



MILANO  
29-30-31  
ottobre  
**2025**

XIV CONGRESSO NAZIONALE

## **PREVENZIONE E CURA DELLE DIPENDENZE**

**Traguardi raggiunti e nuove prospettive  
di intervento e di ricerca**

Centro Congressi QUARK Hotel Milano

**FeDerSerD**

FEDERAZIONE ITALIANA DEGLI OPERATORI  
DEI DIPARTIMENTI E DEI SERVIZI DELLE DIPENDENZE

**Stefano**

**Rusconi**

**NOVITA' NEL MONDO DELLE PROFILASSI PRE- E  
POST-ESPOSIZIONE PER HIV**



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S. Rusconi

# COI

*AstraZeneca, Gilead Sciences, Menarini,  
MSD, ViiV Healthcare*

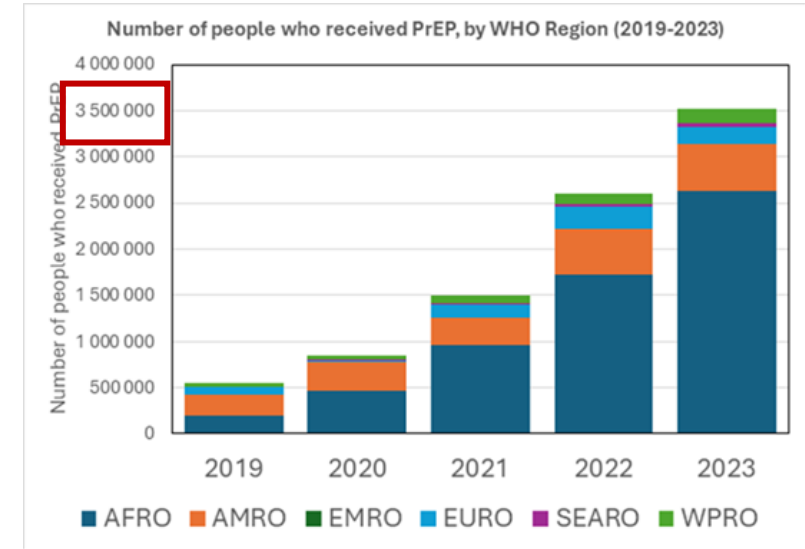


**MEDICI  
CON L'AFRICA  
CUAMM**

# PrEP! Where are we? Where should we go?

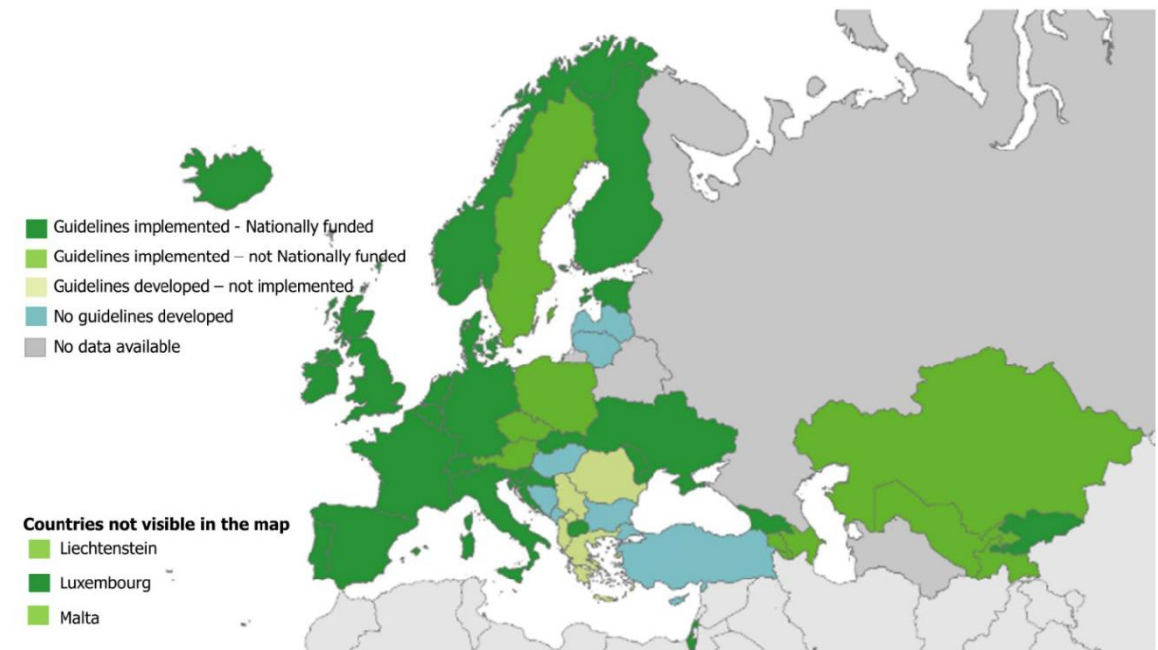


<https://data.prepwatch.org>

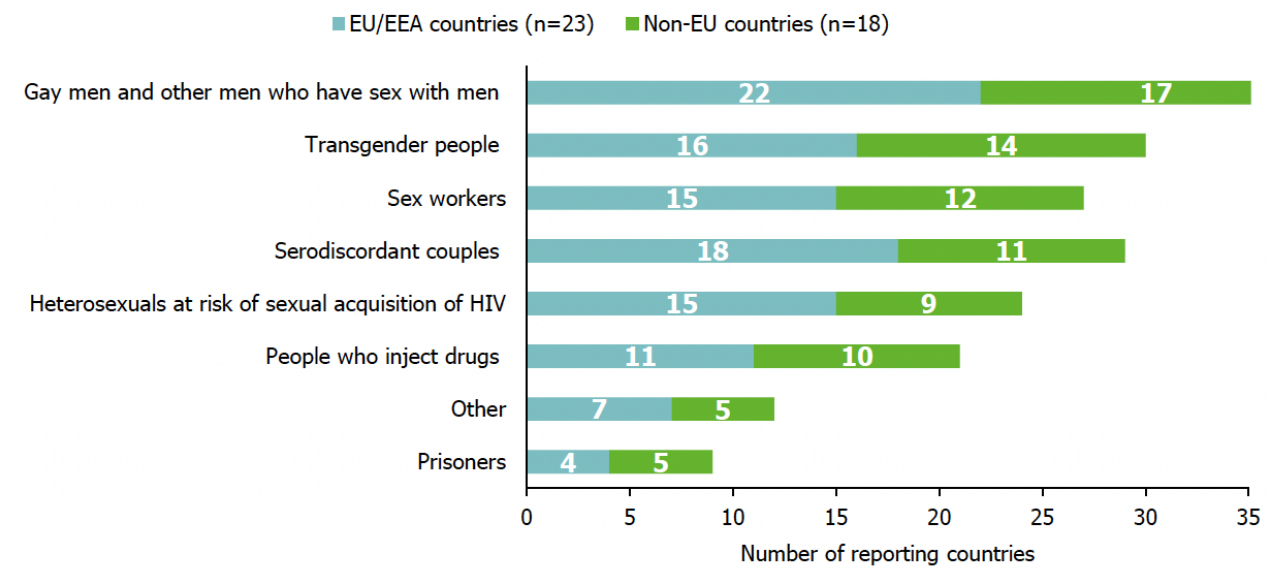


The urgency of now: AIDS at a crossroads. Geneva: Joint United Nations Programme on HIV/AIDS; 2024. Licence: CC BY-NC-SA 3.0 IGO.

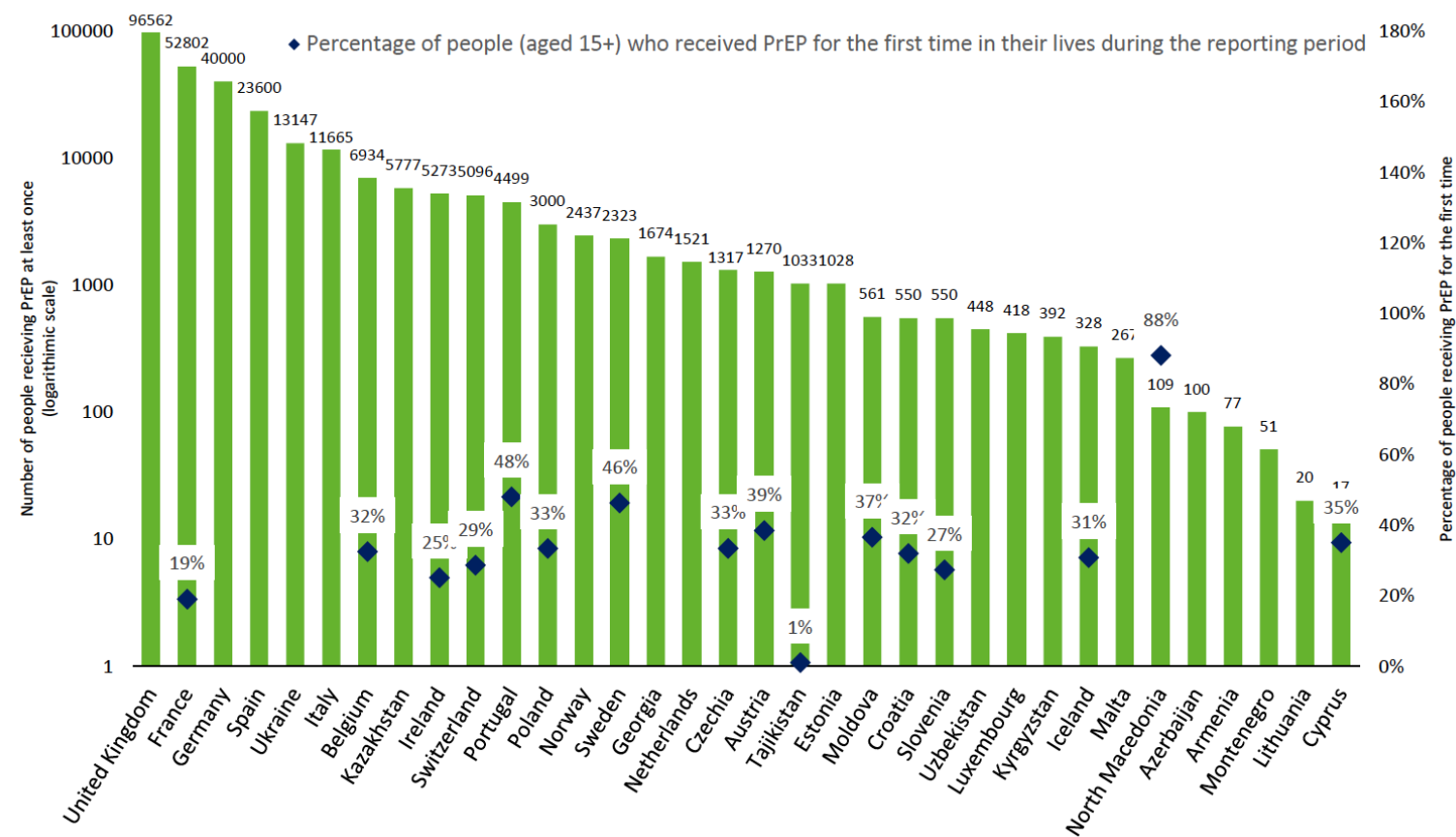
# PrEP implementation and people eligible for PrEP according to national guidelines. Europe and Central Asia, end of 2023



Among the 52 countries in Europe and Central Asia that could provide data, 38 countries (23 EU/EEA countries) reported that PrEP guidelines had been developed and were being implemented



# Number of people (aged 15+) who received PrEP at least once, Europe and Central Asia, end of 2023 (n=34)



In addition to understanding how many people are accessing PrEP, **it is important to identify gaps in access to PrEP.**

**Six countries were able to estimate the proportion of MSM in need of PrEP who were receiving it: Andorra (100%), France (33%), Germany (50%), Kyrgyzstan (1%), Slovenia (85%) and the United Kingdom (74%).**

**However, no country was able to provide an estimate of the unmet needs for PrEP in any other population group.**

# Which could be the PrEP target population in Italy?

| Country | PLWH°   | New HIV diagnosis (2023)° | PrEP users (2023)° | PrEP-to-Need Ratio | Proportion of MSM in need of PrEP receiving it° |
|---------|---------|---------------------------|--------------------|--------------------|-------------------------------------------------|
| UK      | 95,932  | 6,402                     | 96,562             | 15.08              | 74%                                             |
| France  | 178,700 | 4,981                     | 52,802             | 10.60              | 33%                                             |
| Germany | 90,800  | 3,321                     | 40,000             | 12.04              | 50%                                             |
| Italy   | 140,730 | 2,349                     | 11,665             | 4.96               | unknown*                                        |

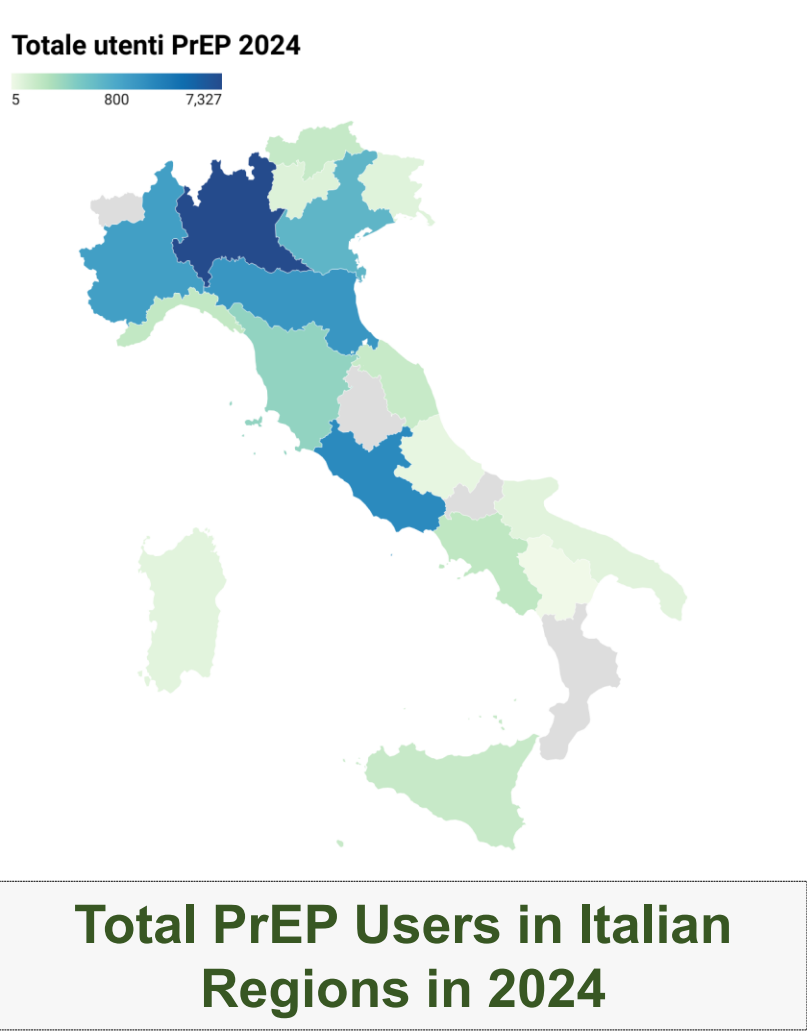
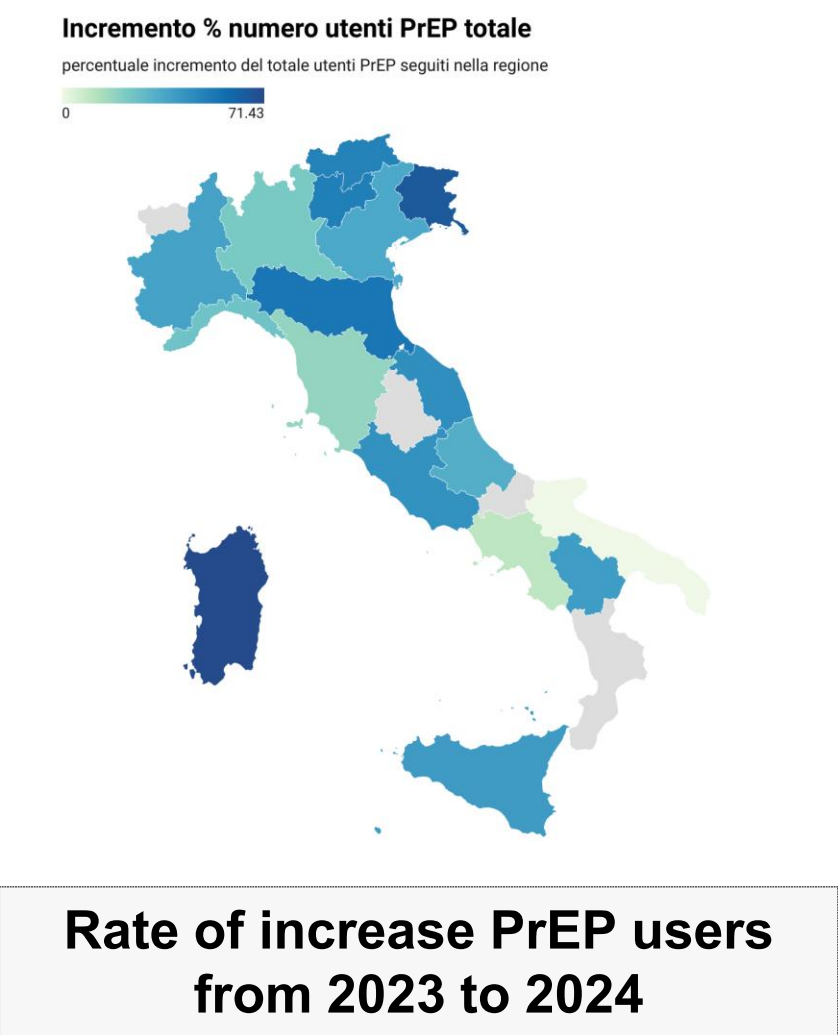
\*assuming a proportion of MSM in need of PrEP receiving it between 24% and 15%, the corresponding final population target in need of PrEP ranged from 49,000 to 77,000.

°Data on PLWH, new HIV diagnosis, number of PrEP users, and proportion of MSM in need of PrEP receiving it were derived from ECDC 2023 surveillance reports.



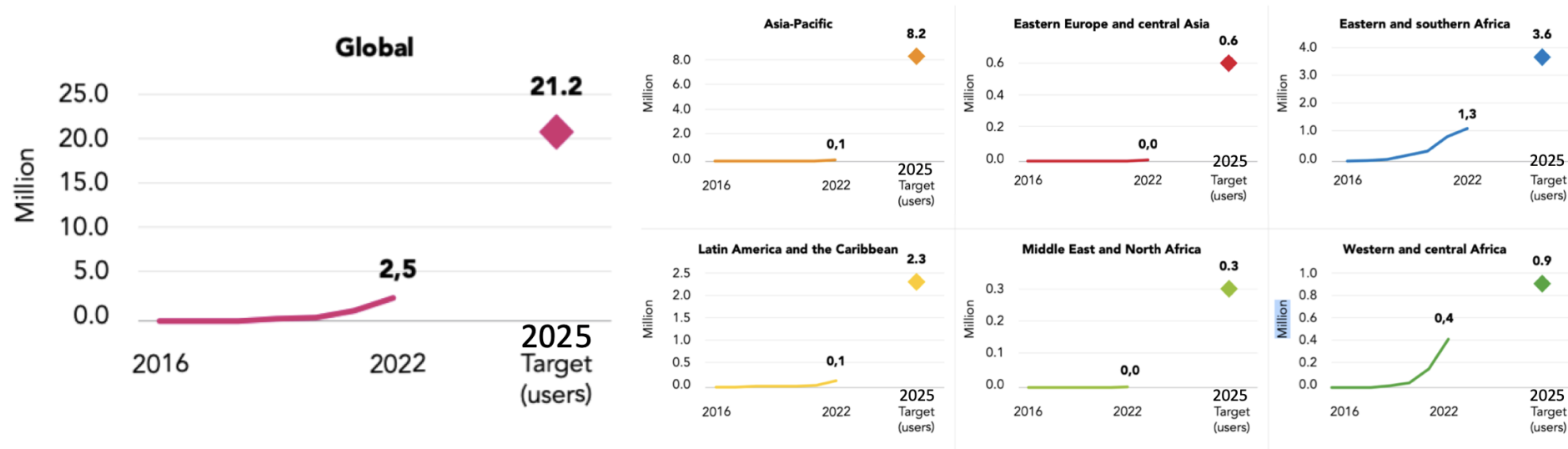
# PrEP increase in Italy between 2023 and 2024

| Regione    | Total increase% | Total users 2024 |
|------------|-----------------|------------------|
| Abruzzo    | +33.33          | 45               |
| Basilicata | +40.00          | 5                |
| Bolzano    | +50.00          | 200              |
| Campania   | +10.09          | 228              |
| Emilia     | +54.67          | 2,067            |
| Friuli     | +65.43          | 81               |
| Lazio      | +44.14          | 2,873            |
| Liguria    | +25.58          | 215              |
| Lombardia  | +23.17          | 7,327            |
| Marche     | +45.31          | 192              |
| Piemonte   | +37.72          | 1,445            |
| Puglia     | 0.00            | 73               |
| Sardegna   | +71.43          | 70               |
| Sicilia    | +40.51          | 195              |
| Toscana    | +18.59          | 425              |
| Trento     | +51.09          | 92               |
| Veneto     | +35.37          | 687              |
| Totale     | +43.22          | 16.220           |



People need access to options so they can use what works for them

# Number of people using HIV PrEP, relative to 2025 targets



1. We need to increase the number of people accessing HIV PrEP  
AND
2. We need more HIV PrEP options – so that people can choose what works for them



# MarketScan Commercial Claims Database: Retrospective cohort study (US)

## Low Rates of PrEP Prescriptions Among Youth



N=100,540

Youth aged 13–21 years  
meeting PrEP indication<sup>a</sup>

### Outcomes

PrEP prescription fill (F/TDF, F/TAF, Q2M IM CAB)

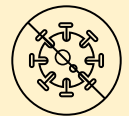


January 2018–  
July 2023

### Demographic and Clinical Factors Associated With PrEP Fill

|                                                              |                    | Adjusted HR (95% CI) |
|--------------------------------------------------------------|--------------------|----------------------|
| Sex                                                          | Male (Ref: Female) | 15.6 (13.4–18.1)     |
| Age, years                                                   | 18–19 (Ref: 13–17) | 2.82 (2.35–3.38)     |
|                                                              | 20–21 (Ref: 13–17) | 3.38 (2.83–4.03)     |
| Year PrEP indication met                                     | 2019 (Ref: 2018)   | 1.24 (1.07–1.43)     |
|                                                              | 2020 (Ref: 2018)   | 1.17 (1.00–1.38)     |
|                                                              | 2021 (Ref: 2018)   | 1.59 (1.36–1.86)     |
|                                                              | 2022 (Ref: 2018)   | 1.64 (1.39–1.94)     |
| Sexual behavior with increased likelihood of HIV acquisition |                    | 2.36 (1.68–3.33)     |
| Syphilis                                                     |                    | 4.52 (2.26–9.03)     |
| Gonorrhea                                                    |                    | 2.47 (1.25–4.87)     |
| Chlamydia                                                    |                    | 0.64 (0.32–1.27)     |
| Number of prior STIs                                         | 1 (Ref: 0)         | 0.75 (0.36–1.56)     |
|                                                              | 2+ (Ref: 0)        | 0.63 (0.16–2.44)     |
| Mental health condition                                      |                    | 2.00 (1.80–2.21)     |
| Substance use                                                |                    | 0.66 (0.55–0.80)     |

Only 1.6% of youth with a PrEP  
indication **received PrEP**



PrEP utilization was **lower** for:

- People aged **<18 years** (vs. ≥18 years)
- **Females** (vs. males)

Time to PrEP fill was **longer** for:

- People aged **<18 years** (vs. ≥18 years)
- **Females** (vs. males)



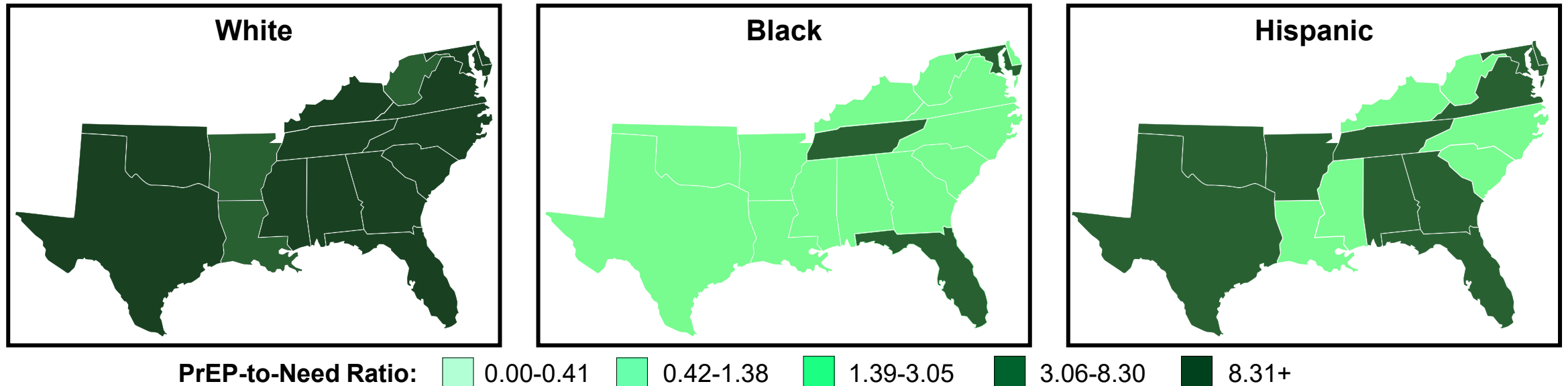
PrEP prescription rates were **lower** in the **Midwest**  
and **South**, as well as in states with less progressive laws

**There are significant gaps in PrEP utilization among youth, especially in those aged under 18 years and in females**

<sup>a</sup>PrEP indication defined as ICD-10 code for gonorrhea, chlamydia, syphilis or high-risk sexual behavior.

# PrEP-to-Need Ratio Has Substantial Racial/Ethnic Disparities

- Substantially greater unmet PrEP need for Black and Hispanic vs White individuals in the South<sup>1</sup>



- US medical professionals are less likely to prescribe PrEP to Black and Hispanic people, contributing to substantial racial/ethnic and geographic disparities<sup>2,3</sup>

1. [aidsvu.org/resources/deeper-look-prep/](https://aidsvu.org/resources/deeper-look-prep/). 2. [aidsmap.com/news/oct-2021/stark-disparities-seen-all-along-us-prep-continuum](https://aidsmap.com/news/oct-2021/stark-disparities-seen-all-along-us-prep-continuum).

3. [aidsmap.com/news/jul-2022/prep-inequities-have-worsened-us-over-last-decade-both-racially-and-regionally](https://aidsmap.com/news/jul-2022/prep-inequities-have-worsened-us-over-last-decade-both-racially-and-regionally).

# PrEP Preferences Among Transgender and Gender Diverse Adults



N=295

HIV-negative transgender and gender diverse adults

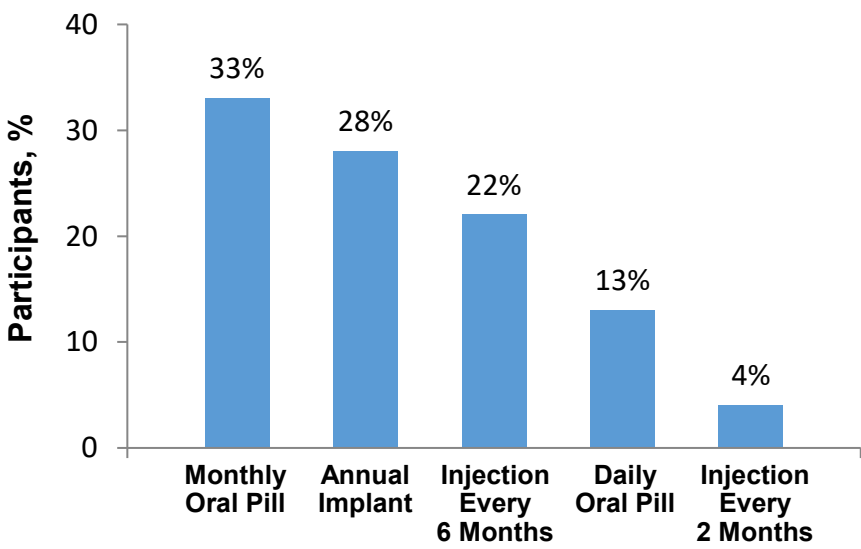
## Outcomes

PrEP preferences; factors associated with reporting injectable PrEP administered every 6 months as the most preferred



April 2022–  
June 2022

Most Preferred PrEP Method



Factors Associated With Reporting Q6M Injectable PrEP as the Most Preferred

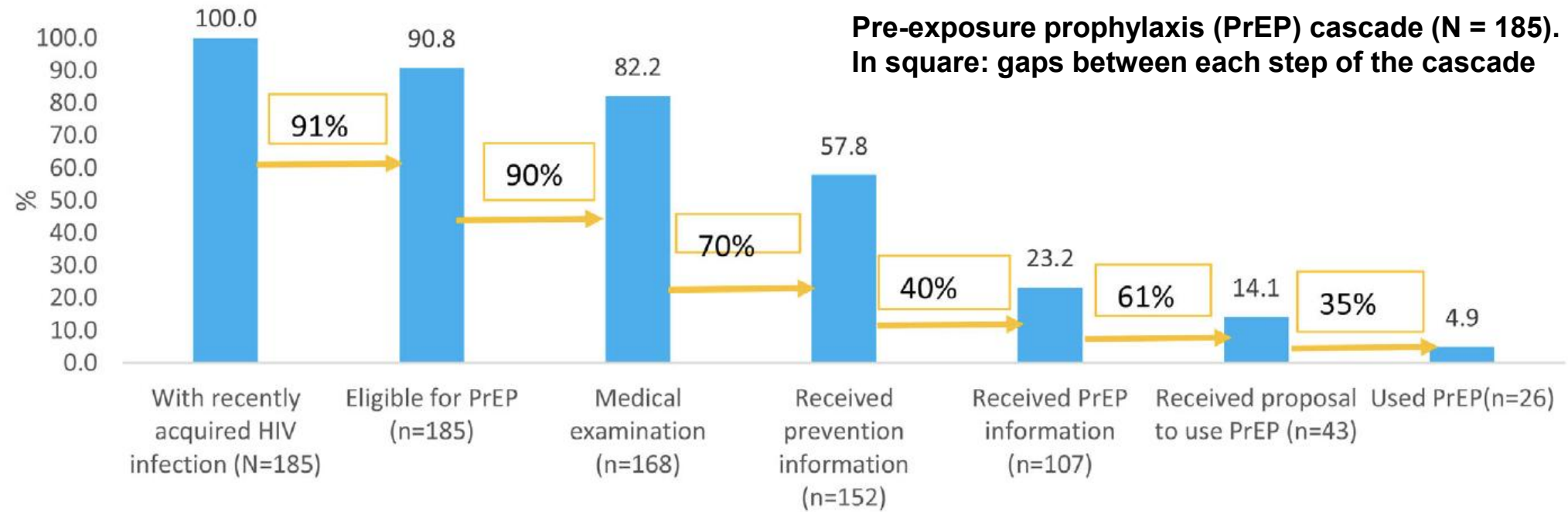
| Race and ethnicity<br>(Reference: Non-Latine White) | Unadjusted OR (95% CI)<br>P value | Adjusted OR (95% CI)<br>P value |
|-----------------------------------------------------|-----------------------------------|---------------------------------|
| Latine, any race                                    | 2.50 (1.19–5.24)<br>P=0.02        | 2.39 (1.10–5.18)<br>P=0.03      |
| Non-Latine Black                                    | 2.41 (1.06–5.52)<br>P=0.04        | 2.77 (1.10–6.98)<br>P=0.03      |
| Non-Latine, another race                            | 1.24 (0.56–2.76)<br>P=0.60        | 1.19 (0.53–2.69)<br>P=0.67      |

Transgender and gender diverse adults preferred twice-yearly injections for PrEP compared with daily oral pills and Q2M injections

# Missed opportunities for HIV pre-exposure prophylaxis among people with recent HIV infection

French national cross-sectional multicentre study enrolling people diagnosed with recent HIV (incomplete Western blot or negative HIV), **analysing missed opportunities for PrEP use via a retrospective PrEP Cascade.**

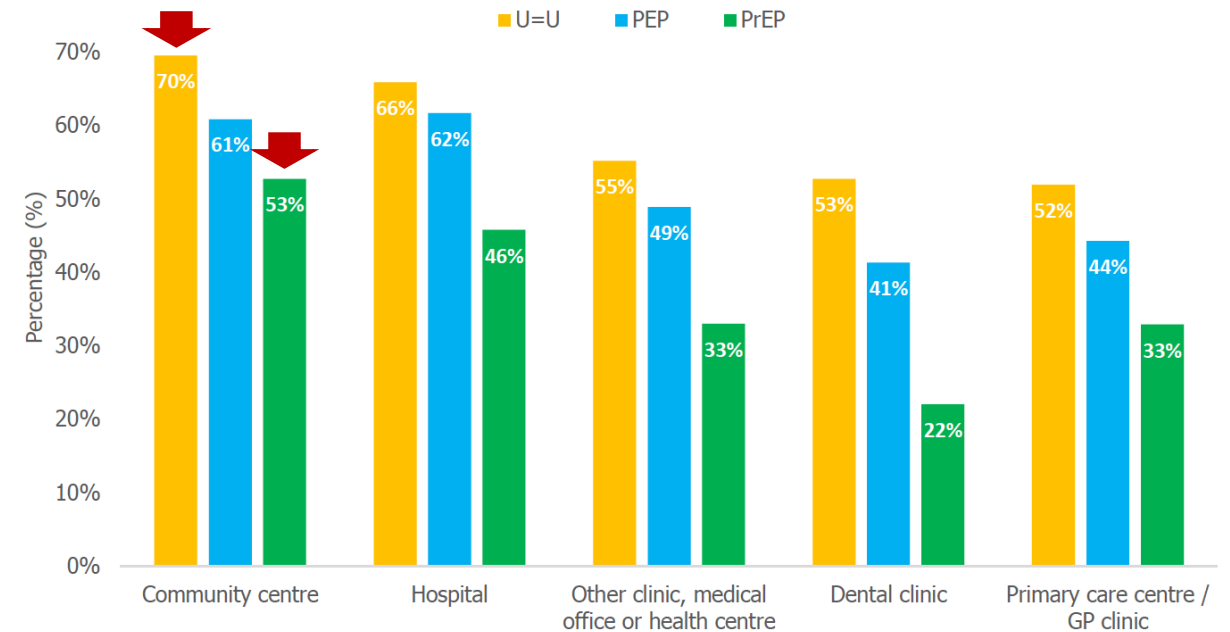
Of the 185 enrolled patients, 168 (91%) were eligible for PrEP.



# May HCPs Approach Contributing to Loss to Follow-up from PrEP Care?

- PrEP persistence may be less about relationship to the drug than the **environment**
  - Among racially and sexually minoritized individuals, **stigma** is a barrier to PrEP persistence<sup>1-3</sup>
  - In a survey of 855 Black individuals in the US, more than one half reported **high levels of racism and discrimination** in their healthcare experiences<sup>4</sup>
  - Barrier to PrEP persistence could be **the healthcare providers (HCPs) and their approach**<sup>1-6</sup>
  - **Sexual prejudice** from HCPs was negatively associated with anticipated PrEP adherence<sup>7</sup>

**In community centers highest (53%) proportion of respondents with correct knowledge of HIV prevention and transmission.**



ECDC. HIV stigma in the healthcare setting. Monitoring implementation of the Dublin Declaration on partnership to fight HIV/AIDS in Europe and Central Asia; 2024.

# ANRS-PREVENIR cohort

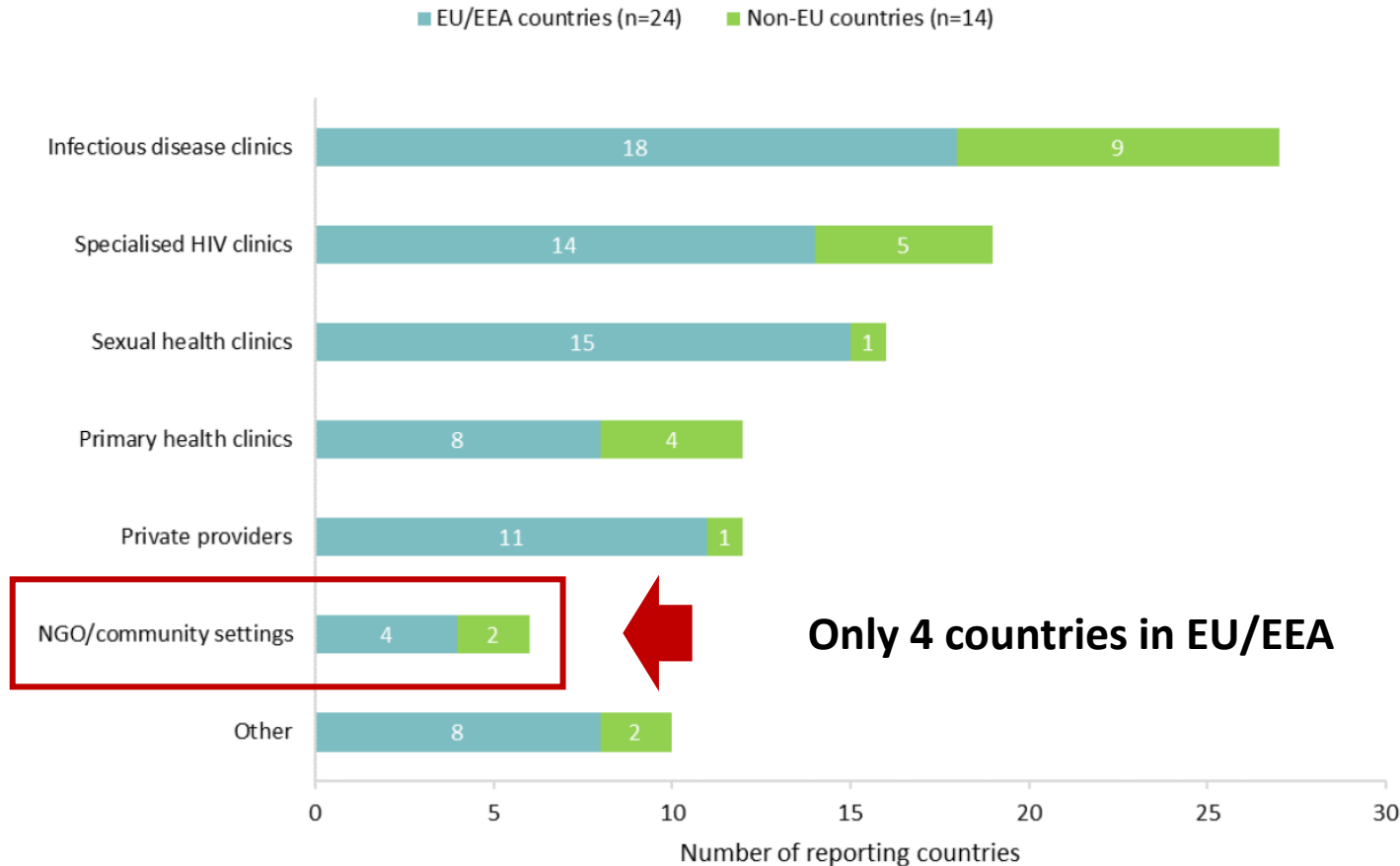
## Perception of PrEP-related stigma in PrEP users

2,567 participants in the ANRS-PREVENIR study answered the outcome question. Almost **one-third of the sample** (comprising mostly cisgender men who have sex with men [94.3%]) considered that **taking PrEP could give others a negative image of them**. **Younger participants, more psychologically vulnerable participants, and higher depression scores people** were also more likely to have this perception.

| Characteristic                                                           | aOR  | 95% confidence interval |      | p-value |
|--------------------------------------------------------------------------|------|-------------------------|------|---------|
| Age                                                                      | 0.98 | 0.97                    | 0.99 | 0.002   |
| Encouraged to take PrEP by main partner                                  | 0.67 | 0.51                    | 0.88 | 0.004   |
| Encouraged to take PrEP by friends                                       | 0.79 | 0.66                    | 0.95 | 0.011   |
| Knowing most recent sexual partner's HIV status                          | 0.83 | 0.69                    | 0.99 | 0.042   |
| Sexual intercourse systematically protected during the previous 3 months | 0.80 | 0.67                    | 0.96 | 0.016   |
| Center for Epidemiologic Studies Depression scale                        | 1.02 | 1.004                   | 1.03 | 0.009   |
| Rosenberg self-esteem scale                                              | 0.98 | 0.96                    | 0.99 | 0.045   |
| Akaike information criterion                                             | 2791 |                         |      |         |



# Settings in which PrEP is available, across Europe and Central Asia, end of 2023 (n=43)



The most frequently reported settings were **public health facilities** (infectious disease clinics, specialised HIV clinics, sexual health clinics, and primary health clinics).

The setting of infectious disease clinics was cited by 27 countries in Europe and Central Asia (19 EU/EEA countries), suggesting that **PrEP is still mainly provided in medicalised settings**.

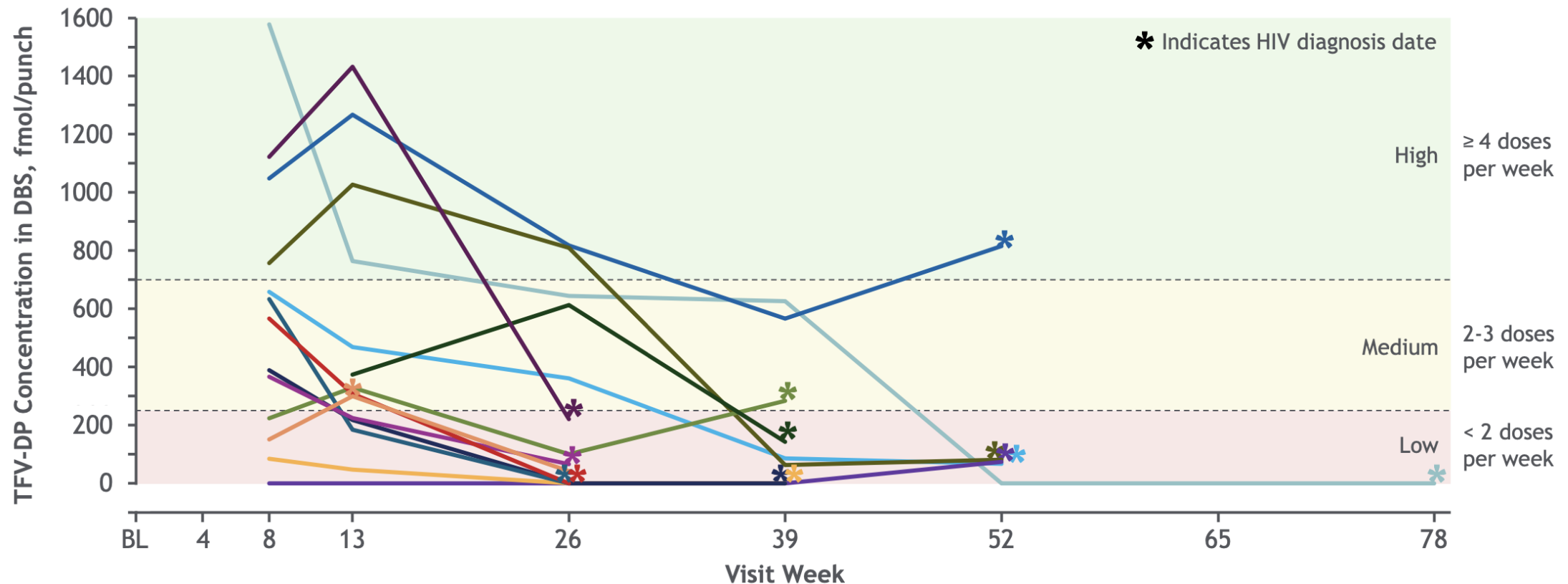
# Resistance Among PLHIV Exposed to PrEP

- Prevalence of major antiretroviral drug resistance mutation (ART-DRM) to emtricitabine (FTC) or tenofovir (TDF) (specifically K65REN,M184VI, K70E) was 24% (12/50; 95% CI:12%-36%)
- Five individuals thought they acquired HIV whilst taking PrEP and being fully adherent: 3 had major ART-DRMs to FTC/TDF, 1 did not have any detected and for one the resistance test was not available

|                                                                                                                      |                                                                                         | Prevalence (n/N) | 95% confidence interval |
|----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|------------------|-------------------------|
| Major antiretroviral drug resistance mutation to FTC or TDF detected with frequency above 15% (K65REN, M184VI, K70E) |                                                                                         | 24% (12/50)      | (12% - 36%)             |
|                                                                                                                      | M184VI exclusively                                                                      | 10               |                         |
|                                                                                                                      | K103N exclusively                                                                       | 1                |                         |
|                                                                                                                      | L10I, L33I, E35D, N37S, R41K, L63T, A71T, I93L, A98S, D123E, E204A, Q207E, R211K, K277R | 1                |                         |

- In our study, 1 in 20 new HIV diagnoses occurred in people who knew about PrEP and had previously used it
- The prevalence of resistance aligns with estimates from randomized controlled trials among individuals with acute HIV at enrolment

# PrEP Failure... or Declining Adherence?



All participants in the F/TDF group of Purpose 1 who were diagnosed with HIV had evidence of low adherence or a decrease in adherence over time

# Challenges with oral PrEP so far...

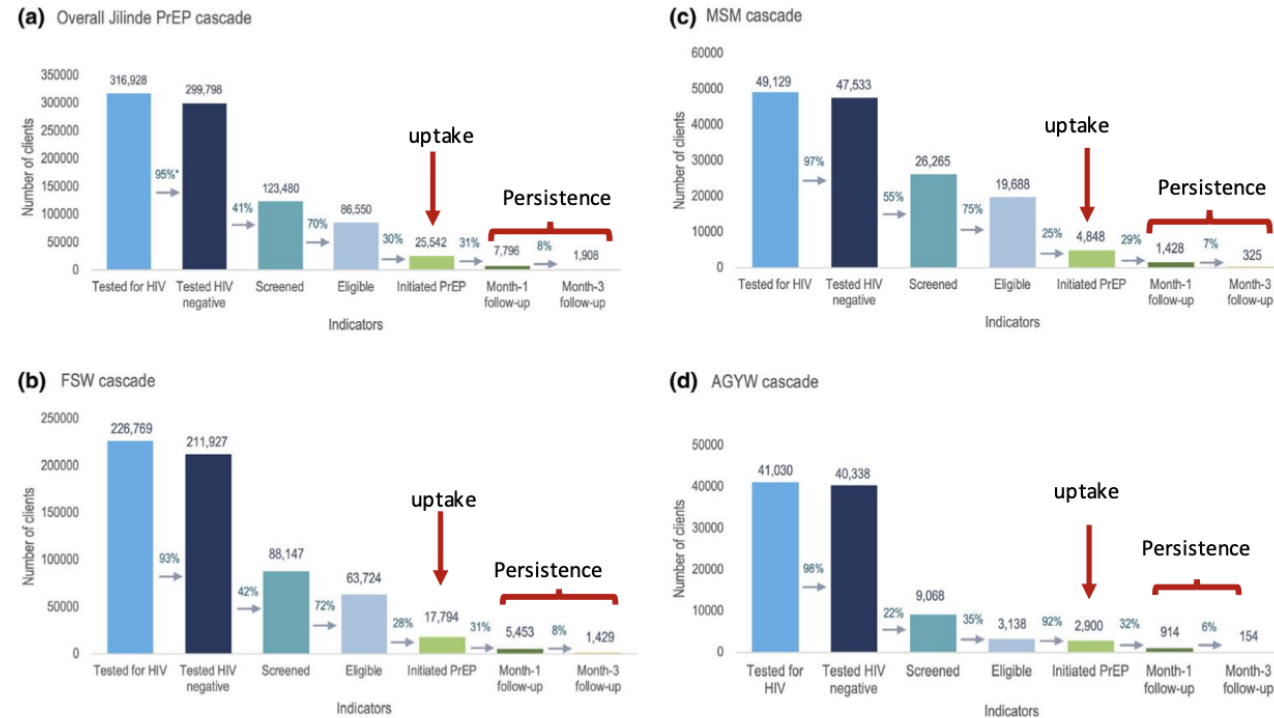


Figure 3. Overall Jilinde project (A) and population-specific (B, FSW; C, MSM; D, AGYW) PrEP cascades from February 2017 to December 2019.

**Uptake, persistence.....impacting effective use.**

# Long Acting PrEP

## 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)**

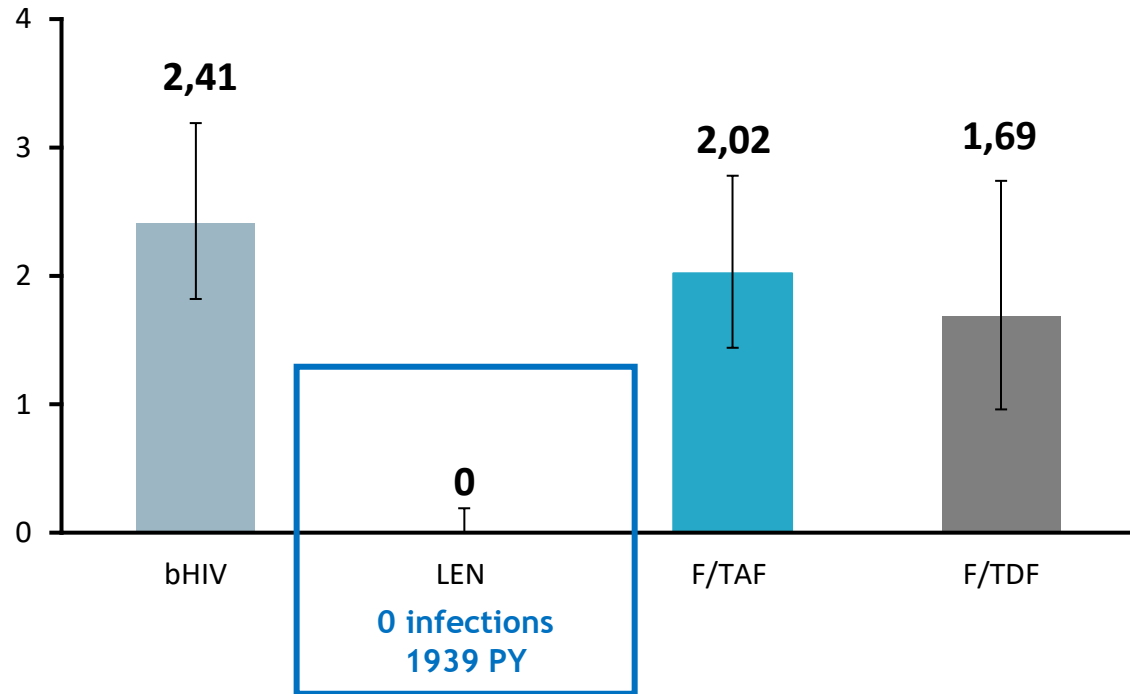
## HPTN 084<sup>2</sup>



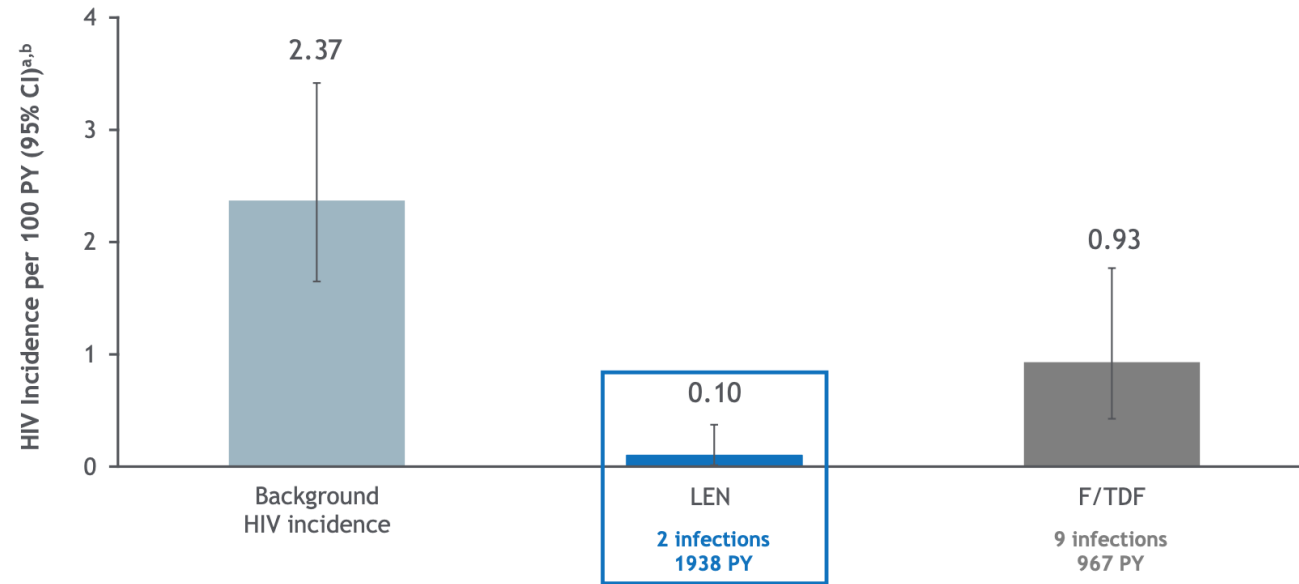
- N = 3224 cisgender women
- 4 incident infections with LA CAB vs 36 with oral FTC/TDF
  - **0 with on-time CAB injections**
  - 1 CAB infection later determined to be baseline infection
- HR for CAB vs FTC/TDF:  
**0.12 (95% CI: 0.05-0.31)**

# Long Acting PrEP

## PURPOSE 1

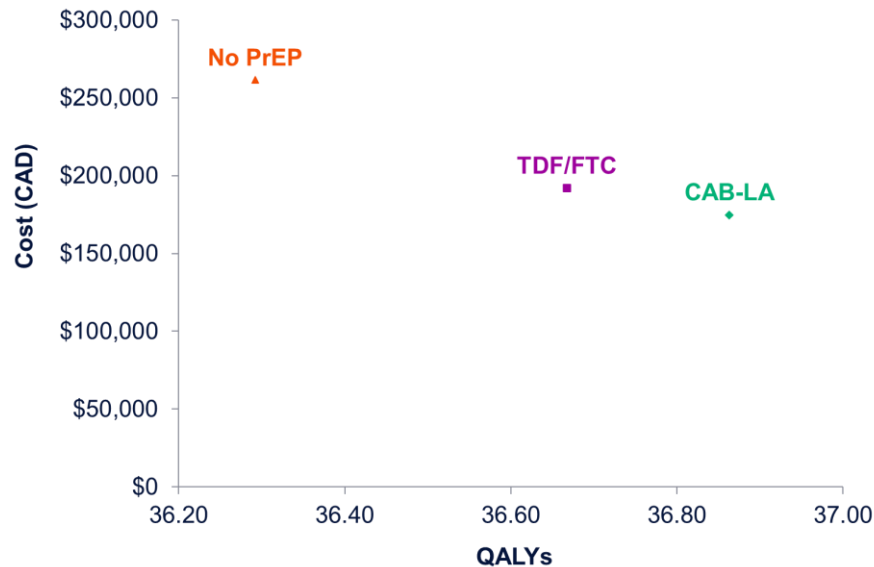


## PURPOSE 2

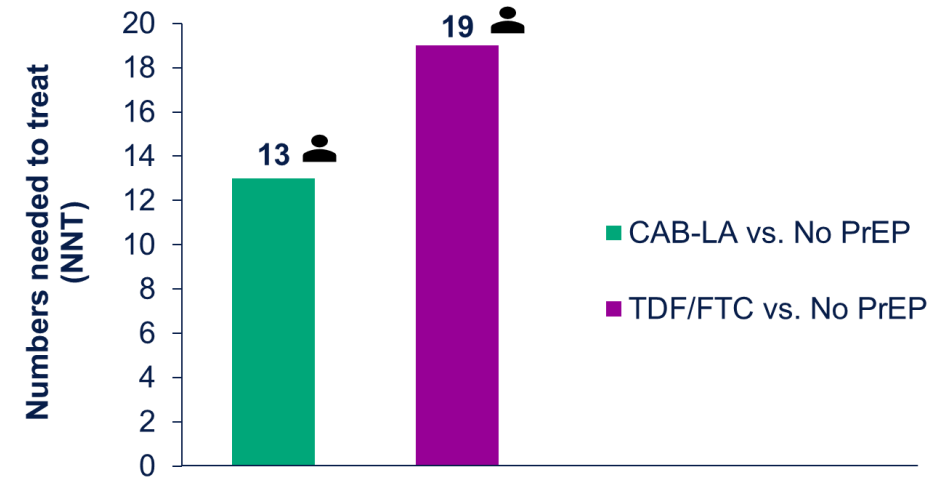


# Cost-Effectiveness and Public Health Impact

At a willingness-to-pay threshold of \$50,000 per QALY,  
100% simulations showed CAB-LA cost-effective



## NNT to Prevent One New HIV-1 Infection



- CAB-LA is cost-effective compared to TDF/FTC and no PrEP
- Overall, compared to TDF/FTC and no PrEP, the results indicate the introduction of CAB-LA as PrEP in Canada would result in substantial public health and monetary benefits by preventing additional HIV infections and reducing the clinical and economic burden of HIV



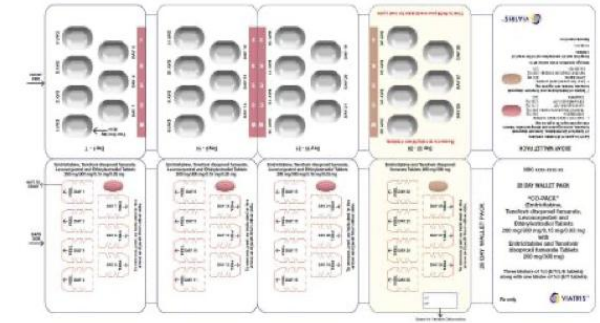
# What's coming in the pill dept.....

- **Multipurpose technology- Dual Prevention Pill :**
- Combines 2 already-approved products—oral PrEP (TDF/FTC) and oral contraception (ethinyl estradiol and levonorgestrel, or EE/LNG). **VIATRIS**
- **MK-8527: MONTHLY pill for HIV prevention**

Figure 1: Proposed DPP tablet colors

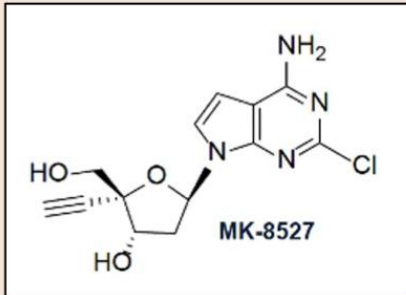


Figure 2: Illustrative mock-up of DPP packaging by Viatris



## Agent class:

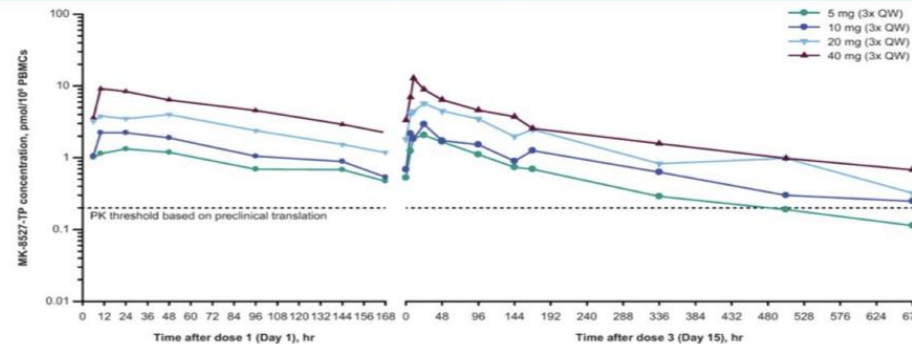
Nucleoside Reverse Transcriptase  
Translocation Inhibitor (NRTTI)



Long half life  
favors  
Monthly pill  
dosing



## Mean MK-8527-TP concentrations after ascending multiple doses of MK-8527 (trial B)



- After multiple doses of MK-8527 (3x QW), the true geometric mean  $C_{168}$  of MK-8527-TP was  $>0.2$  pmol/10<sup>6</sup> PBMCs for all dose levels
- Accumulation of intracellular MK-8527-TP was modest (range of  $C_{max}$  and  $AUC_{0-168}$  ratios was 1.1–1.6)
- Across all dose levels, the range of MK-8527-TP apparent terminal half-life was 216–291 hours

$C_{168}$ , concentration at 168 hours post dose.

Pharmacokinetics (PK) data from multiple doses of MK8527 with potential once monthly (QM) for HIV pre-exposure prophylaxis (PrEP)

Single (0.5–200 mg) and multiple (QW) doses (up to 40 mg) of MK-8527 administered to adults without HIV were generally well tolerated. The safety and pharmacokinetic profiles of MK-8527 support continued clinical investigation.





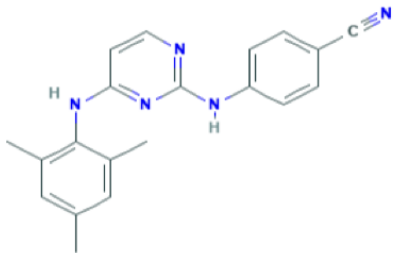
# Dapivirine Ring: Use of a vaginal ring for HIV prevention



## Agent class:

Non-nucleoside reverse transcriptase inhibitors (NNRTI)

## DAPIVIRINE



## Dosing Strategy:

Monthly dapivirine ring

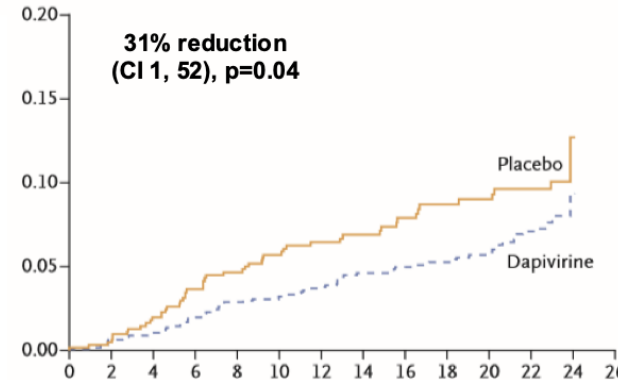
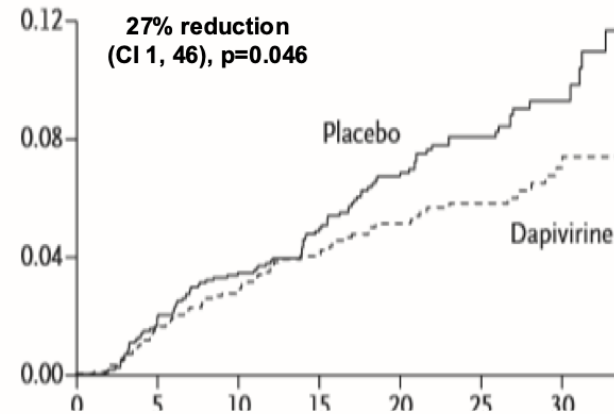
2016

**ASPIRE**  
A Study to Prevent Infection  
with a Ring for Extended Use

Trial sites in South Africa,  
Uganda, Zambia,  
Zimbabwe, Malawi



Trial sites in South  
Africa, Uganda



## The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 1, 2016 VOL. 375 NO. 22

### Use of a Vaginal Ring Containing Dapivirine for HIV-1 Prevention in Women

J.M. Baeten, T. Palanee-Phillips, E.R. Brown, K. Schwartz, L.E. Soto-Torres, V. Govender, N.M. Mgodli

The NEW ENGLAND JOURNAL of MEDICINE

## ORIGINAL ARTICLE

### Safety and Efficacy of a Dapivirine Vaginal Ring for HIV Prevention in Women

A. Nel, N. van Niekerk, S. Kapiga, L.-G. Bekker, C. Gama, K. Gill, A. Kamali,

**In both studies:** Open label extension improved effectiveness - RR 0.50  
EMA approved for section 58: (1) WHO recommendations, (2) Women in LMIC ;  
Second line to PrEP.



# Longer acting (3 month) DapiRing



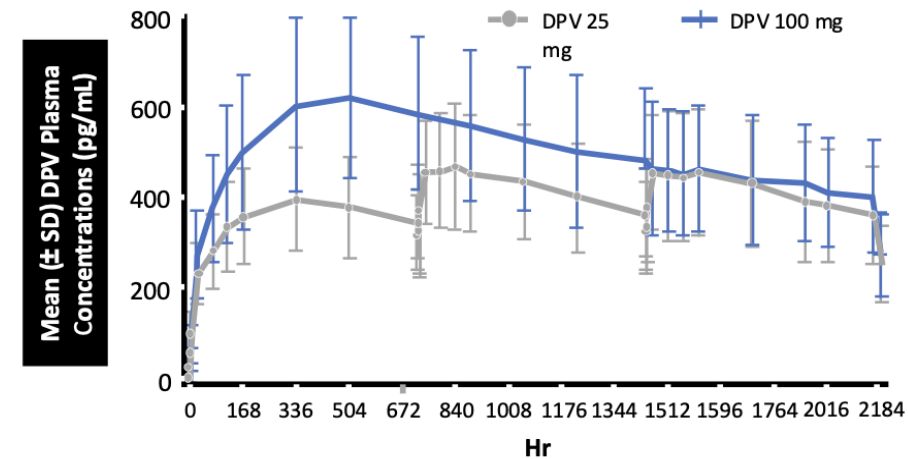
## IPM 054: 1-Mo vs 3-Mo Dapivirine Vaginal Ring Pharmacokinetic Study in South Africa

Nuttal. HIVR4P 2024. Abstr OA0802LB.

shutterstock.com · 357444302

- Monthly (25 mg) DPV ring approved for use in limited areas (not in US)
- **IPM 054:** open-label, randomized, crossover phase I study of 124 HIV-negative women
- **Primary endpoint:** plasma DPV concentration at Day 90 (prior to removal) and exposure during last 30 days
  - Lower bound LS mean ratio 90% CI >0.95 (noninferiority) and >1 (superiority)

- 3-mo (100 mg) ring noninferior and **superior** to 1-mo (25 mg) ring
- **No differences** in treatment-emergent AEs (e.g., discharge, VVC and BV)



- No safety concerns were found in:
  - Cohort 1 (36+ weeks/8-9 months pregnant);
  - Cohort 2 (30-35+ weeks/7-8 months pregnant);
  - Cohort 3 (12-29 weeks/3-7 months pregnant).
- Follow up for cohort 3 concluded in mid 2023, babies followed up for an additional year after birth
- Final results anticipated late 2024 or early 2025



- Favourable safety profile and previous data showing low drug transfer to breastmilk supports updates of WHO to include breastfeeding women when recommending PrEP Ring as an HIV prevention option



# What's coming in topical PrEP....

# MATRIX

## MATRIX Product Pipeline Overview

Ngure K, Matrix



**OneRing:**  
**Antiviral peptide (non-ARV)**  
(protein fragment)

**Non-hormonal contraceptive**  
A soluble Adenylate Cyclase (sAC) inhibitor; affects sperm's ability to move, fertilize eggs

Oak Crest Institute of Science  
**Matrix 003**



**TAF/EVG**

**Fast-dissolving vaginal insert**  
*tenofovir alafenamide & elvitegravir*  
*NRTI & integrase inhibitor (ARVs)*

TAF has also shown activity against HSV, which could be added benefit. CONRAD also evaluating the insert's rectal use.

**MATRIX 001**

**DAPIVIRINE VAGINAL FILM**

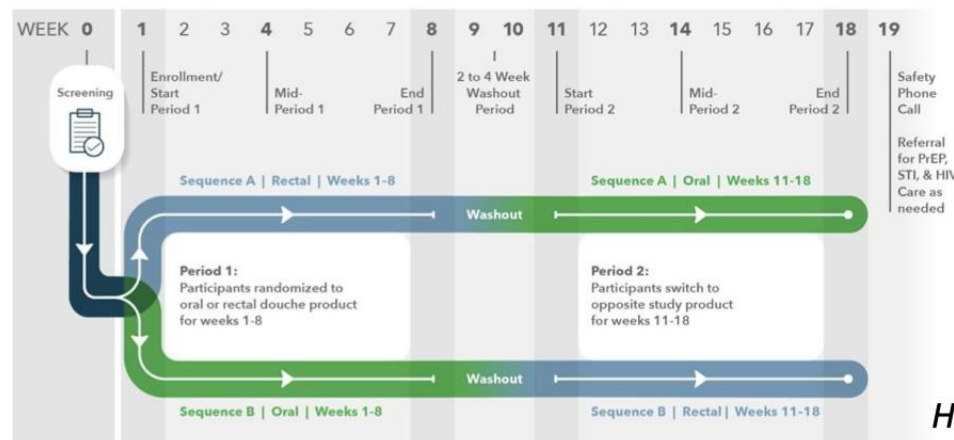
Film would slowly release drug until it completely dissolves (30 dys).

*Also being developed as dual-purpose product*

**MATRIX 002**



## Phase 2: Rectal douche vs. Oral PrEP (HPTN 106)

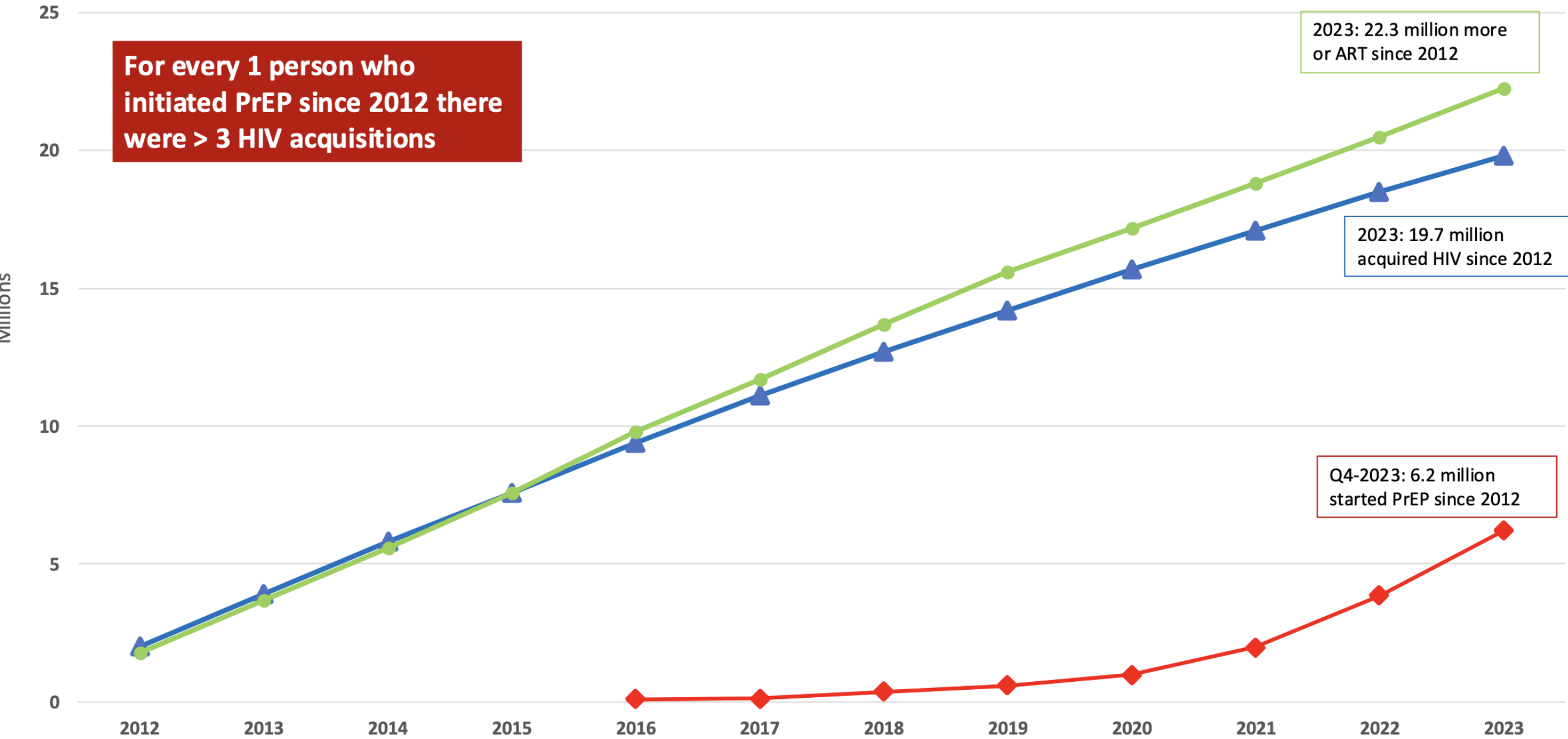


Rectal vs. Oral Use of On-demand PrEP

Hendrix C, HPTN

# HIV/AIDS Key Numbers 2012-2023 – Global

Huub Gelderblom, HVTN (personal comms)





Protocollo per la Gestione della  
**Profilassi Post-Esposizione per HIV**  
a seguito di esposizione occupazionale e  
non-occupazionale nell'adulto

*A Cura di*

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Ospedale "Luigi Sacco"  
Milano*



Regione  
Lombardia

## INTRODUZIONE

Fattori di rischio per **fallimento della PEP**:

- Comportamenti ad alto rischio all'interruzione della profilassi
- Ritardo nell'inizio della profilassi
- Scarsa aderenza al regime prescritto
- Infezioni sconosciute all'inizio della profilassi
- Virus resistente ai farmaci impiegati nel regime





## STIMA DEL RISCHIO

- Tipo di **esposizione** (occupazionale e non occupazionale)
- Rischio che la fonte sia **HIV positiva e viremica**
- **Fattori di rischio** della fonte e del soggetto esposto
  - Soluzioni di continuo delle mucose
  - Esposizione multiple in periodo di tempo limitato
  - IST concomitanti
  - Trauma profondo
  - Iniezione di bolo di sangue

Review > [Lancet Infect Dis. 2004 Jul;4\(7\):456-66. doi: 10.1016/S1473-3099\(04\)01061-8.](#)

### **Syphilis and HIV: a dangerous combination**

W A Lynn <sup>1</sup>, S Lightman

## ESPOSIZIONE OCCUPAZIONALE

Contatto dell'**operatore** con **fluidi corporei o tessuti** che espongono al rischio di trasmissione di HIV



sangue, sperma, secrezioni sessuali, latte materno e altri fluidi visibilmente contaminati con sangue

- ☐ **Ferite percutanee**
- ☐ **Membrane mucose o cute non intatta**
- ☐ **Morsi profondi o multipli** (se fonte molto probabilmente HIV positiva e sangue visibile nella bocca)

## ESPOSIZIONE NON O

☐ Attività sessuale

☐ Utilizzo di droghe iniezione



| Esposizione                                                                                                           | Rischio        |
|-----------------------------------------------------------------------------------------------------------------------|----------------|
| Rapporto anale recettivo <ul style="list-style-type: none"> <li>• con eiaculato</li> <li>• senza eiaculato</li> </ul> | 1:70<br>1:155  |
| Rapporto anale insertivo <ul style="list-style-type: none"> <li>• non circonciso</li> <li>• circonciso</li> </ul>     | 1:160<br>1:900 |
| Rapporto vaginale recettivo                                                                                           | 1:1250         |
| Rapporto vaginale insertivo                                                                                           | 1:2500         |
| Fellatio                                                                                                              | Trascurabile   |
| Cunnilingus                                                                                                           | Trascurabile   |
| Membrane mucose/cute non intatta                                                                                      | 1:1000         |
| Cute intatta                                                                                                          | Trascurabile   |
| Morso di umano                                                                                                        | Trascurabile   |
| Condivisione di presidi endovenosi                                                                                    | 1:125          |
| Puntura accidentale occupazionale                                                                                     | 1:440          |
| Puntura accidentale con ago abbandonato non-occupazionale                                                             | Trascurabile*  |
| Trasfusione di sangue                                                                                                 | 1:1            |

sessuale quando il soggetto fonte  
non stabile soppressione  
ca

di droghe iniettive (e per  
occupazionale)

## VALUTAZIONE CLINICA

1. Informazioni sulla **fonte**, quando identificabile (status HIV e HBV)
2. Informazioni sull'**esposizione** (data e ora, tipo di esposizione)
3. Informazioni sulla **persona esposta**
  - Ultimo test HIV eseguito, pregresso uso di PEP, attuale utilizzo di
  - Esposizioni a rischio negli ultimi 3 mesi
  - Sintomi di IST concomitanti
  - Status vaccinale per HBV
  - Eventuale stato di gravidanza o allattamento e uso di contraccettivi
  - Anamnesi patologica e farmacologica
4. Acquisizione del **consenso informato scritto** per test HIV e PEP



## INDICAZIONI

|                                                                                                            | Fonte HIV positiva          |                            | Fonte HIV non noto |
|------------------------------------------------------------------------------------------------------------|-----------------------------|----------------------------|--------------------|
|                                                                                                            | <u>HIV-RNA &gt;50 cp/ml</u> | <u>HIV-RNA &lt;50cp/ml</u> |                    |
| <b>Esposizione sessuale</b>                                                                                |                             |                            |                    |
| Sesso anale recettivo                                                                                      | PEP                         | NR                         | PEP                |
| Sesso anale insertivo                                                                                      | PEP                         | NR                         | PEP **             |
| Sesso vaginale recettivo                                                                                   | PEP                         | NR                         | PEP***             |
| Sesso vaginale insertivo                                                                                   | PEP                         | NR                         | PEP **             |
| Fellatio                                                                                                   | NR*                         | NR                         | NR                 |
| Cunnilingus                                                                                                | NR                          | NR                         | NR                 |
| Contatto sperma e occhio                                                                                   | NR                          | NR                         | NR                 |
| <b>Esposizioni occupazionali o altre</b>                                                                   |                             |                            |                    |
| Condivisione di presidi per iniezioni endovenose                                                           | PEP                         | PEP                        | PEP                |
| Puntura con ago o altro tipo di tagliente (occupazionale) contaminato da liquido potenzialmente infettante | PEP                         | PEP                        | PEP                |
| Contatto tra mucose e liquidi corporei infettanti                                                          | PEP                         | NR                         | PEP                |
| Morso di umano                                                                                             | NR <sup>#</sup>             | NR                         | NR <sup>#</sup>    |
| Puntura con ago (ambientale)                                                                               | NR                          | NR                         | NR                 |

## QUANDO E COME PRESCRIVERE LA PEP

- Preferibilmente **entro le 24 ore** dall'esposizione e **non oltre le 72 ore** (massima efficacia entro le 4 ore)



Efficacia fortemente tempo-dipendente

- Regimi di prima scelta a base di **2 NRTI + 1 INSTI** (TDF o TAF + FTC + RAL o DTG o BIC), preferibilmente in ***single-tablet regimen***
- Durata di **28 giorni** (possibilmente con immediata fornitura di farmaco per l'intero ciclo di PEP)

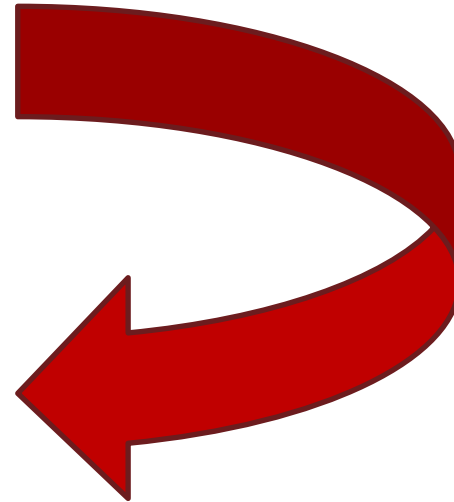


Efficacia fortemente aderenza-dipendente



## INTERRUZIONE PRECOCE DELLA PEP

- **Fonte** identificabile
  - HIV Ag/Ab negativo
  - Non esposizioni a rischio nelle precedenti 6 settimane
- **Individuo esposto** informato e d'accordo



## FOLLOW-UP

| Test                                                                                      | Baseline (BL)       | Settimana 4-6                   | Settimana 12                          |
|-------------------------------------------------------------------------------------------|---------------------|---------------------------------|---------------------------------------|
| <b>HIV</b> (Ag/Ab)                                                                        | X                   | X                               | X                                     |
| <b>Epatite B</b><br>(HBsAg, Anti-HBs and Anti-HBc)                                        | X                   |                                 | X<br><i>(se non vaccinato o noto)</i> |
| <b>Epatite C</b><br>(Ab, e in caso di positività anticorpale ricerca di HCV RNA Qual PCR) | X                   | X                               | X                                     |
| <b>Chlamydia e gonorrea</b><br>(NAAT o colturale)                                         | <b>DO NOT DELAY</b> |                                 | X*                                    |
| <b>Sifilide</b> (anticorpi o RPR/VDRL o TPHA/TPPA)                                        |                     |                                 | X                                     |
| Test di <b>funzionalità renale</b>                                                        | X                   | X                               |                                       |
| Test di <b>funzionalità epatica</b>                                                       | X                   | Solo se alterato a BL o sintomi |                                       |
| Test di <b>Gravidanza</b>                                                                 | X                   | X                               |                                       |

FOLLO

Interp

# Immediate PrEP after PEP: Results from an Observational Nurse-Led PEP2PrEP Study

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• and Amanda Vandyk, RN, PhD<sup>1</sup>

Transiz

## Abstract

• Patients who use post-exposure prophylaxis (PEP) are at ongoing risk for HIV acquisition after completing PEP. While the Centers for Disease Control and Prevention recommends pre-exposure prophylaxis (PrEP) use immediately after PEP, some practitioners are hesitant to offer PEP-to-PrEP (PEP2PrEP). We began offering PEP2PrEP in the sexually transmitted infection clinic in Ottawa, Canada on August 5, 2018. During the first 16 months of PEP2PrEP, 61 patients requested PEP and 46 were initiated; 30 of these patients agreed to PEP2PrEP and 26 followed through. None of our PEP patients had confirmed HIV exposures; all fulfilled the initiation criterion of condomless anal sex with a male partner of unknown HIV-status. During the study, the number of PEP requests and initiations was statistical unchanged, yet the seroconversion rate among patients who used PEP decreased from 1.7% pre-PEP2PrEP to 0% post-PEP2PrEP. Regarding follow-up, most discontinuations occurred between the PrEP intake and 1-month follow-up visit.

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rEP al

## NON SOLO HIV

### HBV

|                                    |                                                                 |                                                                                        |
|------------------------------------|-----------------------------------------------------------------|----------------------------------------------------------------------------------------|
| <b>Precedentemente immunizzati</b> | HBsAb > 10 UI/L dopo ciclo vaccinale oppure pregressa infezione | Nessun ulteriore follow-up                                                             |
| <b>Non immunizzati</b>             | HBcAb e HBsAb negativi                                          | Vaccinazione e follow-up a 6 mesi; eventualmente Ig specifiche se fonte HBsAg positiva |
| <b>HBV positivi</b>                | HBsAg positivi                                                  | Valutazione epatologica per presa in carico                                            |

### HCV

Non disponibile alcuna profilassi post-esposizione

## ESPOSIZIONE A RISCHIO TRASCURABILE

Richiesta **insistente** di accesso alla PEP:

- Stato particolarmente **ansioso** del soggetto esposto
  - Inizio di **PrEP** con duplice attività di profilassi (TDF/FTC 2 cp, quindi 1 cp ogni 24 ore)
  - Screening per HIV con HIV Ag/Ab e HIV-RNA al baseline e dopo 30 giorni dall'inizio
- **Comportamento a maggior rischio** che il soggetto esposto non ha riferito (**stigma**)
  - Inizio di **PEP**

## NUOVE ESPOSIZIONI DURANTE LA PEP

|                                                                            |                                                                             |                                                                                      |
|----------------------------------------------------------------------------|-----------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| <b>MSM cisgender</b>                                                       | Ultima esposizione nelle <b>ultime 48 ore</b> prima della fine della PEP    | Proseguire la PEP per <b>48 ore</b> dopo l'ultima esposizione a rischio              |
| <b>Donne cisgender, uomini e donne transgender e di genere non binario</b> | Ultima esposizione nell' <b>ultima settimana</b> prima della fine della PEP | Proseguire la PEP per <b>7 giorni</b> dopo l'ultima esposizione a rischio            |
| <b>Utilizzatori di sostanze per via endovenosa</b>                         | Esposizione in <b>qualsiasi</b> momento del ciclo di PEP                    | Proseguire la PEP per ulteriori <b>28 giorni</b> dopo l'ultima esposizione a rischio |

## TRANSIZIONE A PEP IN CORSO DI PrEP

| <b>Tipo di esposizione</b>                                              | <b>Aderenza a PrEP*</b>                                                                                  | <b>Raccomandazione<sup>§</sup></b> |
|-------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|------------------------------------|
| Rapporto anale recettivo/insertivo                                      | Almeno 4 dosi                                                                                            | Continuare schema PrEP             |
|                                                                         | Meno di 4 dosi<br>oppure<br>Aderenza incompleta a schema On Demand <sup>#</sup> prima o dopo il rapporto | Transizione a PEP                  |
| Sesso vaginale/neovaginale/organo-genitale frontale recettivo           | Almeno 6 dosi                                                                                            | Continuare schema PrEP             |
|                                                                         | Meno di 6 dosi                                                                                           | Transizione a PEP                  |
| Sesso vaginale/neovaginale/organo-genitale-frontale-recettivo insertivo | Almeno 4 dosi                                                                                            | Continuare schema PrEP             |
|                                                                         | Meno di 4 dosi<br>oppure<br>Aderenza incompleta a schema On Demand <sup>#</sup> prima o dopo il rapporto | Transizione a PEP                  |



## LO STILE DI COMUNICAZIONE D

- Chiedere il **nome scelto dal** per descrivere i propri organi
  - Spiegare la necessità di cono
  - Utilizzare **domande aperte**
  - Informare che i regimi PEP r
- terapie ormonali** di afferma

### ABSTRACT

**Objectives** HIV postexposure prophylaxis (PEP) is indicated after sexual exposure with high risk of transmission. Men who have sex with men (MSM) are the main target of PEP. The aim of our study was to investigate the experience and shortcomings of PEP among people with a high risk of HIV exposure.

**Design and methods** Subjects with ongoing follow-up for HIV infection and PEP history were selected for the qualitative study. Semistructured interviews were conducted at the patients' homes. They were audio-recorded, transcribed and deidentified before data analysis, double coding and thematic analysis with an inductive approach.

**Results** Twenty-three patients were eligible for the qualitative study. Thirteen interviews were carried out. All patients were 20-60-year-old MSM. The median time between PEP and HIV diagnosis was 3.3 years (interquartile range (IQR)<sub>25-75</sub>=0.9-4.9). Many participants reported negative PEP experiences: awkward access to the PEP clinic, uneasiness and shame in the hospital setting, unpleasant interaction and moral disapprobation from the medical staff, treatment intolerance and prevention messages that were 'inconsistent with real life'

**Conclusion** Our data highlight PEP management failures among its target population that may have compromised any subsequent attempts to seek out PEP. Practitioners should be more aware of MSM sexual contexts and practices. PEP consultations should provide the opportunity to discuss prevention strategies with highly exposed HIV-negative subjects, which may include pre-exposure prophylaxis.

rmini che preferiscono utilizzare

razioni farmacologiche con le