



La prevenzione primaria di HIV: is it the key?

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TAsP: Treatment as Prevention

The image shows a digital display board from Ospedale San Raffaele. The top left corner displays the time 17:39 and the date Mercoledì 19 Giugno 2019. The top right corner features the hospital's logo and name, OSPEDALE SAN RAFFAELE. The main content is divided into two sections: a queue list on the left and a public health message on the right.

| Sportello | Chiamata |
|-----------|----------|
| SP 01 | L 043 |
| SP 02 | E 105 |
| SP 01 | E 104 |
| SP 02 | L 042 |

U=U
NON RILEVABILE = NON TRASMISSIBILE
CHIEDI AL TUO INFETTIVOLOGO/A

mpa.it - La Stampa * Cinema America ancora nel mirino:
www.artexe.com 

NEC

THE FOURTH 90

90%

diagnosed

90%

on treatment

90%

virally suppressed

90%

good health-related
quality-of-life



Daily FTC/TDF

Not enough health care providers know about PrEP.

Pre-exposure prophylaxis (PrEP) is a medicine taken daily that can be used to prevent HIV infection. PrEP is for people without HIV who are at very high risk for acquiring it from sex or injection drug use.



90%
Daily PrEP can reduce the risk of sexually acquired HIV by more than 90%.



70%
Daily PrEP can reduce the risk of HIV infection among people who inject drugs by more than 70%.



1 in 3
1 in 3 primary care doctors and nurses haven't heard about PrEP.

SOURCE: CDC and GPO, Feb. 2014



- FDA: daily oral FTC/TDF recommended for all adults and adolescents at risk for HIV through **sex or IDU**

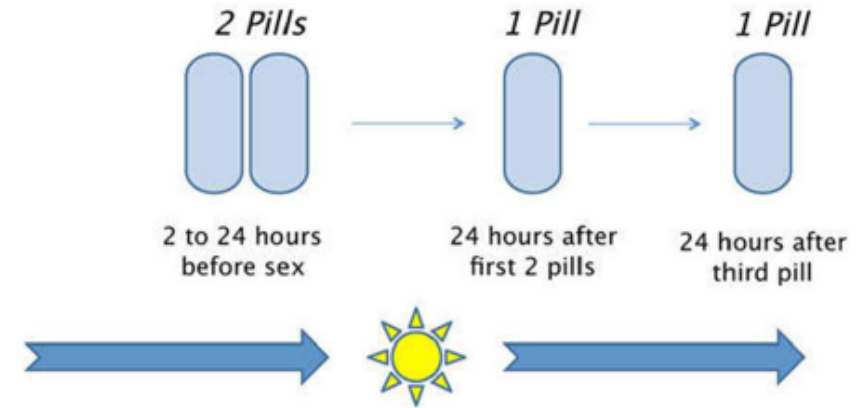
On-Demand FTC/TDF Dosing Options for MSM



- FDA: daily oral FTC/TDF recommended for all adults and adolescents at risk for HIV through **sex or IDU**

- WHO, IAS-USA, and Canadian guidelines include option of on-demand or event-driven (2:1:1) FTC/TDF dosing in MSM (off-label per FDA)

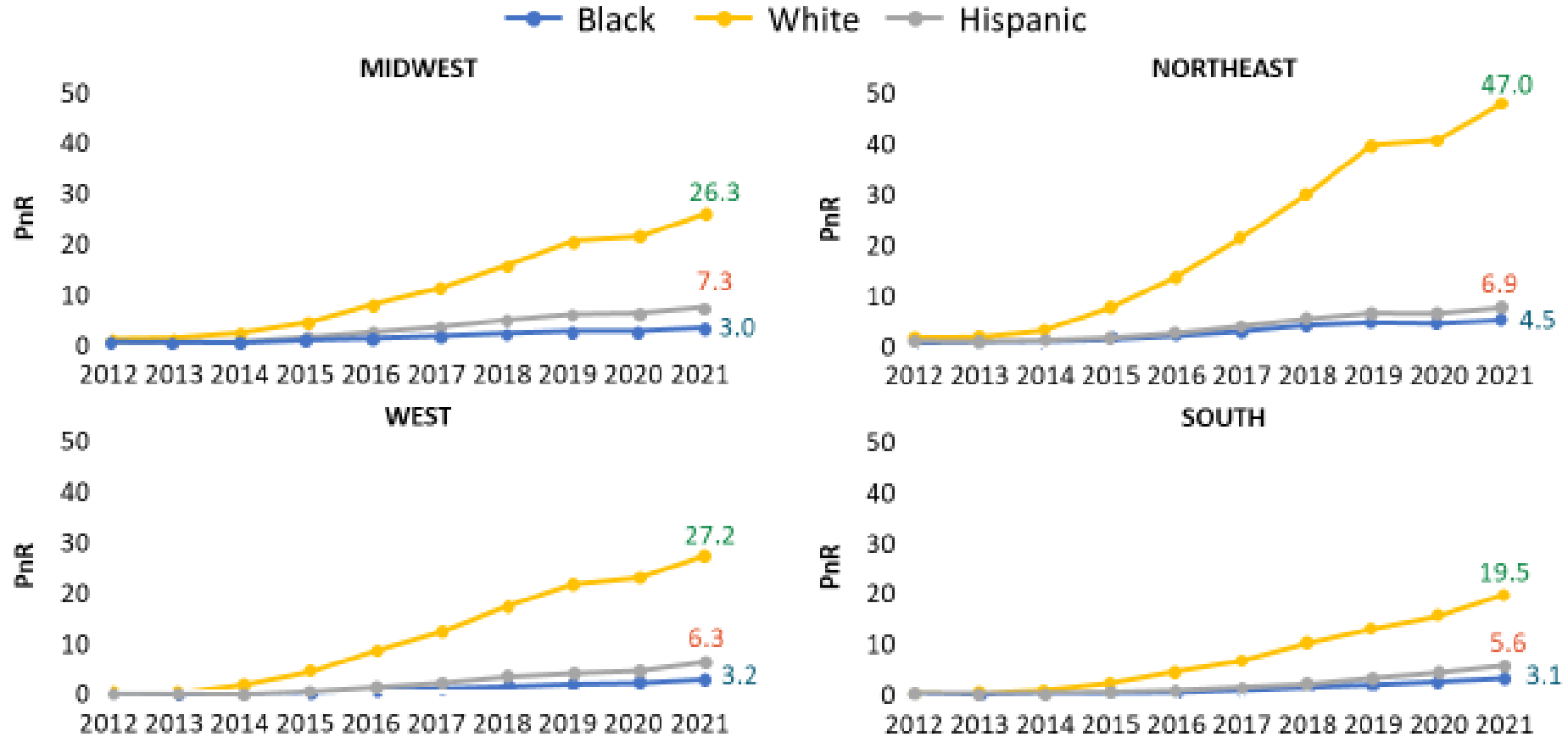
On-demand PrEP



FTC/TDF PI. Saag. JAMA. 2020;324:1651. Tan. CMAJ. 2017;189:E1448.

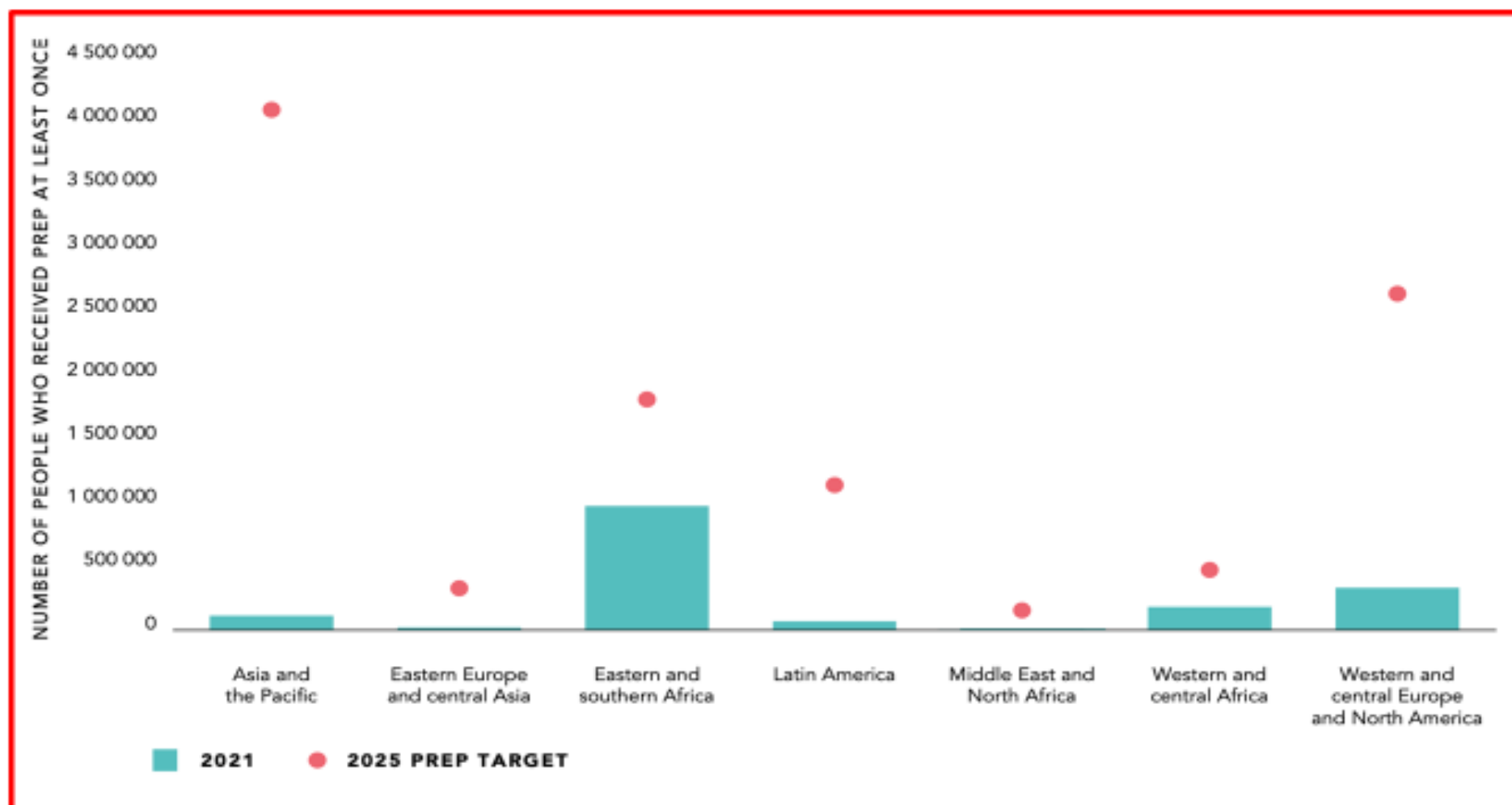
WHO. apps.who.int/iris/bitstream/handle/10665/325955/WHO-CDS-HIV-19.8-eng.pdf.

PrEP Inequity 2012-2021



UNAIDS

Number of people who received pre-exposure prophylaxis (PrEP) at least once during the reporting period, by region, 2021, and 2025 target



AIFA-Rimborsabilità della PrEP

Condizioni cliniche e criteri di rimborsabilità

- La persona candidata alla PrEP deve soddisfare tutte le condizioni sottostanti:
- Età > 18 anni
- Negatività al test HIV Ab/Ag (test di 4° generazione o superiore)

Comportamento sessuale ad alto rischio di acquisizione di HIV per via sessuale, definito come aver avuto, negli ultimi 3 mesi:

- **Almeno un rapporto sessuale senza l'uso del preservativo con partner occasionale HIV-positivo o di sierostato HIV ignoto (storia di uso inconsistente o non uso del profilattico);**
- Trattamento di una malattia sessualmente trasmissibile (MST);
- Precedente utilizzo di profilassi post-esposizione (PEP);
- **Uso di droghe (cocaina, metamfetamina, GHB, MDMA, mefedrone, ketamina) durante i rapporti sessuali (*chemsex*).**

COA DATA-2023

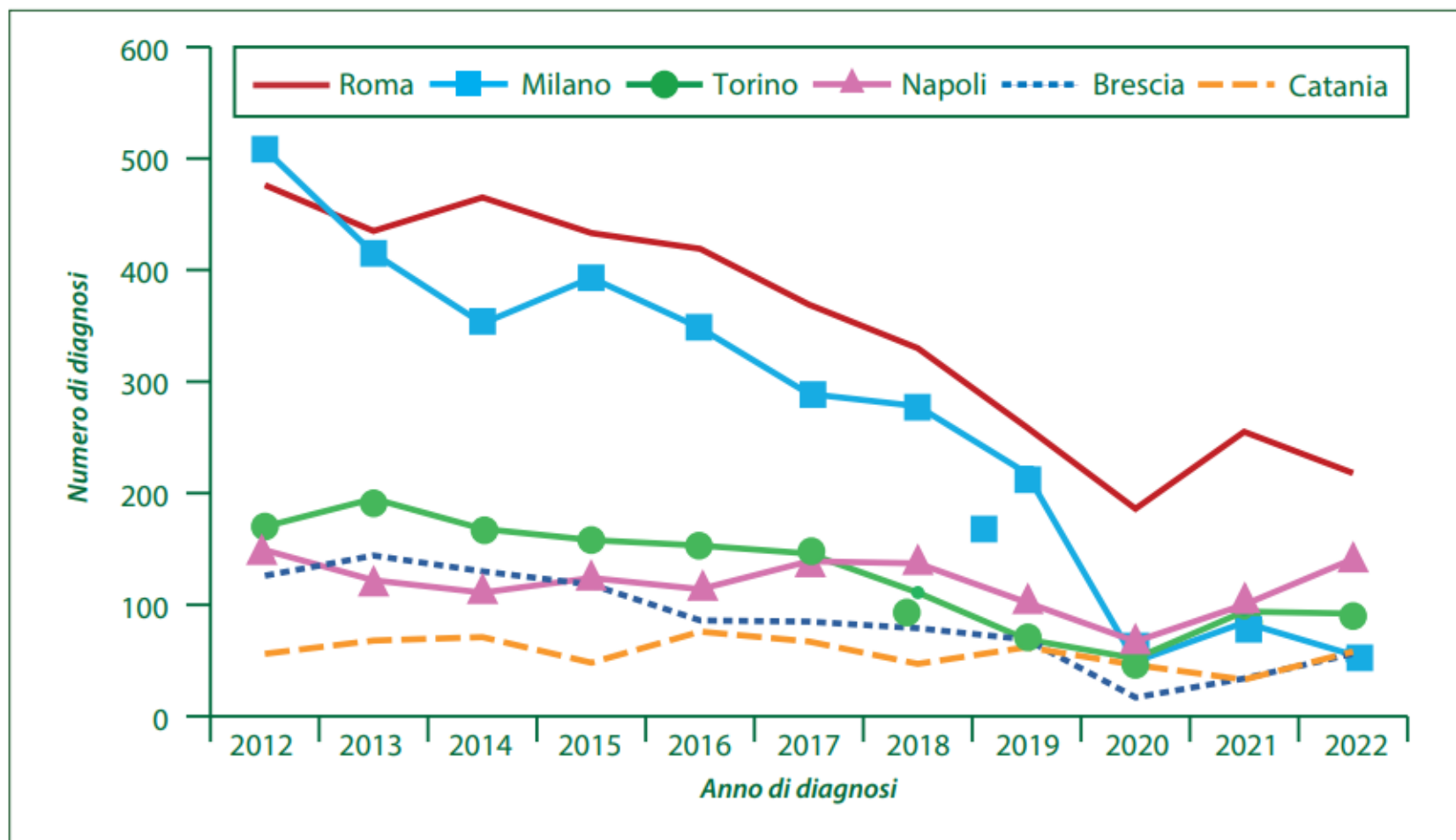
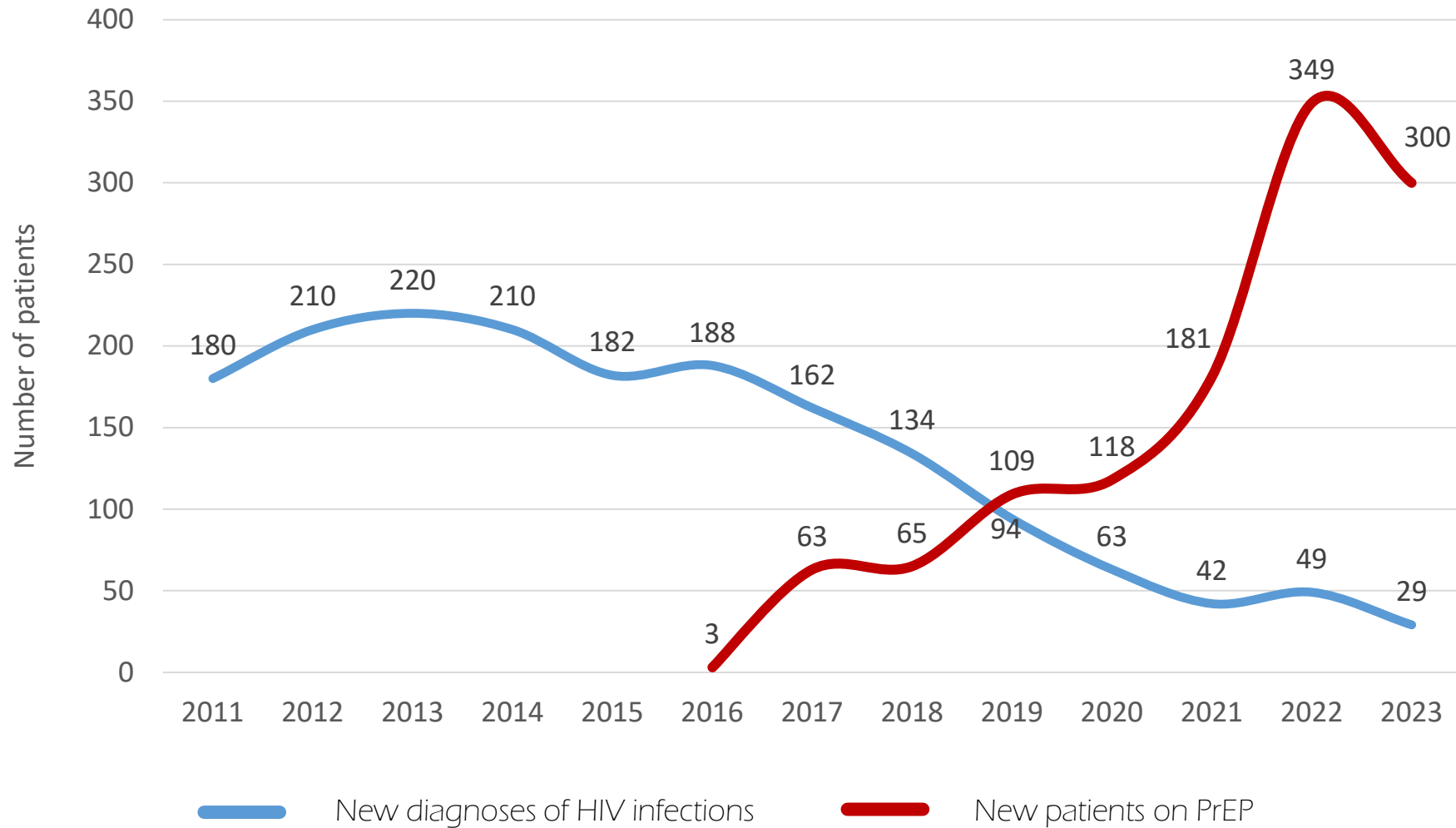
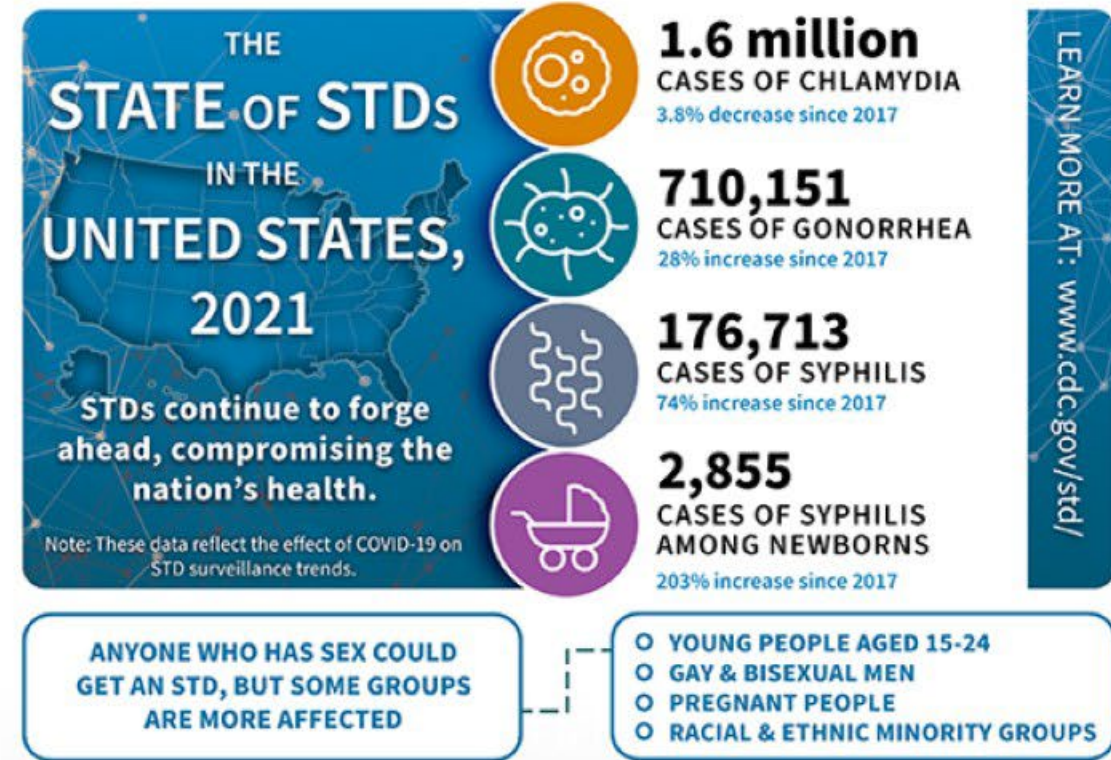
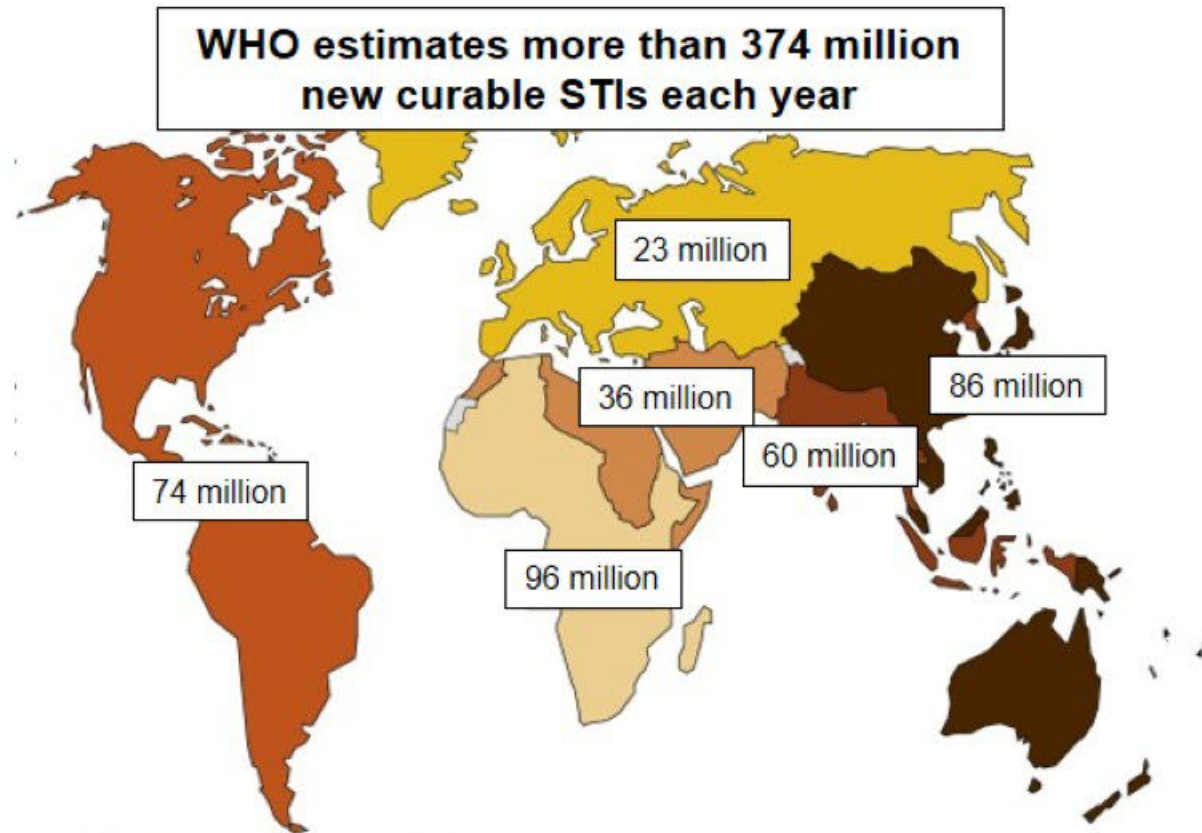


Figura 4 - Nuove diagnosi di infezione da HIV nelle Province con il maggior numero di diagnosi per anno (2012-2022)

OSR Real world data

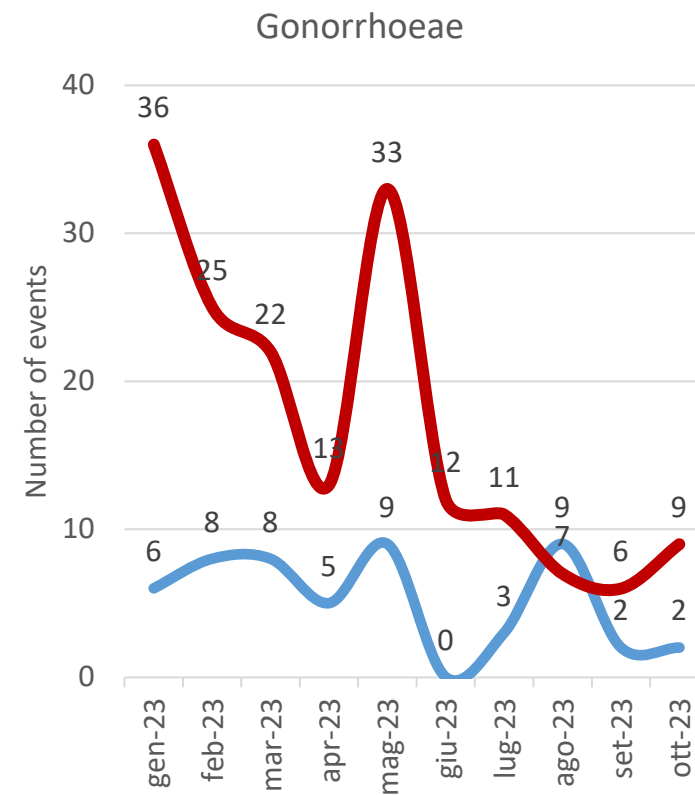
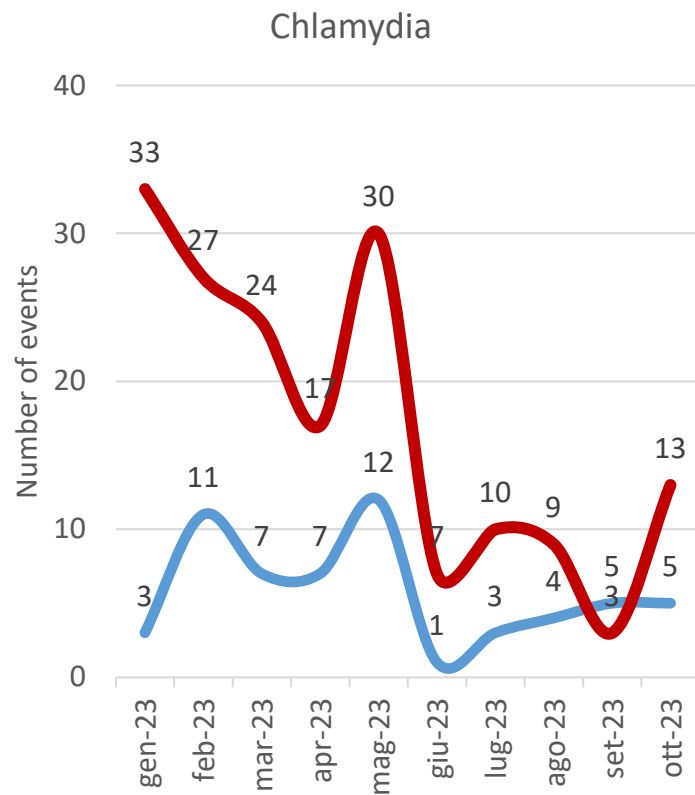
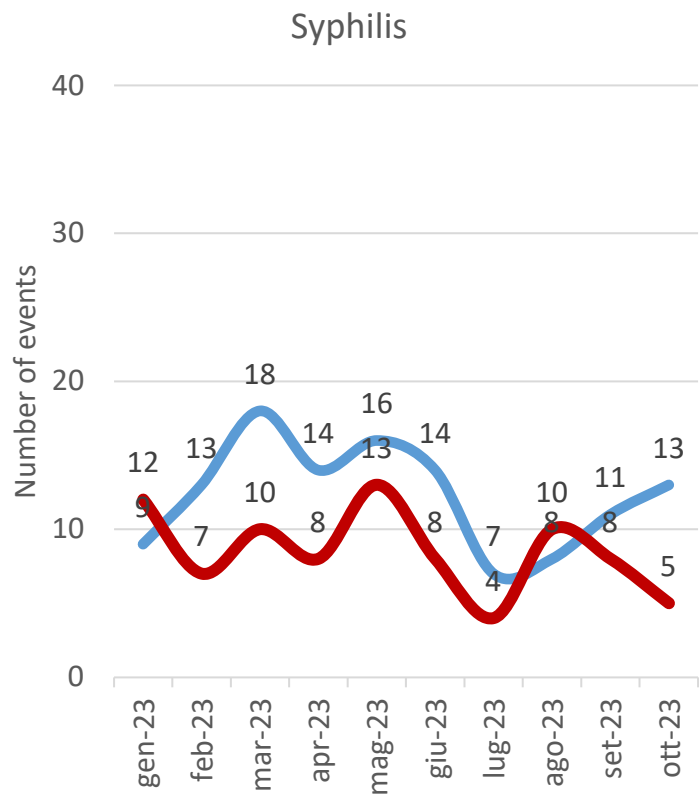


Sustained Increases in Sexually Transmitted Infections in US and worldwide



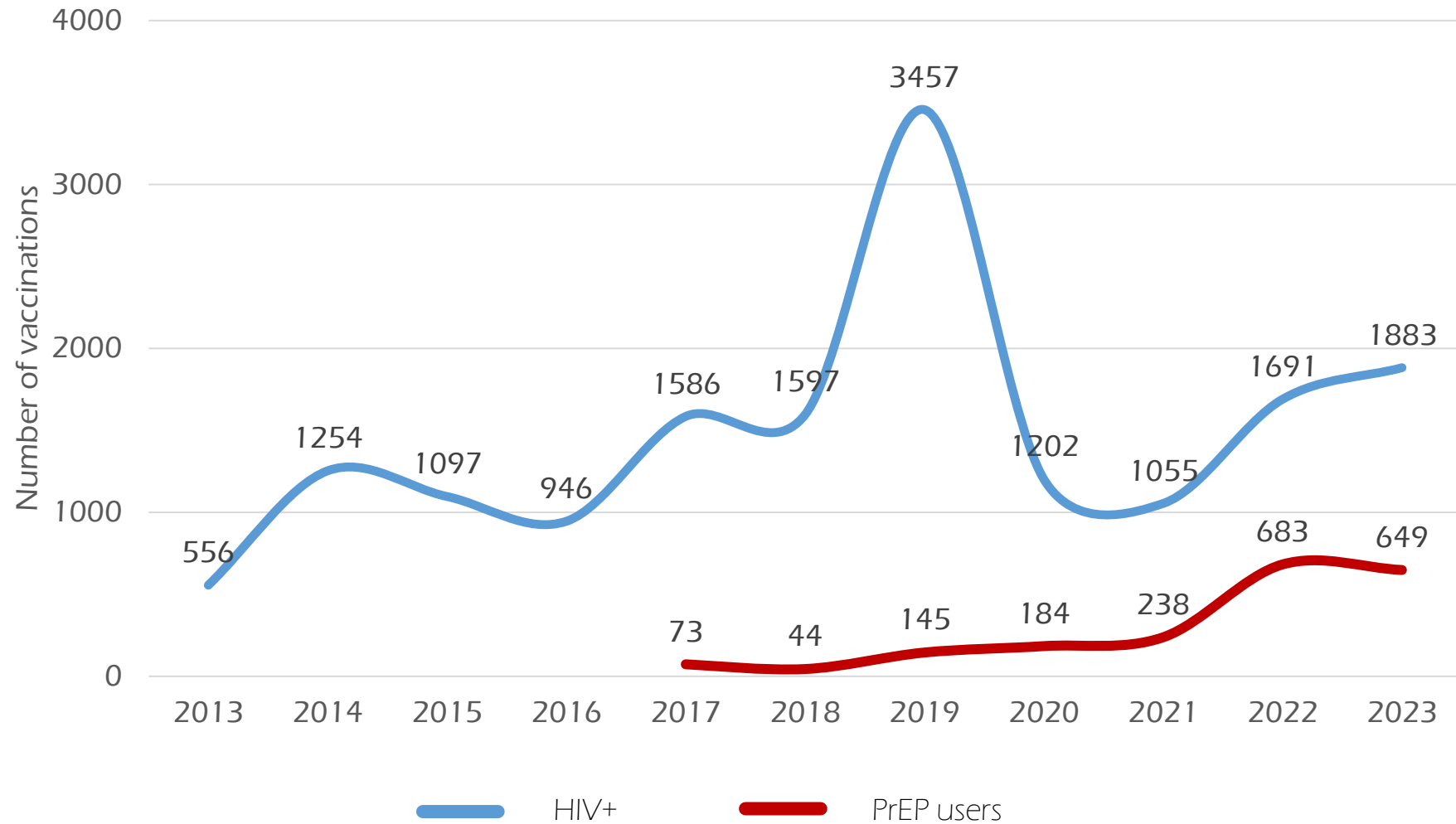
- **Gonorrhea:** threat of increasing incidence of antimicrobial resistance
- **Syphilis:** increase in heterosexual networks with congenital syphilis

IST



— HIV+ — PrEP users

Vaccinations



AIFA-Monitoraggio della PrEP

| Monitoraggio | BASELINE (prima prescrizione) | 1 mese dopo la prima (opzionale) | Ogni 3 mesi (4 mesi se regime on demand) | Ogni 6 mesi (8 mesi se regime on demand) | Ogni 12 mesi |
|--|----------------------------------|-------------------------------------|---|---|----------------|
| Raccolta dati demografici, clinici e sui comportamenti a rischio | X | | | | |
| Definizione dei criteri di eleggibilità | X | | | | |
| Counselling sui comportamenti a rischio | X | X | X | X | X |
| Test HIV Ab/Ag (4a generazione o superiore) | X | X | X | X | X |
| Sierologia per epatite A (HAV Ab) | X | | | X* | X* |
| Sierologia per epatite B (HbsAg, HBsAb e HbcAb) | X | | | X* | X* |
| Sierologia per epatite C (HCV Ab) | X | | | X | X |
| Sierologia Lue | X | | X | X | X |
| Screening per Chlamydia e Gonorrea (t. rettale/ t. orofaringeo/ primo tratto urine/ t. vaginale) | X | | X | X | X |
| Determinazione creatinina e stima GFR | X | | | X | X |
| Determinazione emocromo, AST, ALT | X | | | | X |
| Esame urine chimico fisico | X | | | X [§] | X |
| Determinazione Fosfati, Calcio, Vitamina D | X [§] | | | | X [§] |
| Misura aderenze PrEP | | X | X | X | X |
| Valutazione eventi avversi | | X | X | X | X |
| Controllo terapie concomitanti e verifica di eventuali interazioni farmacologiche | X | X | X | X | X |

* sieronegativi non vaccinati o non responder al vaccino

§ se soggetto a rischio

[§] se fattori di rischio renali

PrEP and HIV Resistance

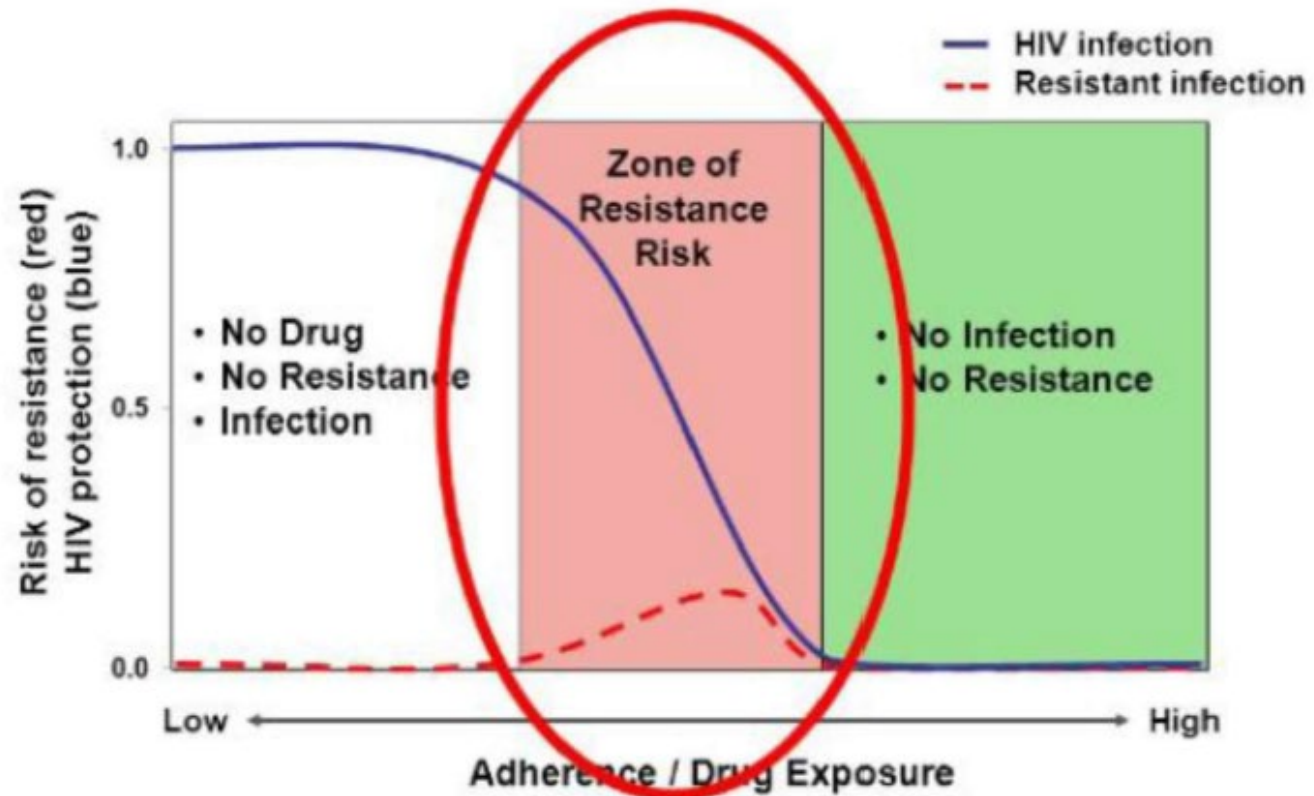


Table 1. Baseline characteristics, immuno-virological characteristics and genotypic resistances in individuals newly diagnosed with HIV according to recent exposure to PrEP status.

| Baseline characteristics | HIV+ reporting recent PrEP exposure, <i>n</i> = 52 | HIV+ with no recent PrEP exposure, <i>n</i> = 978 | <i>P</i> |
|--|--|---|-----------------|
| Age, years (IQR) | 34 (28–42) | 32 (27–40) | 0.52 |
| MSM, <i>n</i> (%) | 51 (98) ^a | 935 (95) | 0.42 |
| White ethnicity, <i>n</i> (%) | 34 (65) | 644 (66) | 0.54 |
| UK-born, <i>n</i> (%) | 18 (35) | 326 (33) | 0.88 |
| Baseline HIV viral load, log ₁₀ <i>n</i> (IQR) | 3.48 (2.56–4.88) | 4.72 (4.16–5.36) | <0.01 |
| Baseline CD4 ⁺ cell count, mmc (IQR) | 632 (468–886) | 474 (347–655) | <0.01 |
| Individuals with a HIV viral load <200 copies/ml at baseline, <i>n</i> (%) | 10 (19) | 32 (3) | <0.01 |
| Genotypic resistance test at baseline, <i>n</i> (%) | | | <0.01 |
| - Not performed | 0 | 41 (4) | |
| - Unable to amplify viral DNA | 9/52 (17) | 27/939 (3) | |
| - Performed, with DNA amplification | 43/52 (83) | 912/939 (97) | |
| PrEP-related NRTI mutations, <i>n</i> (%) ^b | | | <0.01 |
| - M184V/I | 13 (30) | 5 (1) | |
| - K65R | 0 | 1 (<1) | |
| Other NRTI mutations, <i>n</i> (%) ^b | | | 0.11 |
| - L74V | 1 (2) | 0 | |
| - M41L and/or L210W and/or T215Y/F | 1 (2) | 4 (<1) | |
| - D67N and/or K70R and/or K219Q/E/R/N | 0 | 7 (1) | |
| NNRTI mutations, <i>n</i> (%) ^b | | | 0.54 |
| - K103N/S | 3 (7) | 29 (3) | |
| - V108V/I | 1 (2) | 8 (1) | |
| - E138A | 0 | 26 (3) | |
| - G190A/S/E | 1 (2) | 0 | |
| PI mutations, <i>n</i> (%) ^b | | | 0.62 |
| - M46I/L | 0 | 6 (1) | |
| - L90M | 0 | 18 (2) | |

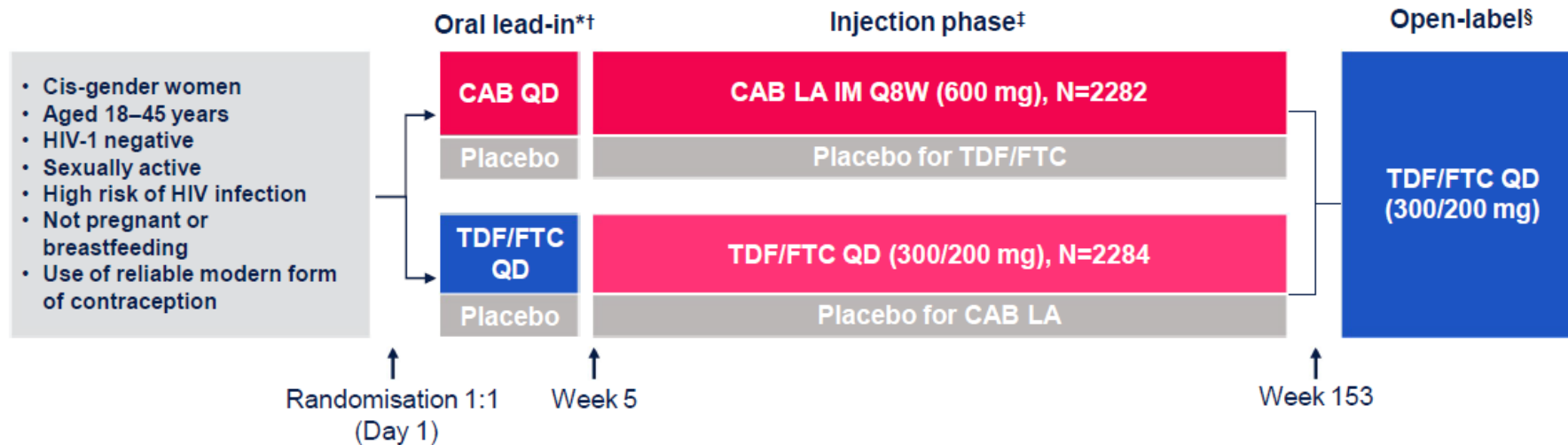
IQR, interquartile range; MSM, men having sex with men; NNRTI, non-nucleoside reverse transcriptase inhibitors; NRTI, nucleoside reverse transcriptase inhibitor; PI, protease inhibitor; PrEP, preexposure prophylaxis.

^aOne individual identified themselves as a trans-woman.

^b% are calculated taking into account only individuals where viral DNA was amplified.

New PrEP Options

Phase III, double-blind/double dummy study to evaluate the efficacy and safety of CAB LA Q8W vs daily oral TDF/FTC for PrEP in HIV-uninfected African cis-gender women:



Primary endpoints:

**Incident HIV infections during blinded comparison
Grade 2 or higher clinical and laboratory AEs**

New PrEP Options

Prevention Option(s):

Combination Prevention

Study Design:

Blind, Randomized

Arms and Assigned Interventions

Description

Experimental: Blinded Phase: LEN + Placebo-to-match (PTM) F/TAF
Participants will receive the following for at least 52 weeks: Subcutaneous (SC) lenacapavir (LEN) 927 mg every 26 weeks Oral PTM
Emtricitabine/Tenofovir Alafenamide (F/TAF) once daily Oral LEN 600 mg on Days 1 and 2 Drug: Oral Lenacapavir (LEN) Tablets administered orally without regard to food Other Name: GS-6207 Drug: Subcutaneous (SC) Lenacapavir (LEN) Administered via SC injections Other Name: GS-6207 Drug: PTM F/TAF Tablets administered orally

Mode of Delivery

Subcutaneous, Tablet

Start Date

August 30, 2021

End Date

July 13, 2027

Enrollment:

5,010

Age range:

16 Years ↔ 25
Years

Population:

Cisgender Women

Sites

Madibeng Centre for Research
Brits
South Africa

**Wits Reproductive Health and
HIV Institute (Wits RHI)**
Johannesburg
South Africa

TAKE HOME MESSAGES

- PrEP works!
- PrEP is part of global prevention.
- STIs are a silent pandemic.
- Key point: access to PrEP.
- The dark side of the moon: increasing resistance in new naive.

Thank you

