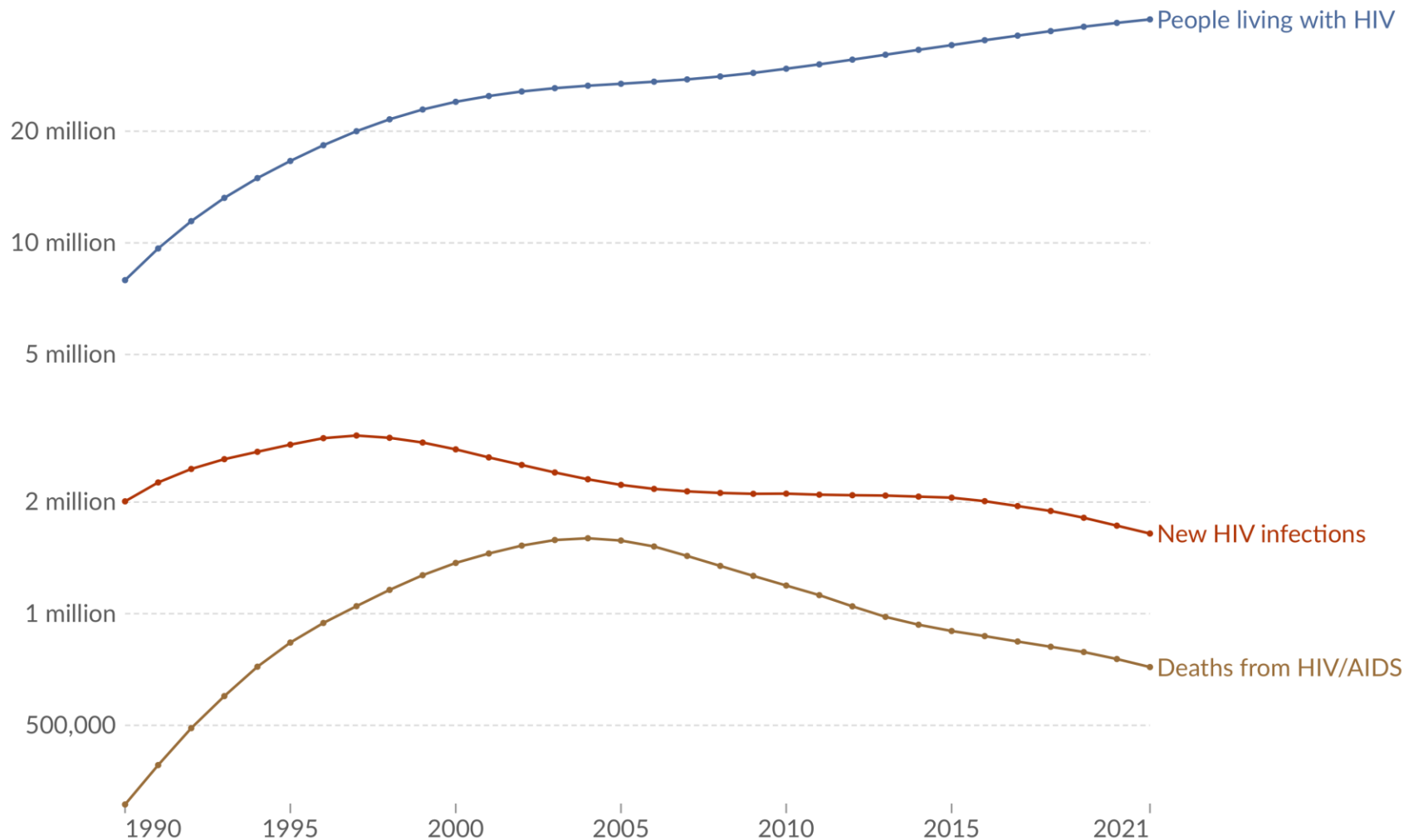
IL RUOLO DELL'OSPEDALE,  
DELL'INFERMIERE E DELLA COMMUNITY

Dr. Davide Moschese  
Ospedale Luigi Sacco» - Milano

Dr. D. Moschese received grants and fees for the speaker bureau and CME activities from *ViiV Healthcare*, *Merck & Co. Inc.*, *Gilead Science Inc.*, and *Viatrix Inc.*; fees for advisory boards from *Johnson & Johnson* and *Gilead Science Inc.*, and non-financial educational support from *Gilead Sciences Inc.* and *ViiV Healthcare*.

## New cases, deaths, and people living with HIV/AIDS, World

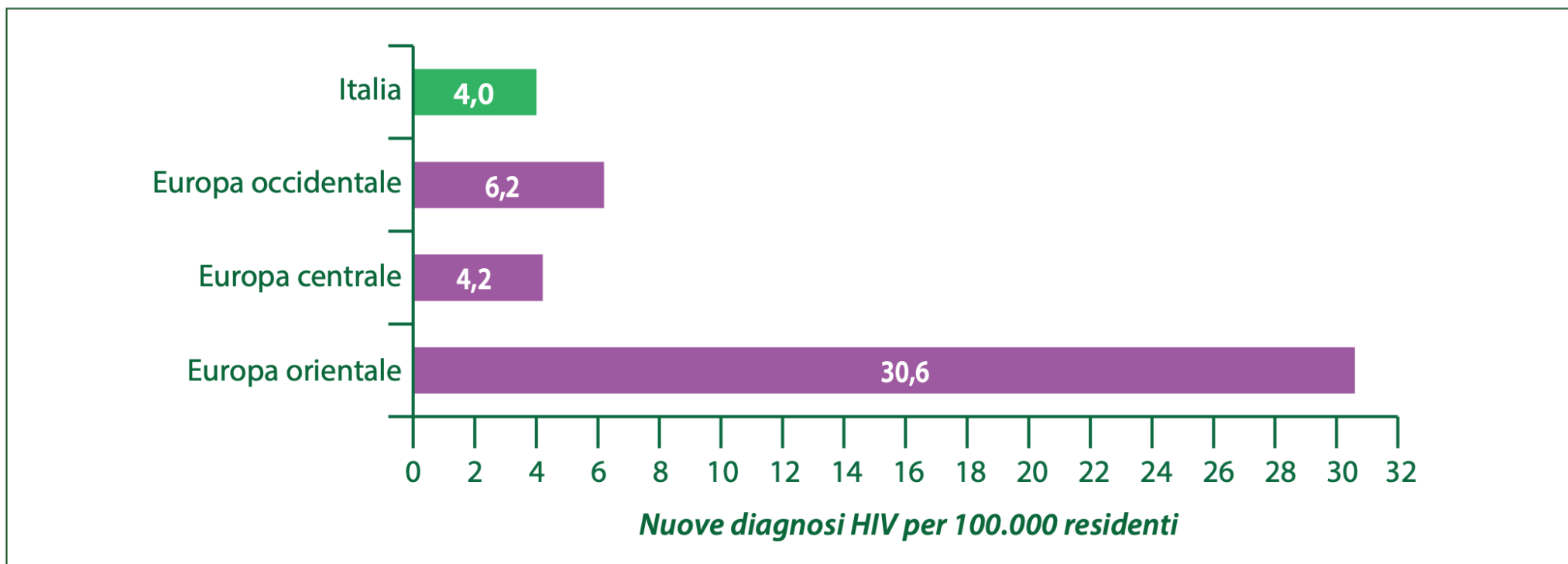
Our World  
in Data



Data source: IHME, Global Burden of Disease (2024)

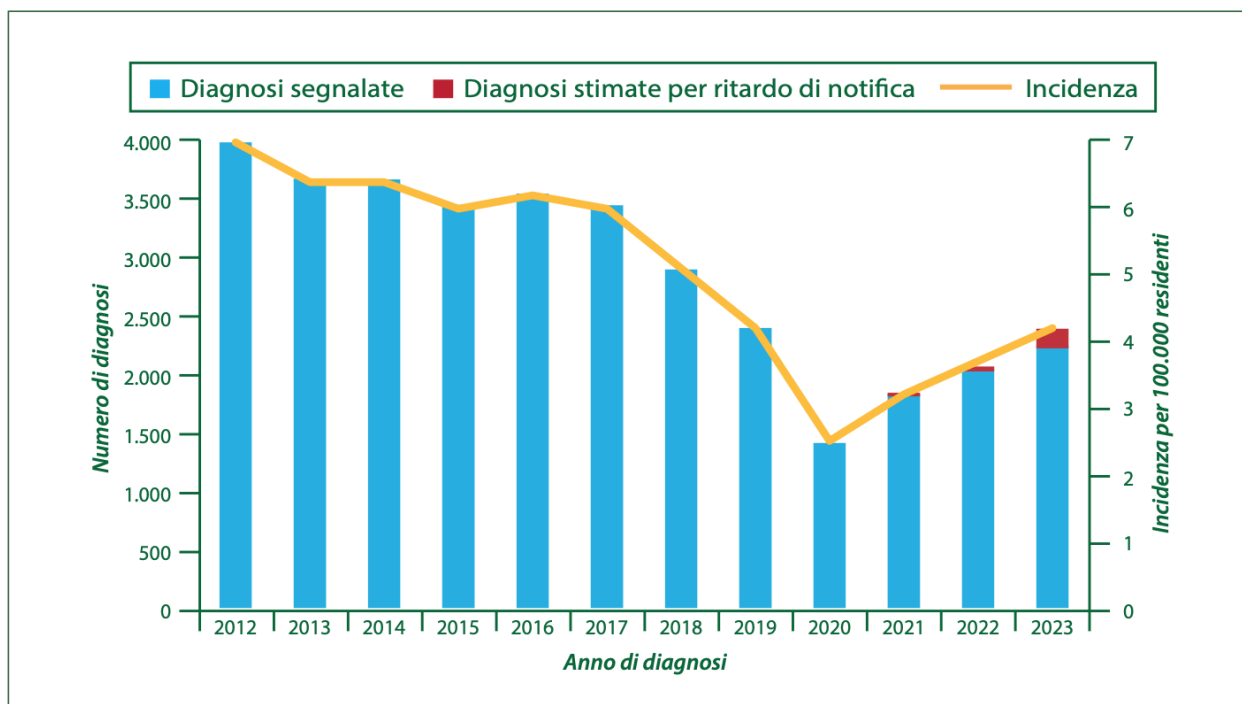
OurWorldinData.org/eradication-of-diseases | CC BY

### Incidenza HIV 2023

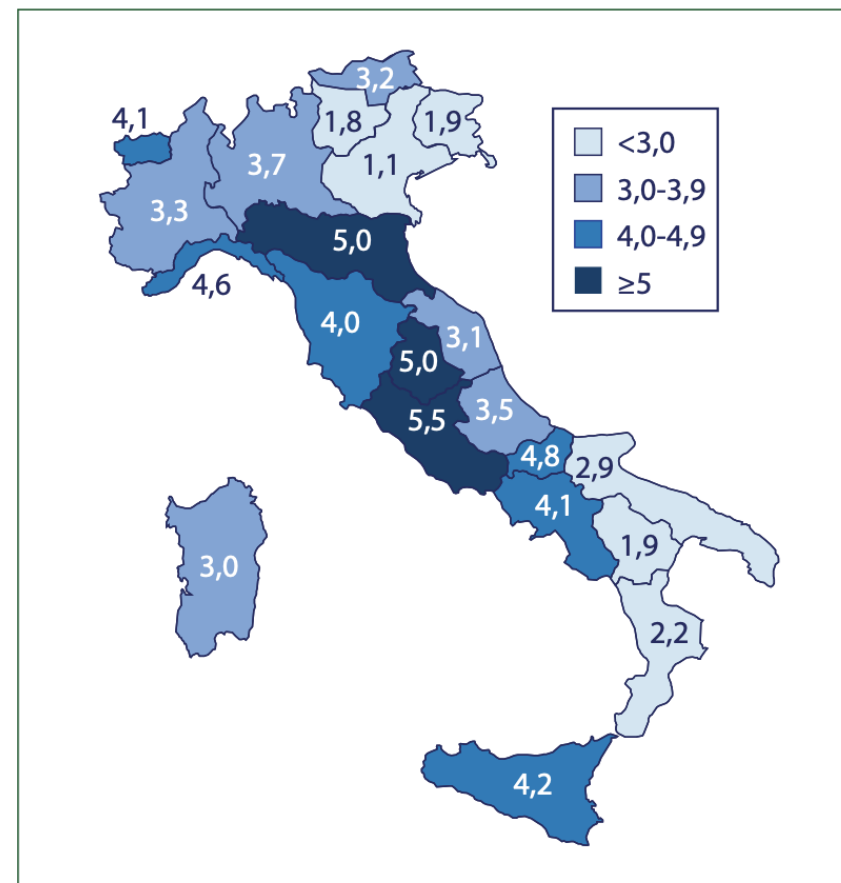


Incidenza HIV: numero di nuove diagnosi HIV per 100.000 residenti in Italia e nelle principali aree geografiche europee.  
 Fonti: Sistema di Sorveglianza HIV nazionale, ECDC/WHO. HIV/AIDS Surveillance in Europe 2024-2023 data (1)



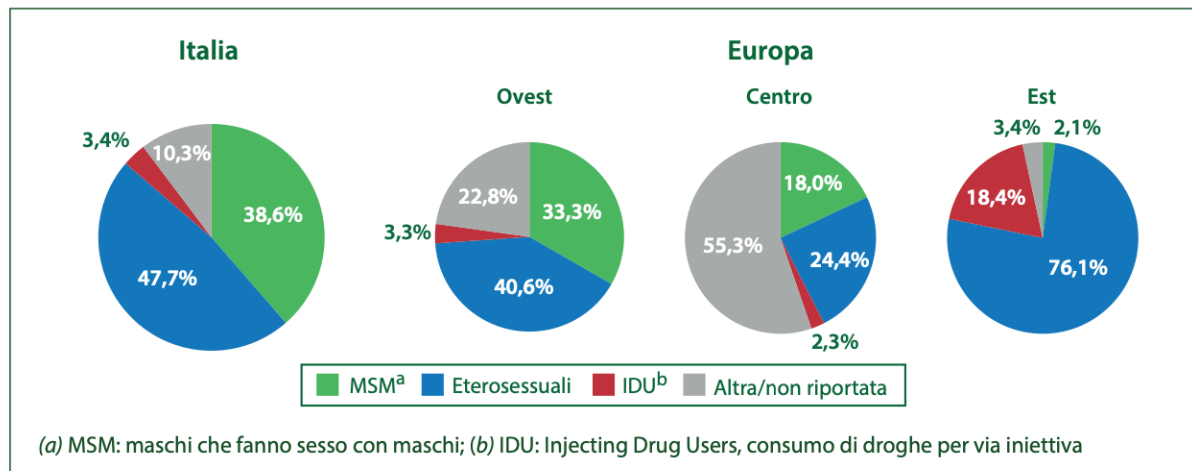


**Figura 1** - Nuove diagnosi di infezione da HIV e incidenze corrette per ritardo di notifica (2012-2023)



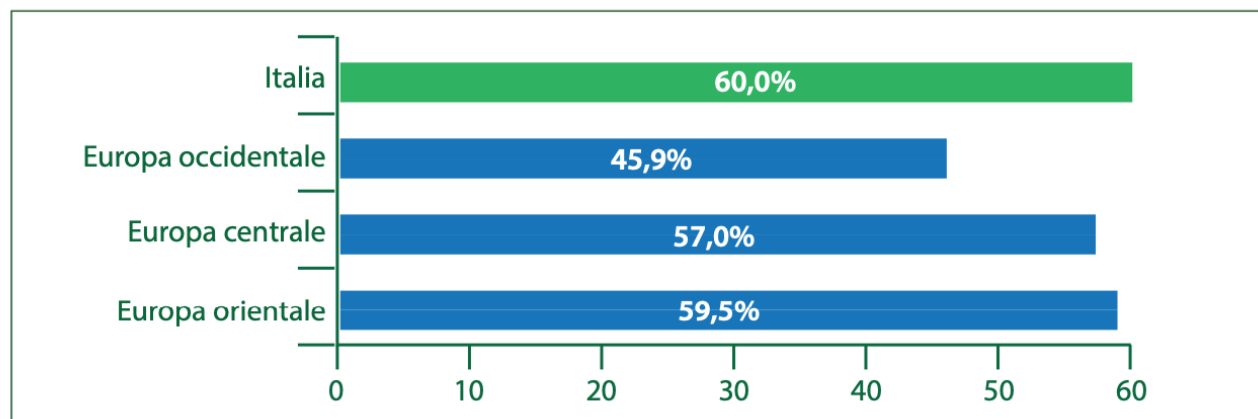
**Figura 3** - Incidenza delle nuove diagnosi di infezione da HIV (per 100.000 residenti) per Regione di residenza (2023)

## Modalità di trasmissione 2023

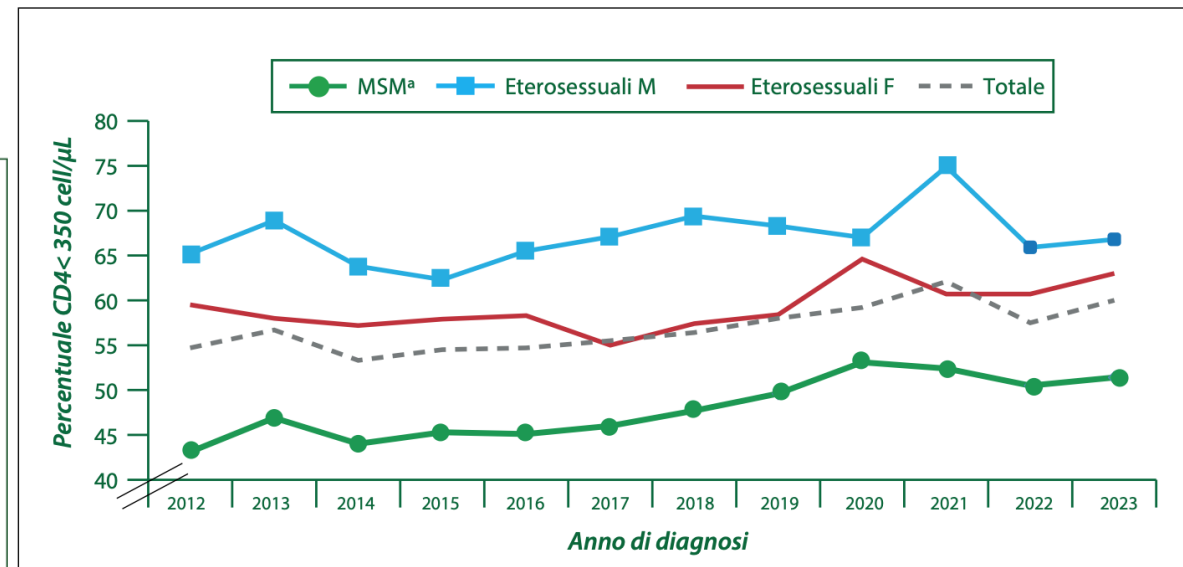
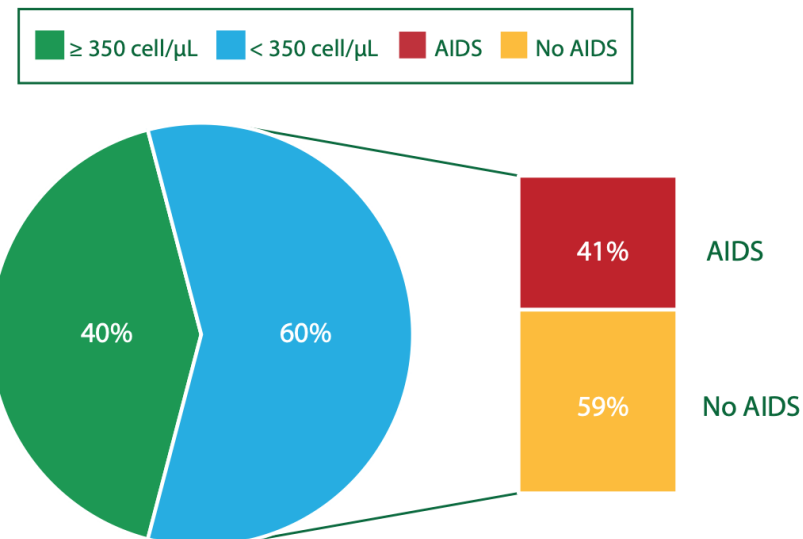


Distribuzione percentuale delle nuove diagnosi di infezione da HIV per modalità di trasmissione 2023.  
Fonti: Sistema di Sorveglianza HIV nazionale, ECDC/WHO. HIV/AIDS Surveillance in Europe 2024-2023 data (1)

## Late presenters\* 2023

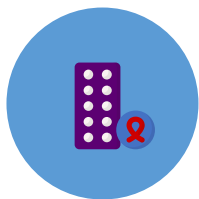


(\*) Late presenters: nuove diagnosi di infezione da HIV con numero di linfociti CD4 < 350 cell/μL.  
Fonti: Sistema di Sorveglianza HIV nazionale, ECDC/WHO. HIV/AIDS Surveillance in Europe 2024-2023 data (1)



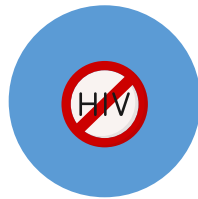
**Figura 14** - Proporzione di nuove diagnosi di infezione da HIV con numero di linfociti CD4 < 350 cell/μL per le principali modalità di trasmissione e anno di diagnosi (2012-2023)

# WHAT'S NEW



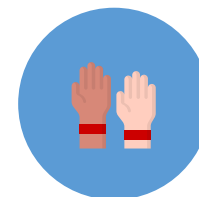
**PARTNER**

Undetectable  
=  
Untransmittable  
(U=U)



**START**

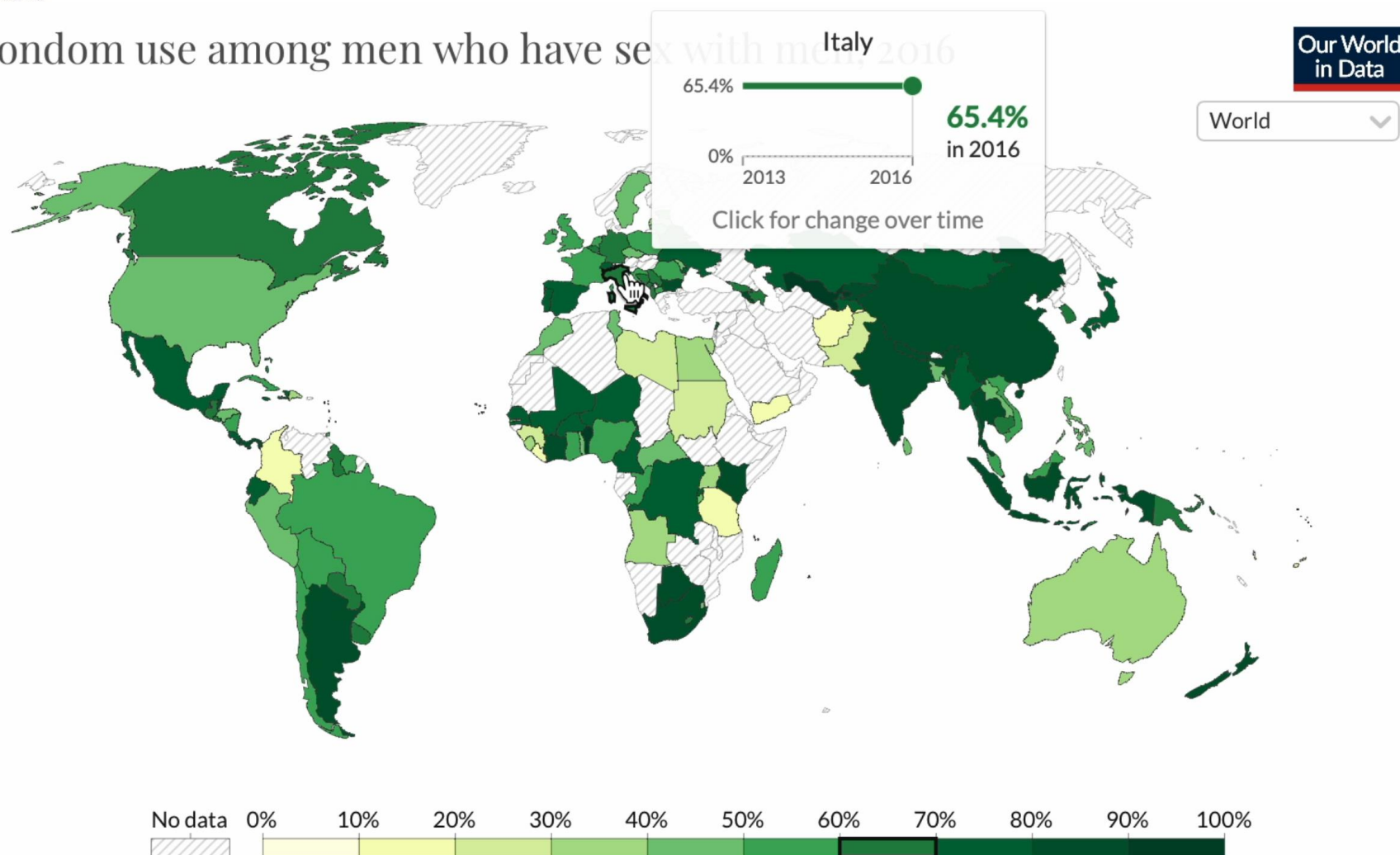
Treatment  
As  
Prevention  
(TasP)



**PROUD  
iPREX  
IPERGAY**

Pre-Exposure  
Prophylaxis  
(PrEP)

## Condom use among men who have sex with men, 2016



Source: UNAIDS

OurWorldInData.org/hiv-aids • CC BY

► 2011

○ 2016

OurWorldInData.org/hiv-aids



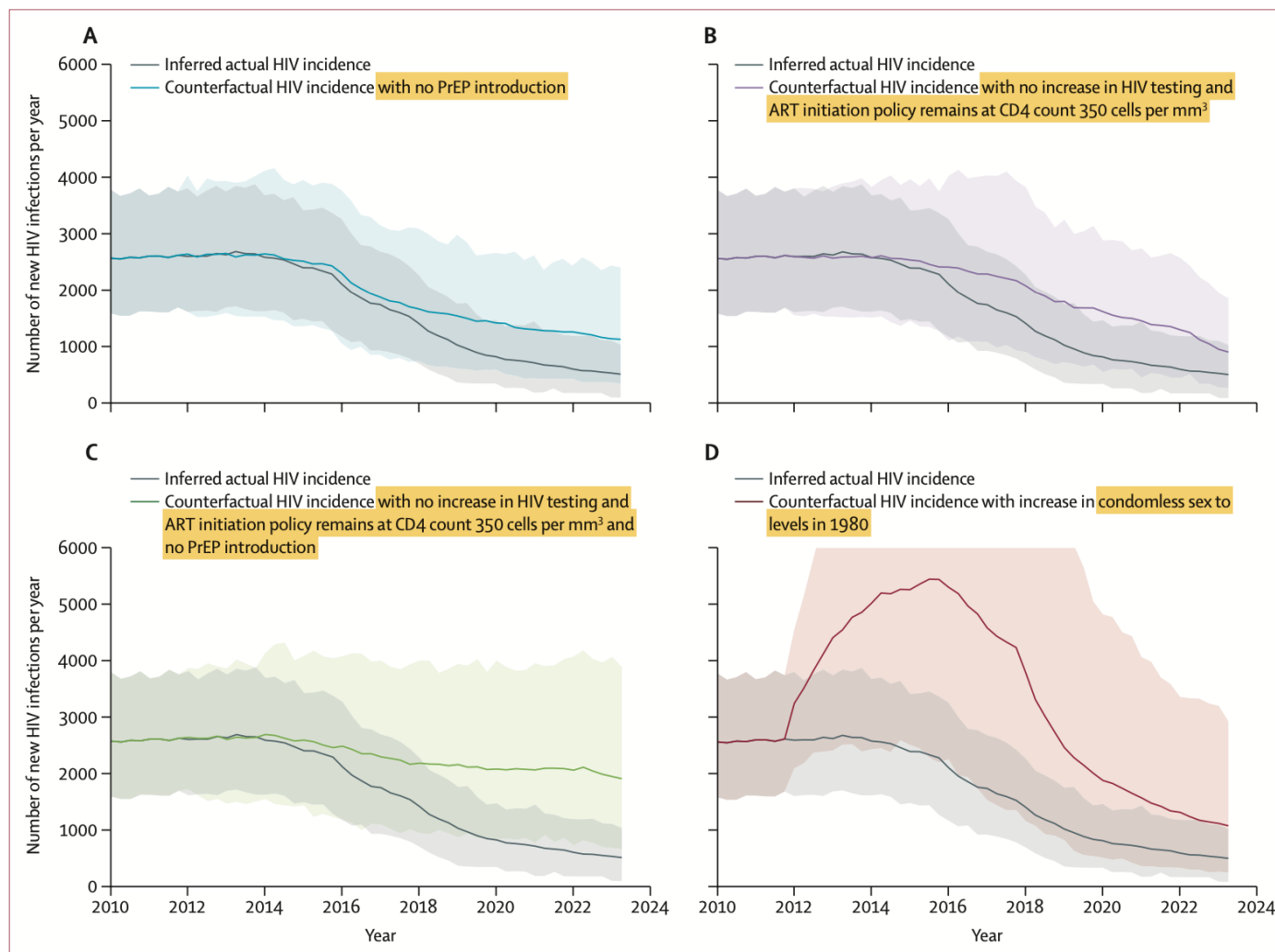
# Oral FTC/TDF PrEP Efficacy in Placebo-controlled RCT

Population	Study	Phase	Participants		Efficacy for Reducing HIV Incidence, %
			Study Drug	Control	
MSM	iPrEx <sup>[1]</sup>	III	FTC/TDF (n = 1251)	Placebo (n = 1248)	44.0 (P = .005)
	<b>IPIRGAY<sup>[2]</sup></b>	<b>III</b>	<b>On-demand FTC/TDF (n = 199)</b>	<b>Placebo (n = 201)</b>	<b>86.0 (P = .002)</b>
HS men & women	Partners PrEP <sup>[3]</sup>	III	FTC/TDF (n = 1583)	Placebo (n = 1586)	75.0 (P < .001)
	TDF2 <sup>[4]</sup>	II/III	FTC/TDF (n = 611)	Placebo (n = 608)	62.2 (P = .03)
PWID	BTS <sup>[5]</sup>	II/III	TDF (n = 1204)	Placebo (n = 1207)	48.9 (P = .01) If detectable TDF: 73.5 (P = .03)

## Effectiveness in open-label/extension/demonstration project studies (MSM)

- iPrEx OLE: 49% reduction with vs without PrEP after adjusting for sexual practices<sup>[6]</sup>
- **PROUD: 86% reduction** with immediate vs deferred (12 mos) PrEP initiation (P = .0001)<sup>[7]</sup>
- Demo Project: 557 initiated PrEP, 437 retained 48 wks; 2 HIV infections occurred, both with TFV-DP levels consistent with < 2 doses/wk at seroconversion<sup>[8]</sup>
- **IPIRGAY extension: 97% reduction with on-demand PrEP (vs placebo arm of randomized trial)<sup>[9]</sup>**

# Oral PrEP as a Game-Changer



Our model estimated a **77%** (90% uncertainty interval [UI] 61–88) **decline in HIV incidence since around 2014**, with an estimated 597 infections ([90% UI 312–956]; 1·1 per 1000 person-years [90% UI 0·6–1·8]) in men aged 15–64 years in 2022.

We estimate there would have been:

- **Without PrEP introduction, 2·16 times the number of infections that actually occurred** (90% UI 1·06–3·75) between 2012 and 2022;
- **without increased HIV testing and ART initiation at diagnosis 2·18 times the number of infections that actually occurred** (1·18–3·60),
- and if **condomless sex** was at the levels before the HIV epidemic, **2·27 times the number of infections that actually occurred** (0·9–5·4).

Press release No. 704

11 May 2023



### **AIFA approves reimbursability of drugs for pre-exposure prophylaxis to HIV-1 (PrEP)**

With Resolution of the BoD No. 15 of 26 April 2023, the Italian Medicines Agency admits the reimbursability of the association Emtricitabine/Tenofovir Disoproxil for “Pre-exposure prophylaxis (PrEP) and with a view to reducing the risk of sexually transmitted HIV-1 infection in adults and adolescents at high risk”. It is an additional prevention tool for HIV-negative people with high-risk sexual behaviours and a measure of significant impact on public health.



Centers for Disease Control and Prevention  
CDC 24/7: Saving Lives, Protecting People™



# PrEP EFFECTIVENESS

## How effective is PrEP?

PrEP is highly effective for preventing HIV.

- PrEP reduces the risk of getting HIV from sex by about 99% when taken as prescribed.

## Effectiveness Improves With Adherence

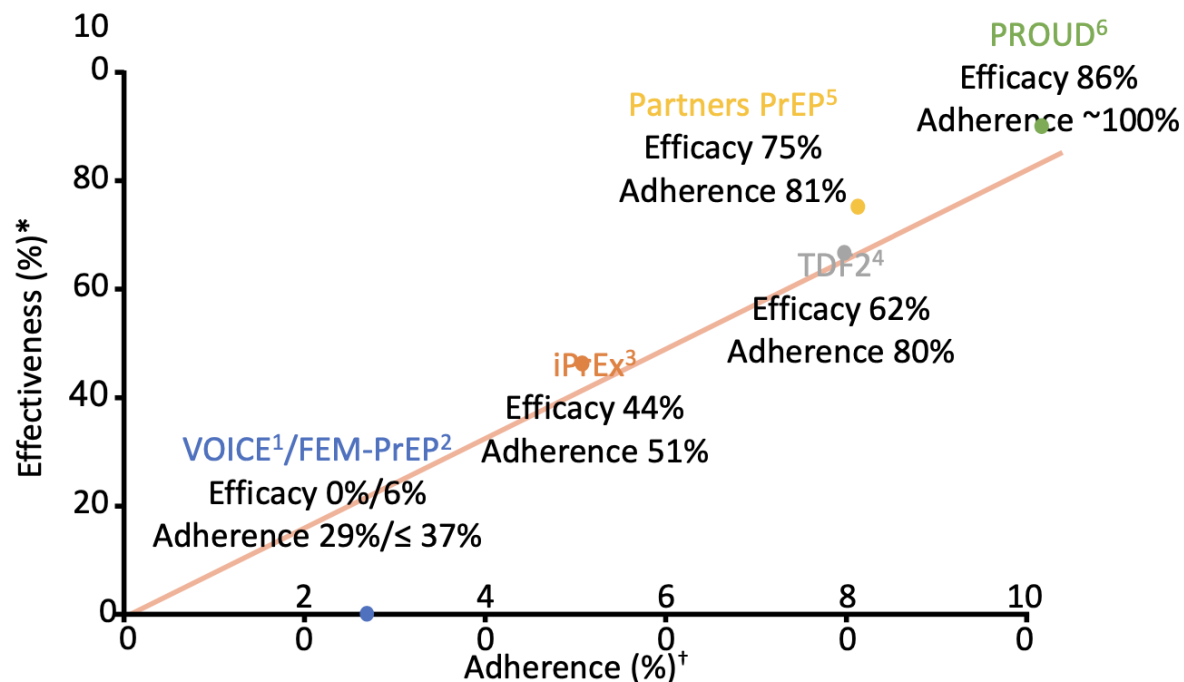


Figure 5: Adherence and F/TDF PrEP Efficacy in MSM

Weekly Medication Adherence Estimated by Drug Concentration	HIV Incidence per 100 person/years
None	4.2
≤2 pills/week	2.3
2-3 pills/week	0.6
≥4 pills/week	0.0

1. Marrazzo. NEJM. 2015;372:509. 2. Van Damme. NEJM. 2012;367:411. 3. Grant. NEJM. 2010;363:2587.  
4. Thigpen. NEJM. 2012;367:423. 5. Baeten. NEJM. 2012;367:399. 6. McCormack. Lancet. 2016;387:53.

### Why?

Daily pill not a suitable or desirable prevention strategy for everyone. More options = expanded access/use by people at risk

LA IM CAB met criteria for **superiority** vs daily oral FTC/TDF in both trials

## HPTN 083<sup>1</sup>



- N = 4566 MSM and TGW
- 13 incident infections with LA CAB vs 39 with oral FTC/TDF
  - **4 with on-time CAB injections**
  - 1 CAB infection later determined to be baseline infection
- HR for CAB vs FTC/TDF:  
**0.34 (95% CI: 0.18-0.62)**

## HPTN 084<sup>2</sup>



- N = 3224 cisgender women
- 4 incident infections with LA CAB vs 36 with oral FTC/TDF
  - **0 with on-time CAB injections**
  - 1 CAB infection later determined to be baseline infection
- HR for CAB vs FTC/TDF:  
**0.12 (95% CI: 0.05-0.31)**





## PURPOSE 1



The NEW ENGLAND  
JOURNAL of MEDICINE

ORIGINAL ARTICLE

Twice-Yearly Lenacapavir or Daily F/TAF for  
HIV Prevention in Cisgender Women

## PURPOSE 2

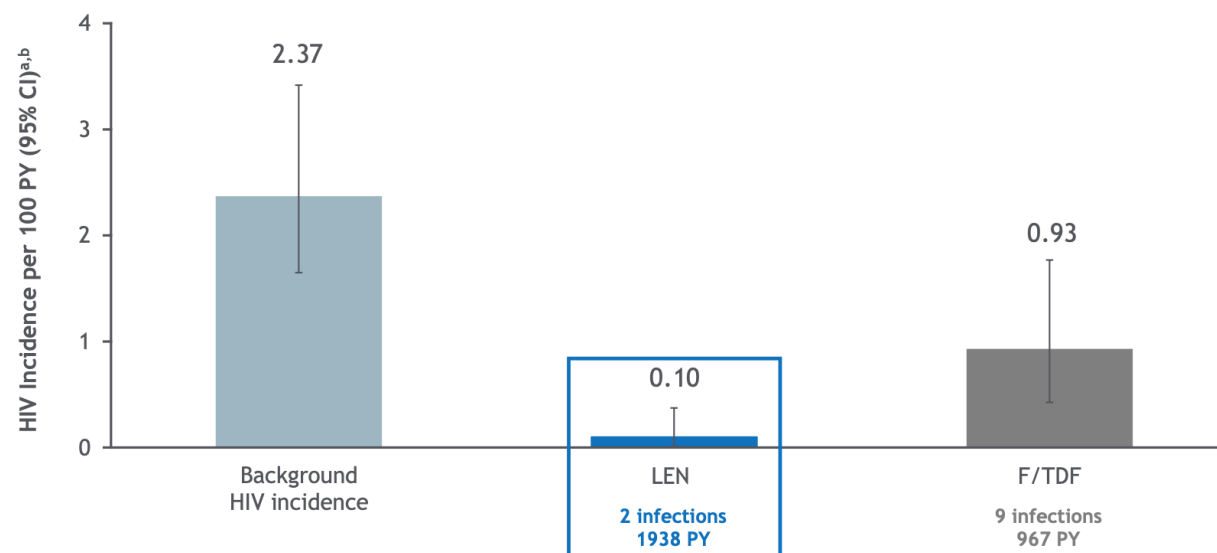
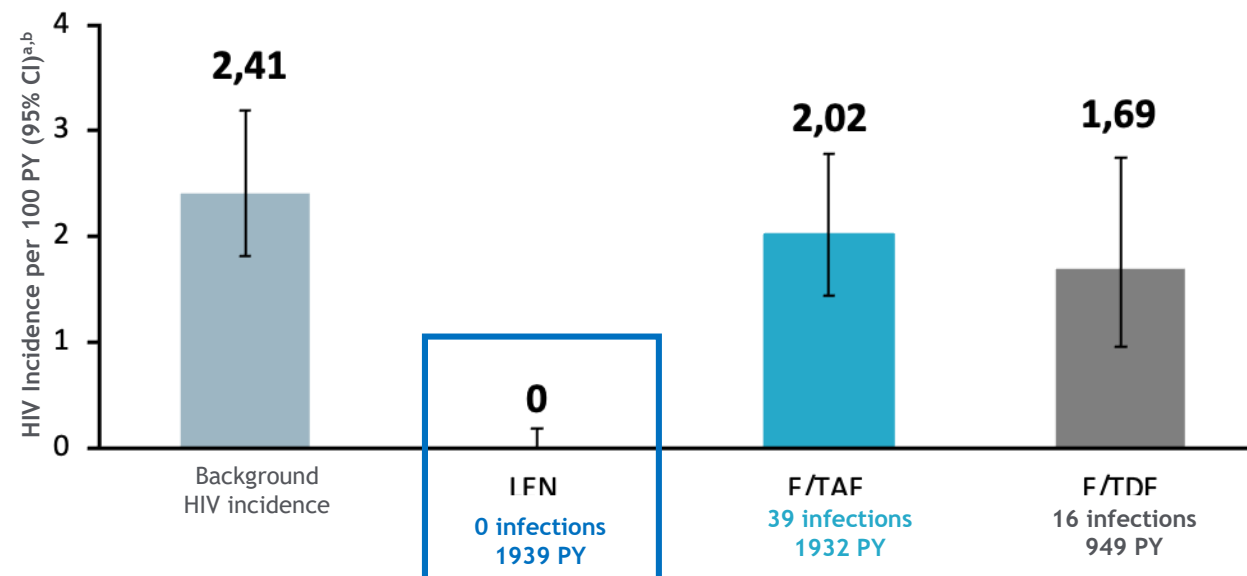


The NEW ENGLAND  
JOURNAL of MEDICINE

ORIGINAL ARTICLE

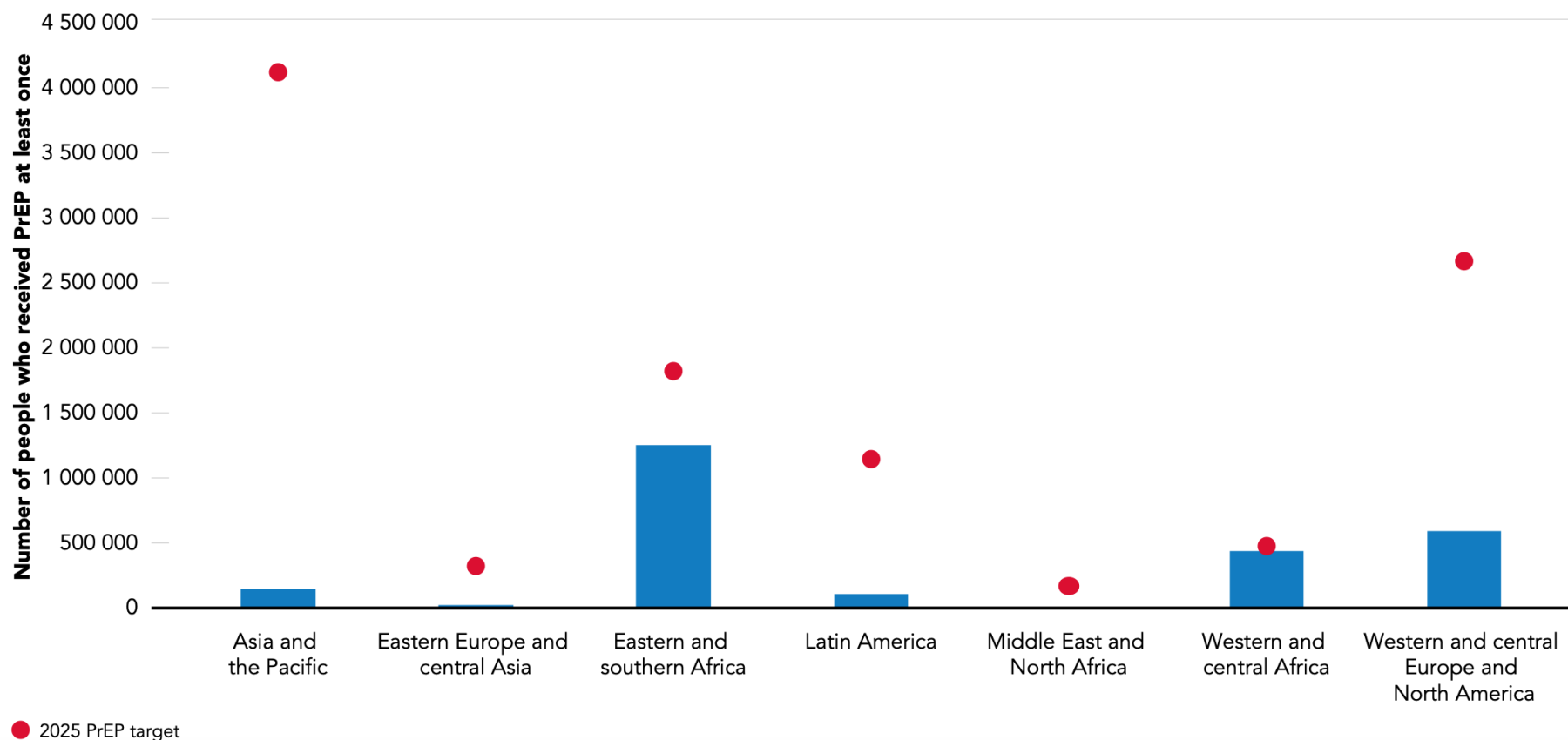
Twice-Yearly Lenacapavir for HIV Prevention  
in Men and Gender-Diverse Persons

### HIV Incidence



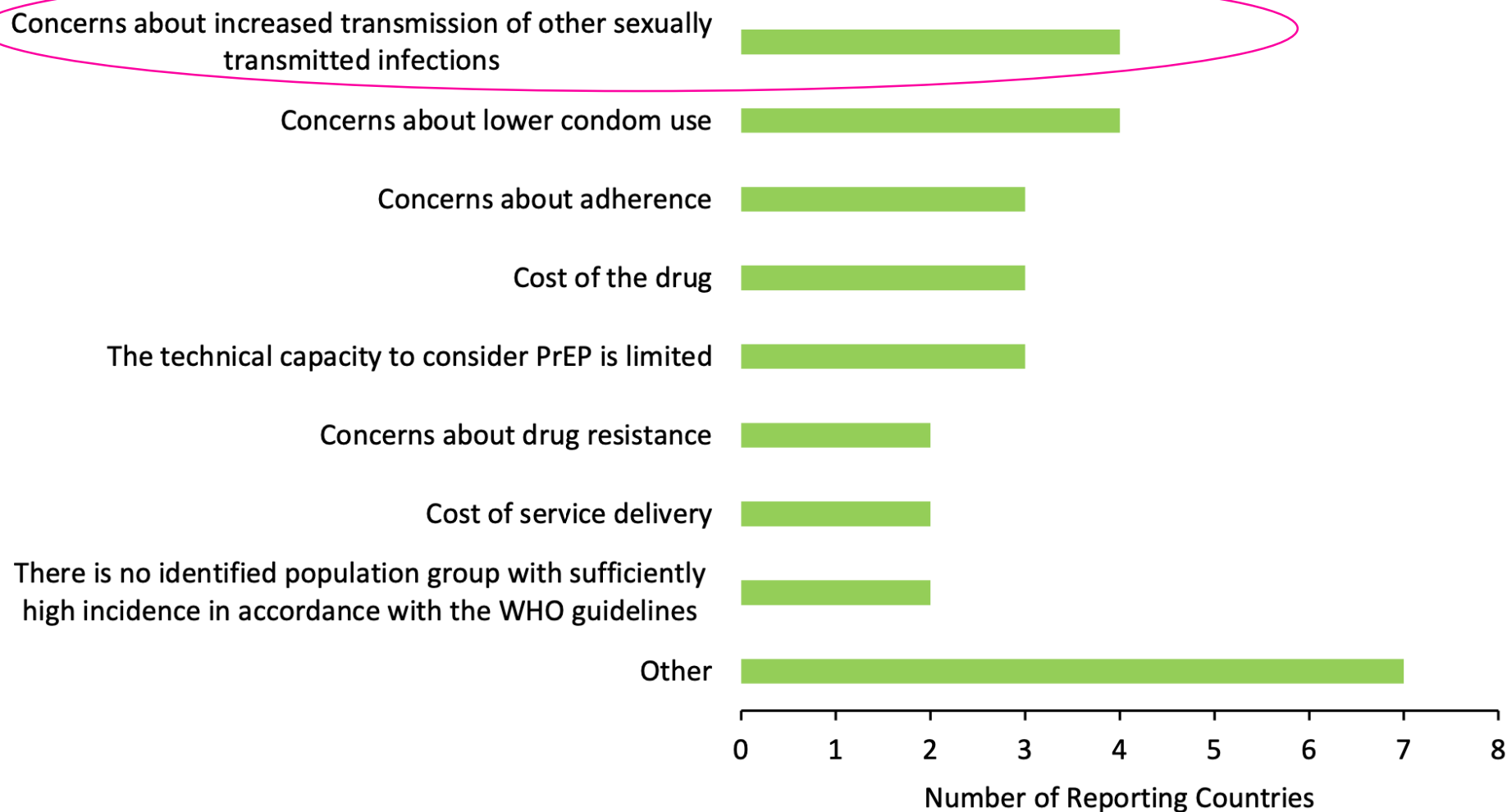
# PrEP is Vastly Underutilized

**Figure 2.6** Number of people who received PrEP at least once during the reporting period, by region, 2022, and 2025 target



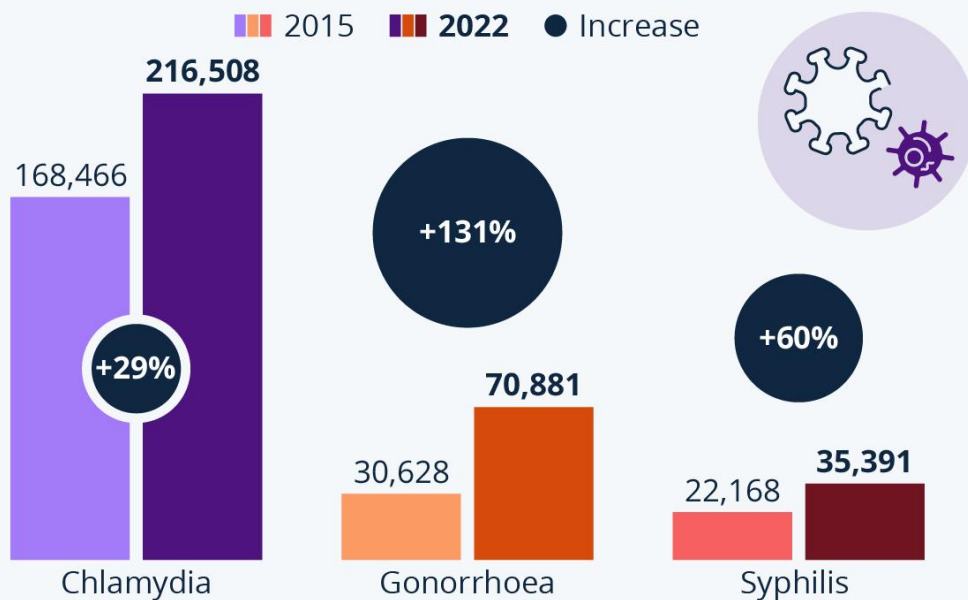


**Figure 2. Issues preventing or limiting PrEP implementation across Europe and Central Asia (n=15)**



## STIs Are on the Rise in Europe

Reported number of confirmed cases of gonorrhoea, syphilis and chlamydia in 2015 and 2022 in the EU/EEA\*



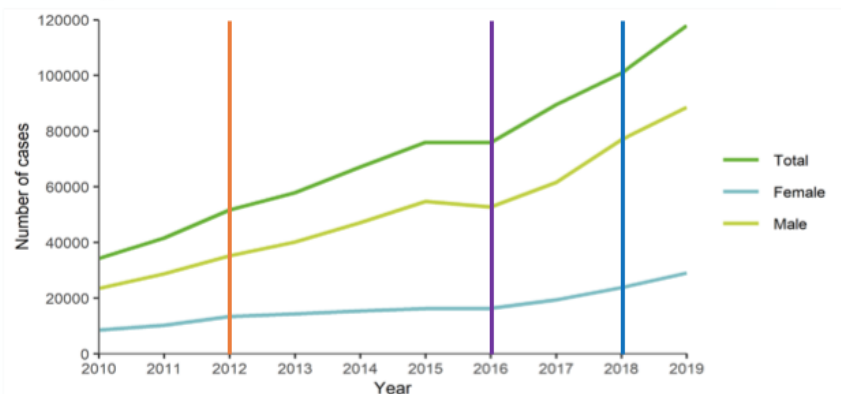
\* Excluding UK. No data for Germany, incomplete data for Austria, Liechtenstein.  
France, Netherlands, Belgium likely an undercount due to non-comprehensive reporting system.  
Source: ECDC Surveillance Atlas of Infectious Diseases

Adapted from Tabesh et al STI 2022 | Kent et al CID 2005

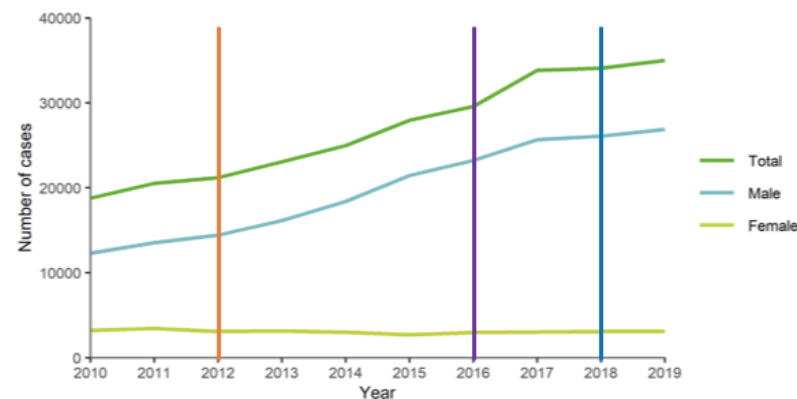


Ultra sensitive testing  
Expansion of accessible testing

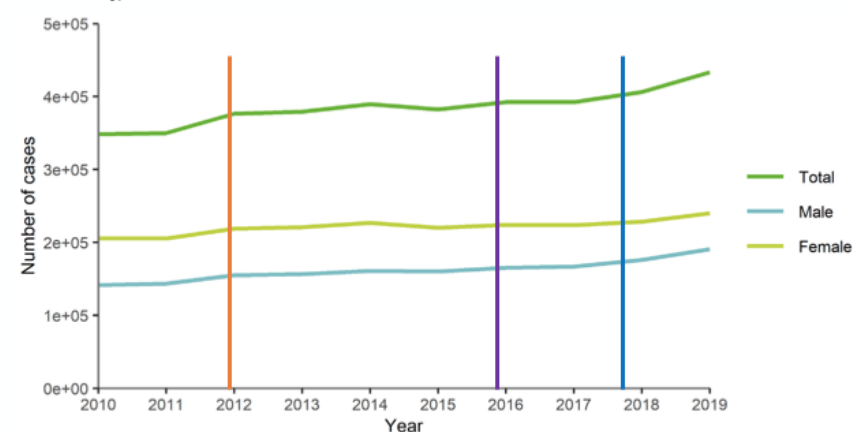
**Figure 4. Number of confirmed gonorrhoea cases by sex and year in EU/EEA countries reporting consistently, 2010–2019**



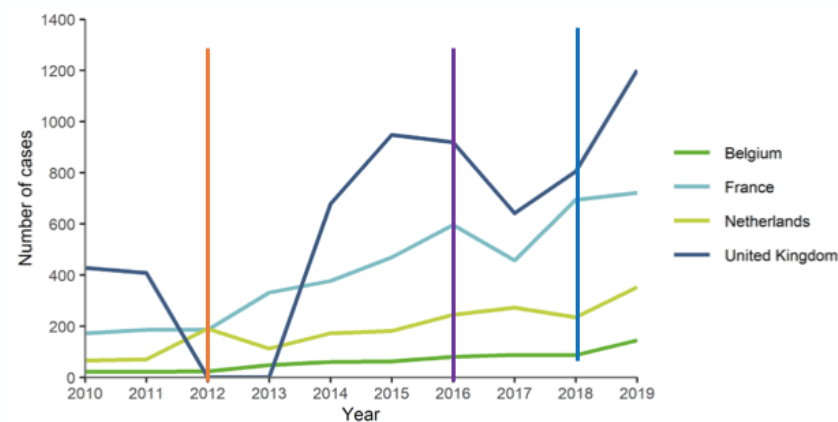
**Figure 4. Number of confirmed syphilis cases by gender and year in EU/EEA countries reporting consistently, 2010–2019**



**Figure 3. Number of confirmed chlamydia cases by sex and year in EU/EEA countries reporting consistently, 2010–2019**



**Figure 2. Number of confirmed lymphogranuloma venereum cases during the period 2010–2019 in the four EU/EEA Member States with the highest number of cases in 2019**

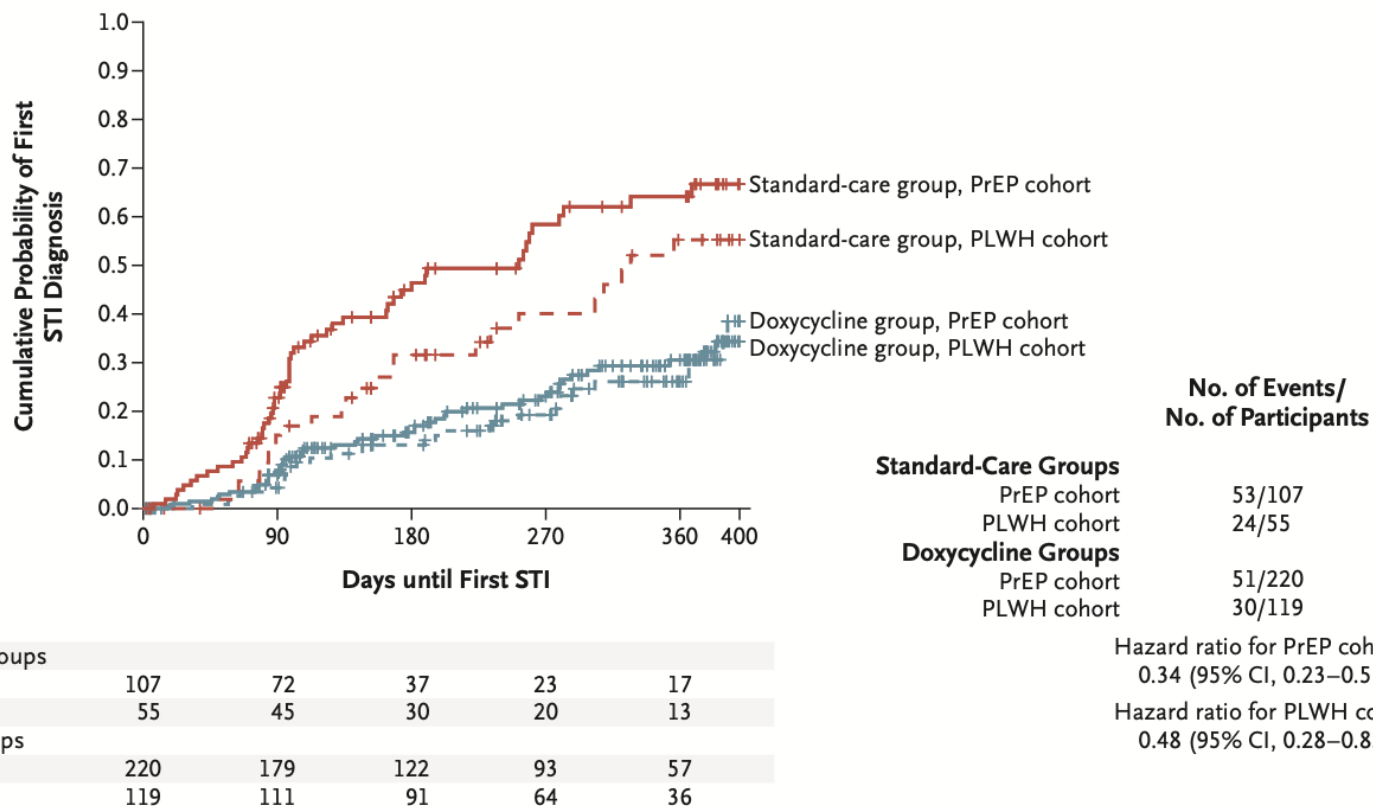


**FDA  
approval**

**EMA  
approval**

**Italy  
introducit.**

# DoxyPEP



**Figure 3. Kaplan–Meier Estimate of Time to First STI Diagnosis.**

The cumulative probability of any incident bacterial STI (chlamydia, gonorrhea, or syphilis) is shown according to study group (doxycycline and standard care) and participant cohort (PrEP and PLWH).

## Efficacy against STI's in HIV-negative people



**Chlamydia**



**Syphilis**



**Gonorrhoea**

## Efficacy against STI's in people living with HIV



**Chlamydia**



**Syphilis**



**Gonorrhoea**

# What about AMR?

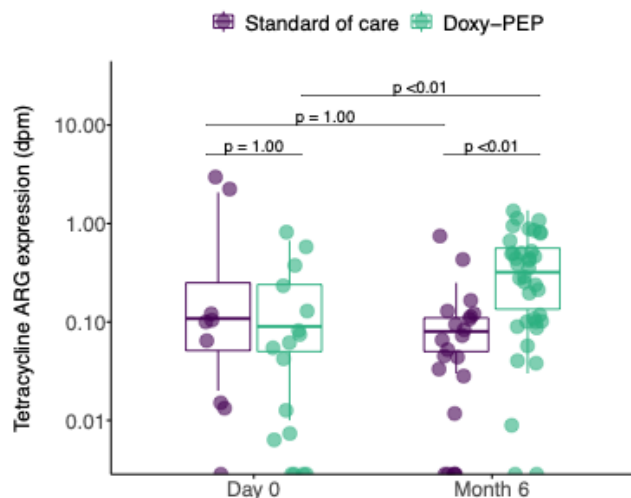


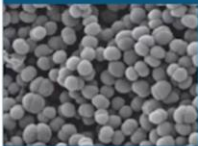


Figure. Tetracycline antimicrobial resistance gene (ARG) normalized expression, measured in average ARG sequencing depth per million reads sequenced (dpm), between the Month 0 and Month 6 samples in the doxy-PEP and SOC arms.

- Comparison of actively expressed AMR genes in 46 dPEP and 24 SOC pts
- No difference in gut bacterial microbiome  $\alpha$ - or  $\beta$ -diversity or total abundance between arms at M0 or M6, or over time by arm
- Actively expressed TCN-R genes increased by median of 2 in dPEP group ( $P < 0.01$ ) without change to non-TCN classes

	<i>N. gonorrhoeae</i>	<ul style="list-style-type: none"> <li>• In the setting of &gt;50% reduction of GC with doxy-PEP, TCN-R was present in 4 baseline GC isolates, 6 incident GC isolates in doxy-PEP arm, and 2 incident GC isolates in SOC arm.</li> <li>• Suggests doxy-PEP may be less protective against TCN-R strains; however, limited by small numbers</li> <li>• Unable to assess doxy-PEP as driver of TCN-R in GC.</li> </ul>
	<i>S. aureus</i>	<ul style="list-style-type: none"> <li>• Doxy-PEP associated with 14% absolute reduction in colonization and an 8% absolute increase in doxycycline resistance compared to baseline.</li> <li>• MRSA prevalence was low (6%) &amp; doxy-R MRSA was unchanged with doxy-PEP use.</li> </ul>
	Non-pathogenic <i>Neisseria</i> species	<ul style="list-style-type: none"> <li>• Nearly two thirds of isolates had pre-existing doxycycline resistance.</li> <li>• No significant change associated with doxy-PEP use.</li> </ul>

#### Limitations:

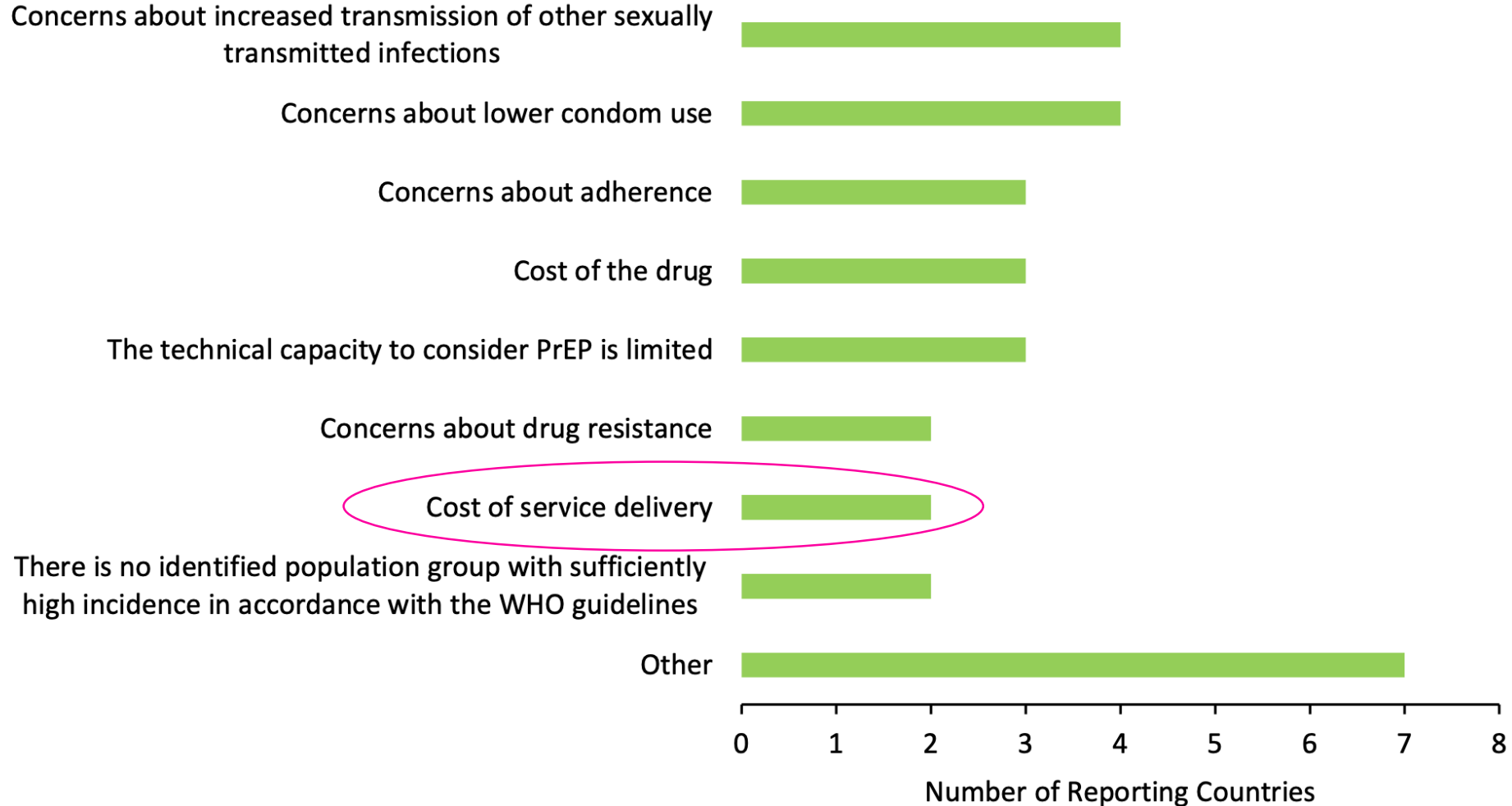
- Small number of GC isolates available from incident cases
- $\leq 12$  months of follow-up
- SOC participants also received doxycycline for incident STIs

DOXYPEP

30<sup>th</sup>  
CROI 2023

DoxyPEP associated with higher number of AMR genes without significant alteration of gut microbiome diversity

**Figure 2. Issues preventing or limiting PrEP implementation across Europe and Central Asia (n=15)**

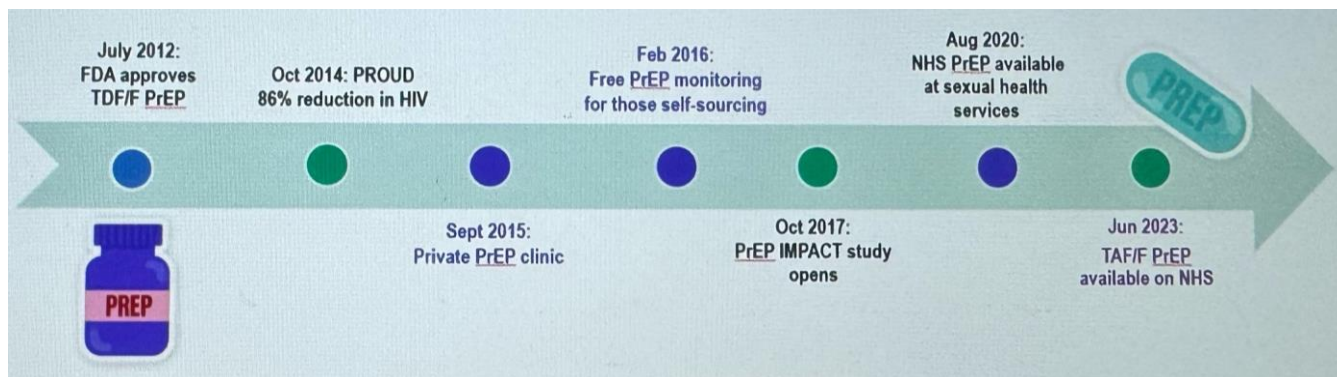




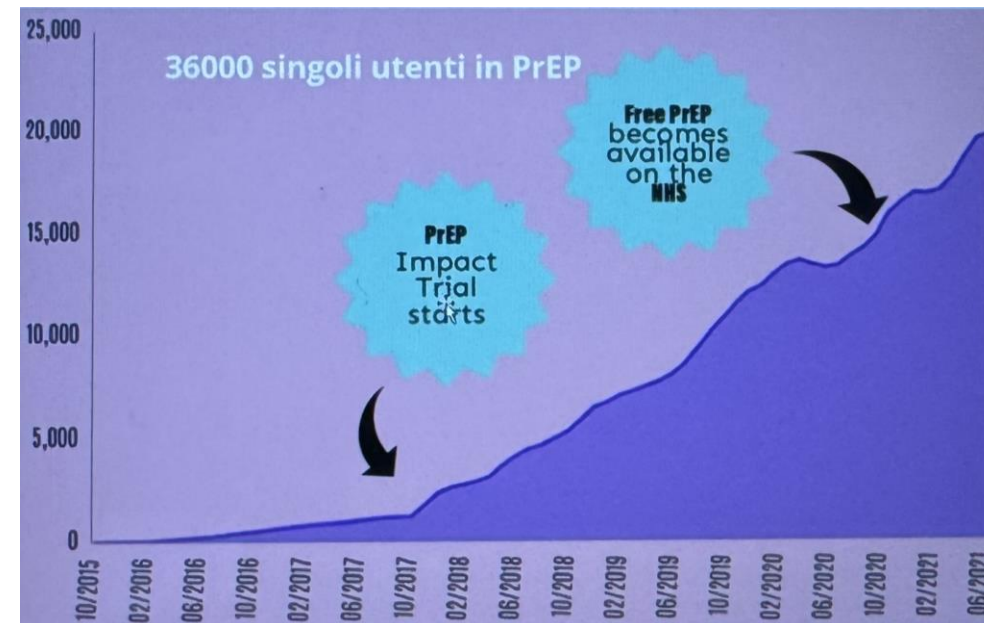
# THE LANCET HIV

## Nurse-led PrEP provision at 56 Dean Street

[Gary Whitlock](#)  · [Jon Clark](#) · [Vicky Tittle](#) on behalf of the [Dean Street Collaborative Group](#)

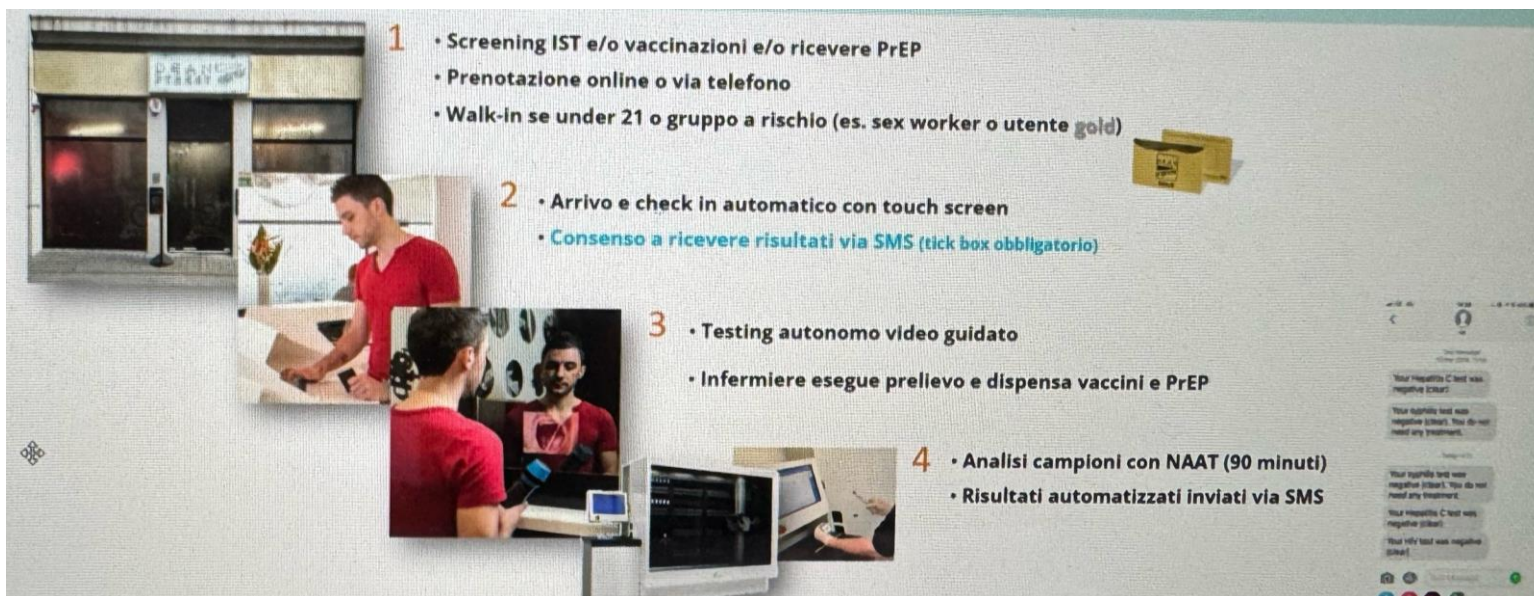


- Free HIV testing (no IDs required)
- STIs Screening (both asymptomatic or with symptoms)
- Vaccinations (HAV, HBV, HPV, mpox)
- HIV healthcare
- PEP and PrEP Services
- Risk Reduction Counselling (chemsex)
- Female Health and Contraception
- Gender Identity Clinic



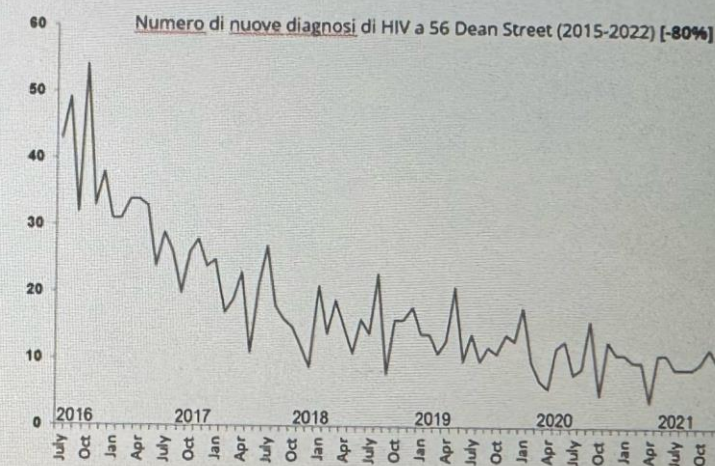
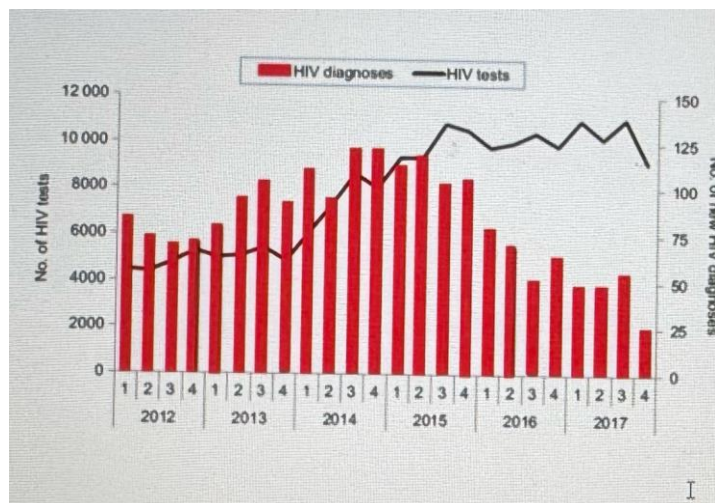
### Team of 140 people

- 6 full time consultants
- 4 associates, 7 junior doctors
- 70 nurses
- 20 administrative workers
- 3 pharmacists

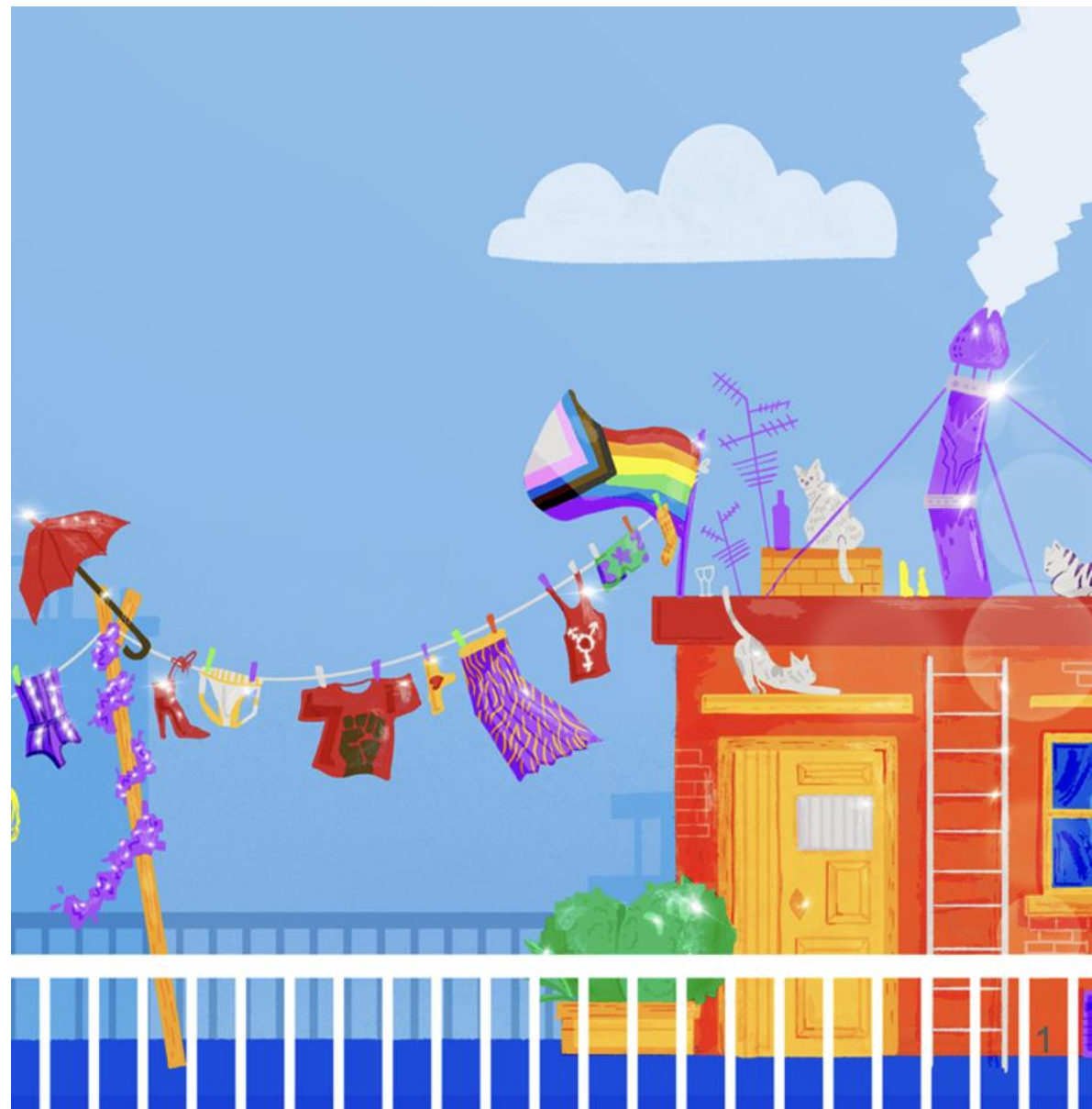


Who can prescribe PrEP in UK?

- STI consultants in Sexual Health Clinics
- Nurses with PGD in Sexual Health Clinics







# Background

- HIV/AIDS surveillance in Europe 2022–2021 data
  - 56% of all individuals diagnosed with CD4 count  $<350$  cells/mm<sup>3</sup>
  - 36% of cases with advanced infection (CD4 count  $<200$  cells/mm<sup>3</sup>)
- Barriers to HIV testing
  - Stigma and discrimination
  - Fear of result
  - Low perception of risk
  - Lack of awareness of health-care professionals
- ***Community Based Voluntary Counselling and Testing (CBVCT) services***
  - Make testing more accessible & engage communities through outreach
  - Provide support after testing



Here we present data on HIV and syphilis screening during the period 2019-2023, carried out by Milano Check Point in different informal settings

# Methods

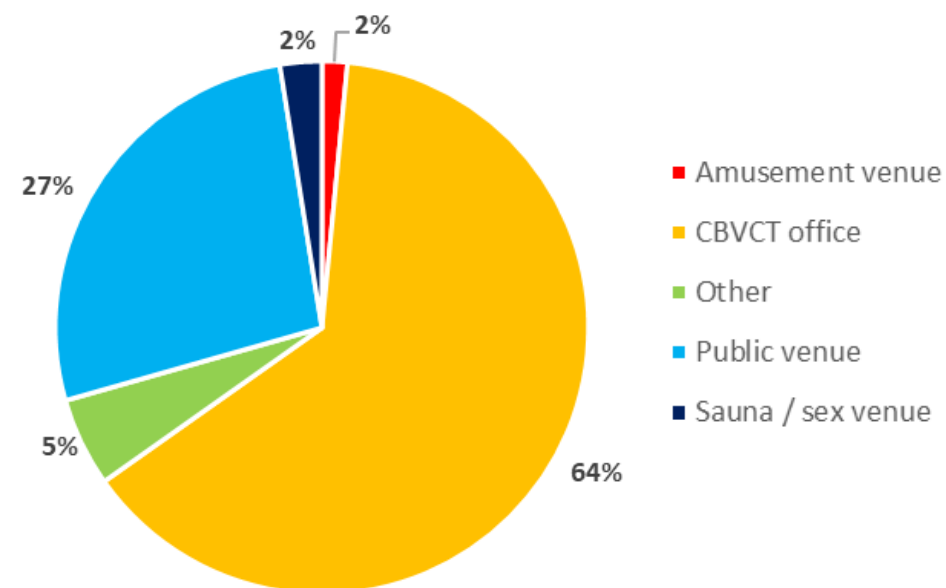
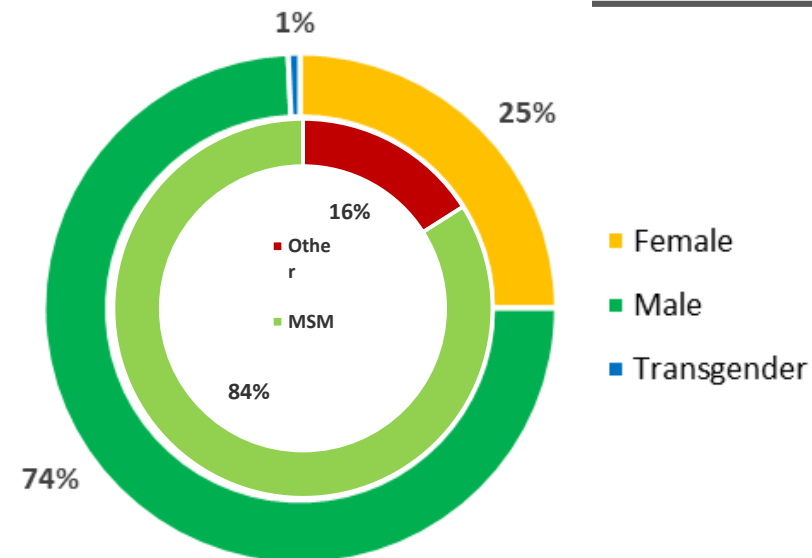
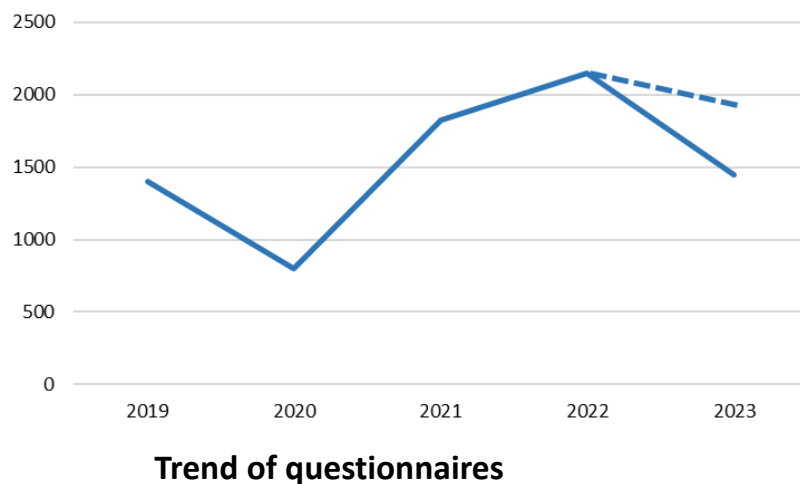


## Capillary point-of-care rapid HIV and syphilis tests

- Indoor screening sessions in the association site
  - Outdoor offer during public events (e.g. Pride)
  - Amusement venues (cruising, sauna, disco, etc.)
- 
- Anonymous, self-administered questionnaires about sex attitudes and risky behaviour Data collected through a protected web platform (<http://cobatest.org>)

# Results

- 5 years (2019-2023)
  - 7626 questionnaires
  - 7504 HIV and 5617 syphilis tests
  - Median age 29 yo (IQR 25-37)

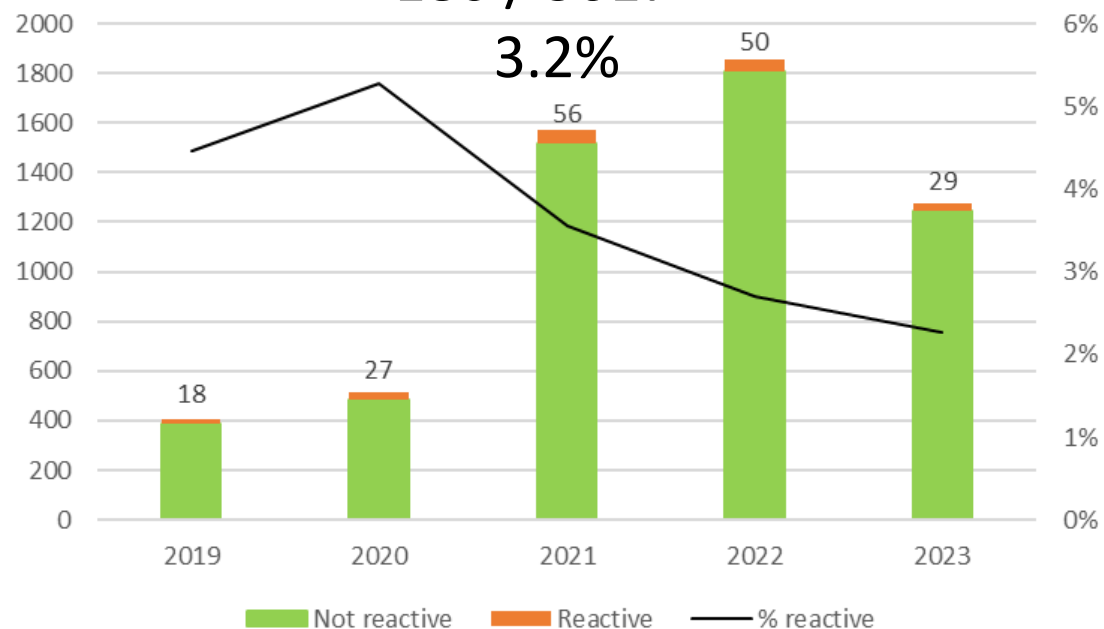


# Trends of syphilis and HIV screening

## Syphilis

$$180 / 5617 =$$

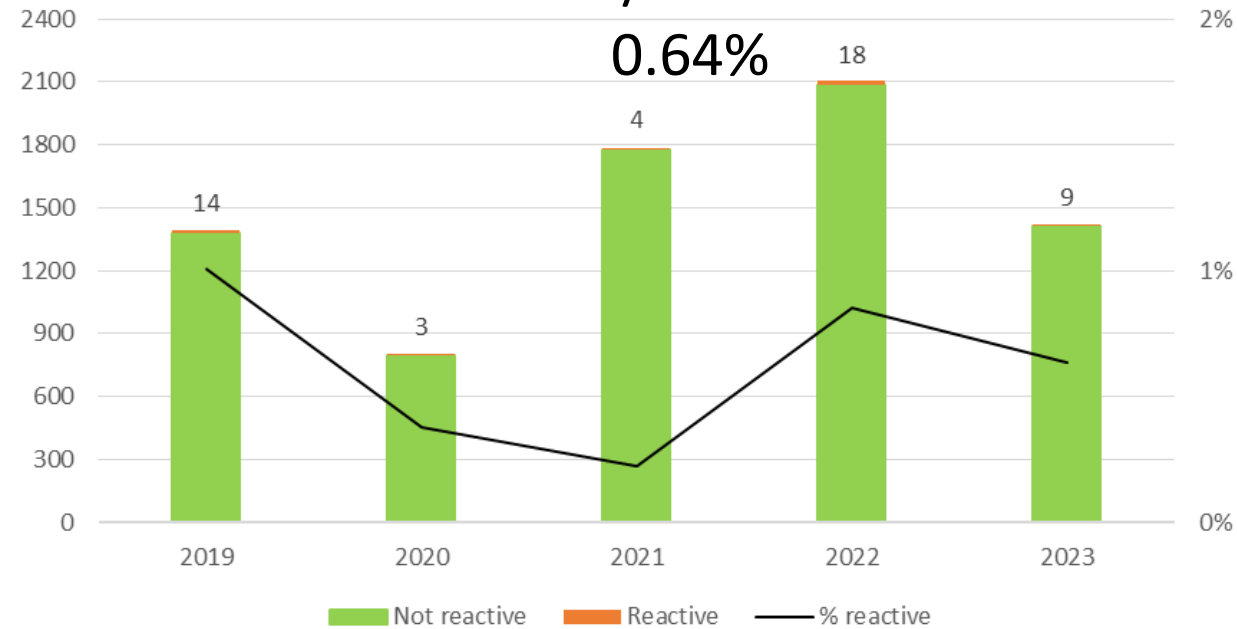
**3.2%**



## HIV

$$48 / 7504 =$$

**0.64%**



# Conclusion

- CBVCT maintain a fundamental role in offering HIV screening in informal setting, especially for “harder-to-reach” groups
  - Factors independently associated with a positive HIV test result
    - Increasing age
    - Foreigner
    - Transgender
    - Syphilis coinfection
    - Imprisonment



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**HEADING FOR THE FUTURE**

THANKS FOR LISTENING!

Questions to:

[davide.moschese@unimi.it](mailto:davide.moschese@unimi.it)