Congresso Nazionale
AGGIORNAMENTI INFETTIVOLOGICI:
HIV, EPATITI & …..
Firenze, 15-17 Gennaio 2024
Centro Congressi Hotel Albani

L'esperienza romana e le prospettive future della PreP

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Disclosures

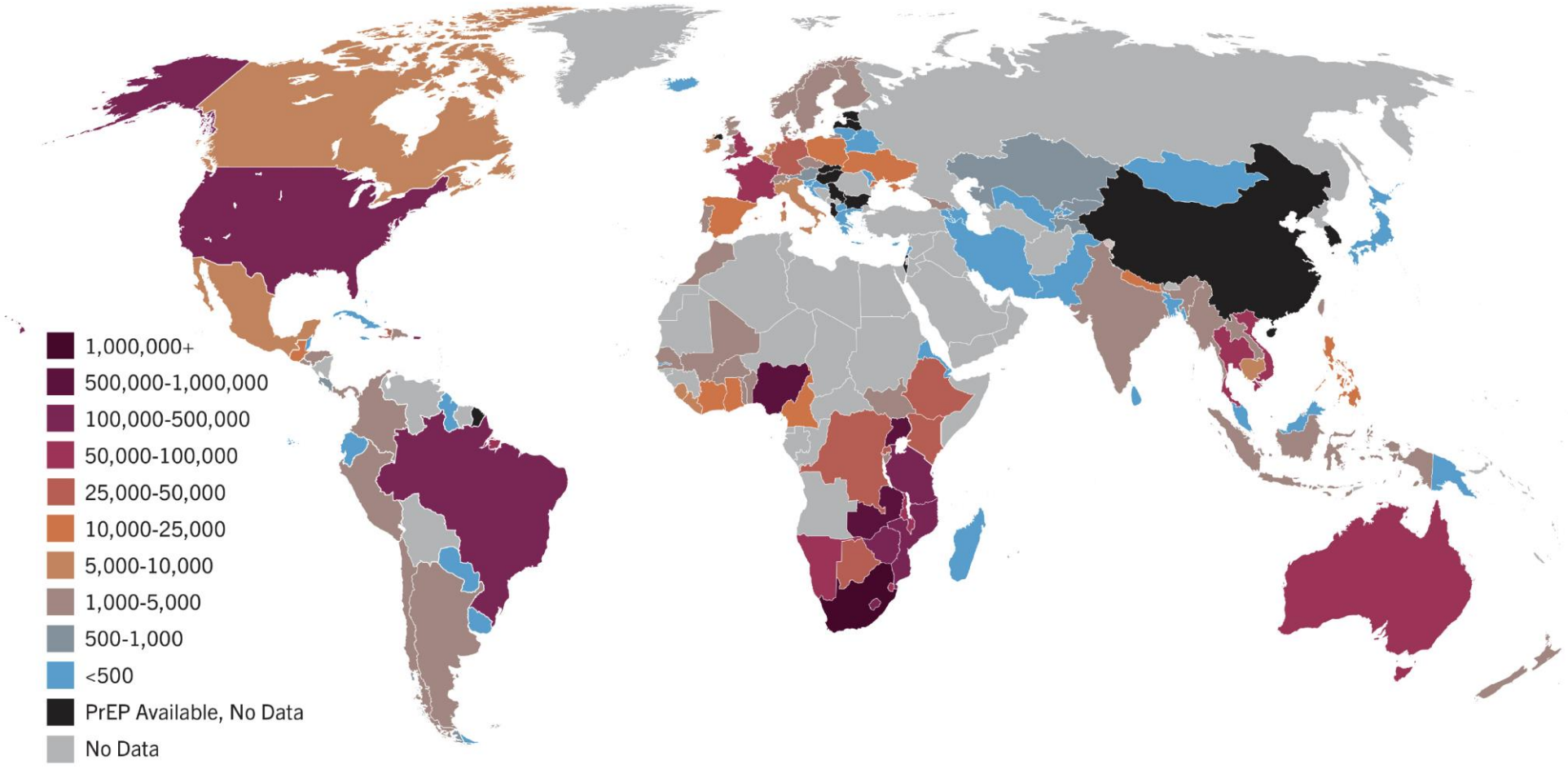
Dr. Antinori has served as a paid consultant to Astra Zeneca, Gilead Sciences, GSK, Janssen-Cilag, Merck, Moderna, Pfizer, Roche, Viatris, and ViiV Healthcare and received research fundings through National Institute for Infectious Diseases Lazzaro Spallanzani IRCCS from Astra Zeneca, Gilead Sciences and ViiV Healthcare.

PrEP Initiations by Country, September 2023

AVAC
Global Advocacy for HIV Prevention

Q3 2023
5.676.649 PrEP initiations

203 projects
69 countries approved selected products



Source: AVAC Global PrEP Tracker, Q3 2023,
https://www.prepwatch.org/data-by-country/

Daily and on-demand HIV pre-exposure prophylaxis with emtricitabine and tenofovir disoproxil (ANRS PREVENIR): a prospective observational cohort study

Jean-Michel Molina, Jade Ghosn, Lambert Assoumou, Constance Delaugerre, Michèle Algarte-Genin, Gilles Pialoux, Christine Katlama, Laurence Slama, Geoffroy Liegeon, Lydie Beniguel, Michel Ohayon, Hanane Mouhim, Lauriane Goldwirt, Bruno Spire, Bénédicte Loze, Laure Surgers, Juliette Pavie, Jérémy Lourenco, Mohamed Ben-Mechlia, Soizic Le Mestre, Daniela Rojas-Castro, Dominique Costagliola, on behalf of the ANRS PREVENIR Study Group*

Lancet HIV 2022; 9: e554–62
Published Online
June 27, 2022

Between May 3, 2017, and May 2, 2019, 3082 people were assessed for eligibility and 3065 participants were enrolled. **3056 (99·7%) of 3065 participants reported using PrEP and were included in the analyses.**

Median follow-up was **22·1 months** (IQR 15·9–29·7) and incidence of **study discontinuation was 17·6** participants (95% CI 16·5–18·7) per 100 person-years.

At the data cutoff on Sept 30, 2020, there had been **six HIV-1 seroconversions** (three participants using daily PrEP and three using on-demand PrEP; all were MSM) over 5623 person-years.

Overall HIV-1 incidence was 1·1 cases (95% CI 0·4–2·3) per 1000 person-years, and did not differ between participants using daily PrEP and those using on-demand PrEP

	Person-years	Number of HIV-1 seroconversions	Incidence per 1000 person-years (95% CI)	p value
Overall	5623	6	1·1 (0·4–2·3)	..
PrEP regimen*	..	..	..	0·99
Daily	2713	3	1·1 (0·2–3·2)	..
On-demand	2723	3	1·1 (0·2–3·2)	..
Period of follow-up	..	..	..	0·69
1st year	2821	1	0·3 (0·0–2·0)	..
2nd year	2024	3	1·5 (0·3–4·3)	..
3rd and 4th years	778	2	2·6 (0·3–9·3)	..
Calendar period of follow-up	..	..	..	0·66
May, 2017–April, 2018	668	0	0·0 (0·0–5·5)	..
May, 2018–April, 2019	1975	2	1·0 (0·1–3·7)	..
May, 2019–September, 2020	2980	4	1·3 (0·4–3·4)	..

Data are n unless otherwise stated. HIV-1 incidences rates were calculated as the total number of infections over person-years of observation, and were compared between groups using a Poisson distribution. According to the type of dosing regimen used by participants between visits, the follow-up time per dosing regimen was calculated during the study period to assess HIV-1 incidence per dosing regimen. PrEP=pre-exposure prophylaxis. *Information on the PrEP dosing regimen was missing for seven participants.

Table 2: **HIV-1 incidence over time and by PrEP regimen**

Long-term protection from HIV infection with oral HIV pre-exposure prophylaxis in gay and bisexual men: findings from the expanded and extended EPIC-NSW prospective implementation study

*Andrew E Grulich, Fengyi Jin, Benjamin R Bavinton, Barbara Yeung, Mohamed A Hammoud, Janaki Amin, Gesalit Cabrera, Shawn Clackett, Erin Ogilvie, Stefanie Vaccher, Tobias Vickers, Anna McNulty, David J Smith, Nila J Dharan, Christine Selvey, Cherie Power, Karen Price, Iryna Zablotska, David A Baker, Mark Bloch, Katherine Brown, Christopher J Carmody, Andrew Carr, Daniel Chanisheff, Nicholas Doong, Robert Finlayson, David A Lewis, Josephine Lusk, Sarah Martin, Catriona Ooi, Phillip Read, Nathan Ryder, Don Smith, Clara Tuck Meng Soo, David J Templeton, Emmanuel Vlahakis, Rebecca Guy, for the Expanded PrEP Implementation in Communities New South Wales (EPIC-NSW) research group**

Lancet HIV 2021; 8: e486–94

Published Online
July 1, 2021

In this cohort of almost **10,000 mostly gay and bisexual men** who were dispensed PrEP and **followed up for up to 3 years**, there were **only 30 new HIV infections**, with a **very low HIV incidence of 1·61 per 1000 person years**.

This incidence was 92% less than the expected incidence of at least 20 per 1000 person-years in the absence of PrEP.

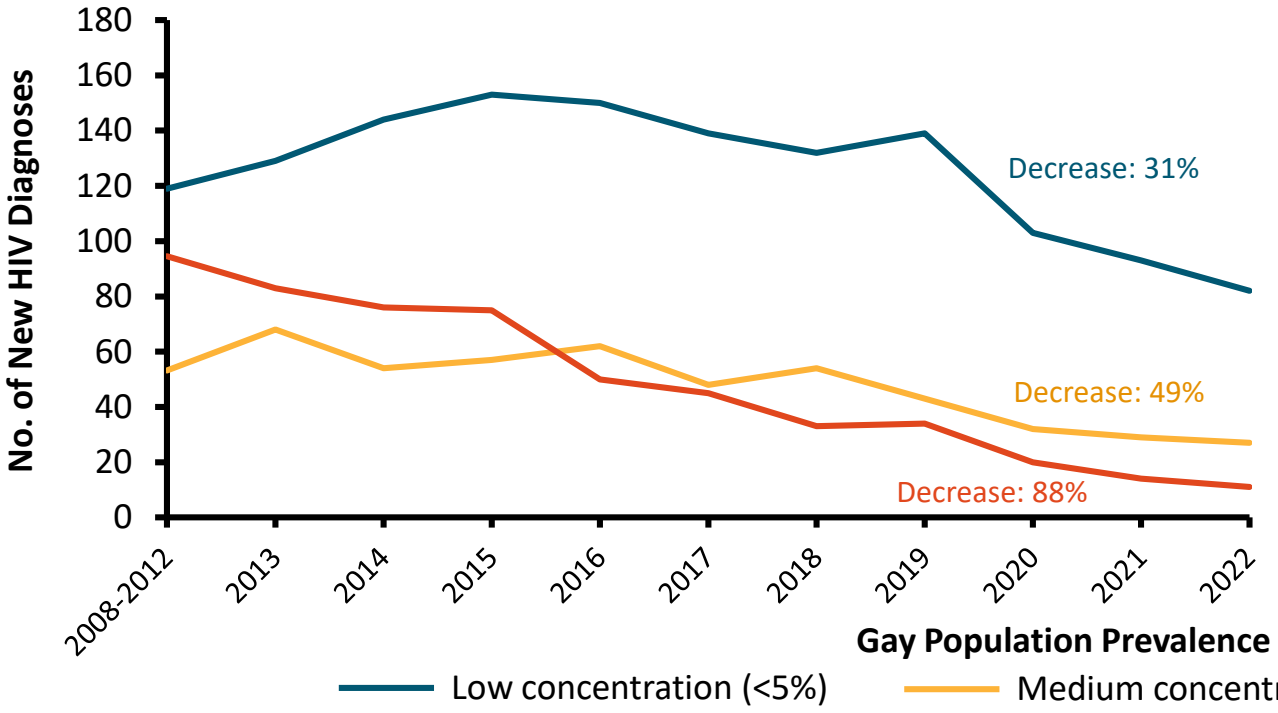
	Number of HIV sero-conversions	Incidence per 1000 person-years	Incidence rate ratio (95% CI)	p value
Years since first PrEP dispensed				
<1	10	1·09	1 (ref)	0·086*
1–2	14	2·10	1·93 (0·86–4·35)	..
2–3	6	2·18	2·01 (0·73–5·53)	..
Calendar period of follow-up				
Year 1 (March, 2016–February, 2017)	1	0·38	1 (ref)	0·018*
Year 2 (March, 2017–February, 2018)	8	1·20	3·15 (0·39–25·21)	..
Year 3 (March, 2018–March, 2019)	21	2·24	5·88 (0·79–43·69)	..
Mean MPR†				
<0·6	17	4·76	1 (ref)	<0·0001
0·6–1·0	5	0·39	0·08 (0·03–0·22)	..

MPR=medication possession ratio. PrEP=pre-exposure prophylaxis. *p_{trend}. †Mean MPR during follow-up was calculated for participants with at least 6 months of adherence data available.

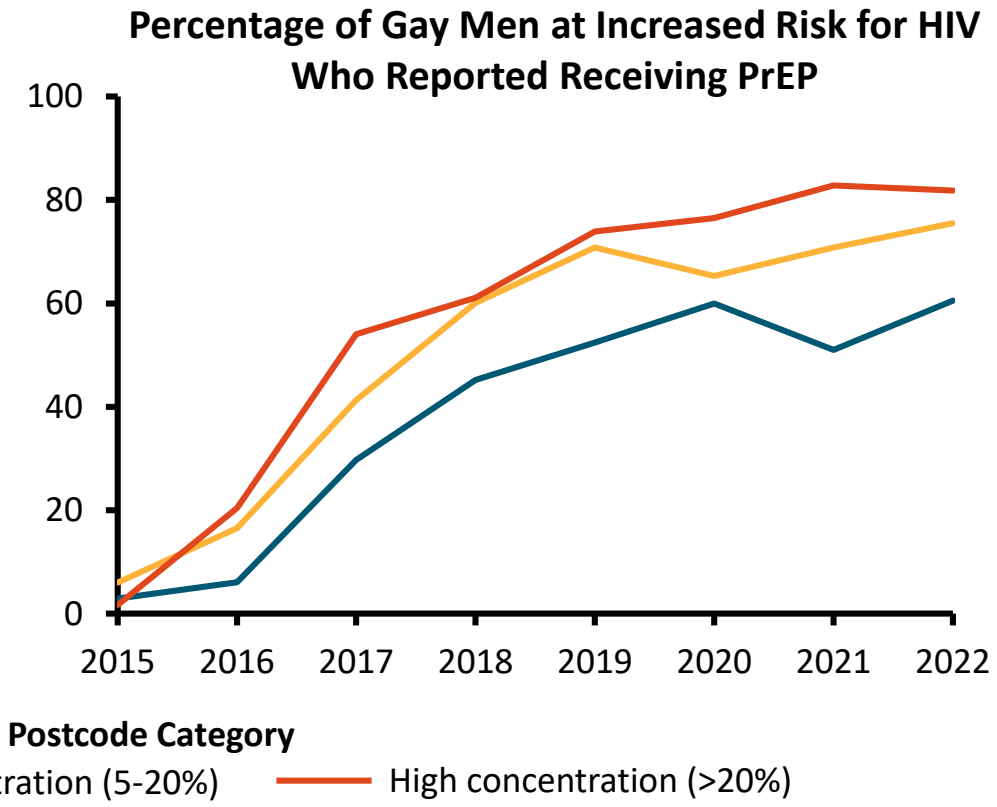
Table 4: Years since first dispensed PrEP, calendar period of follow-up, and mean MPR during follow-up and risk of HIV infection

Sydney: Example of Successful HIV Prevention Program

- In 2022 in central Sydney, decline in HIV diagnoses approached UNAIDS target



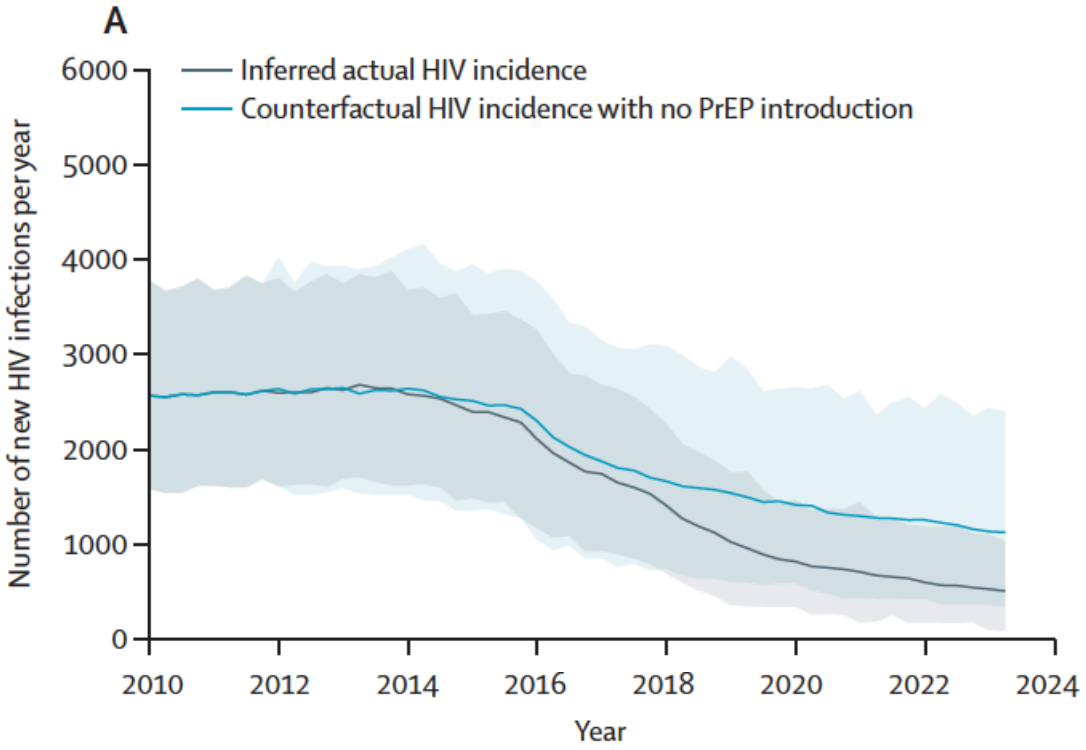
- Contributing to decline in HIV diagnoses: high percentages of those who could benefit from PrEP were receiving it in 2022

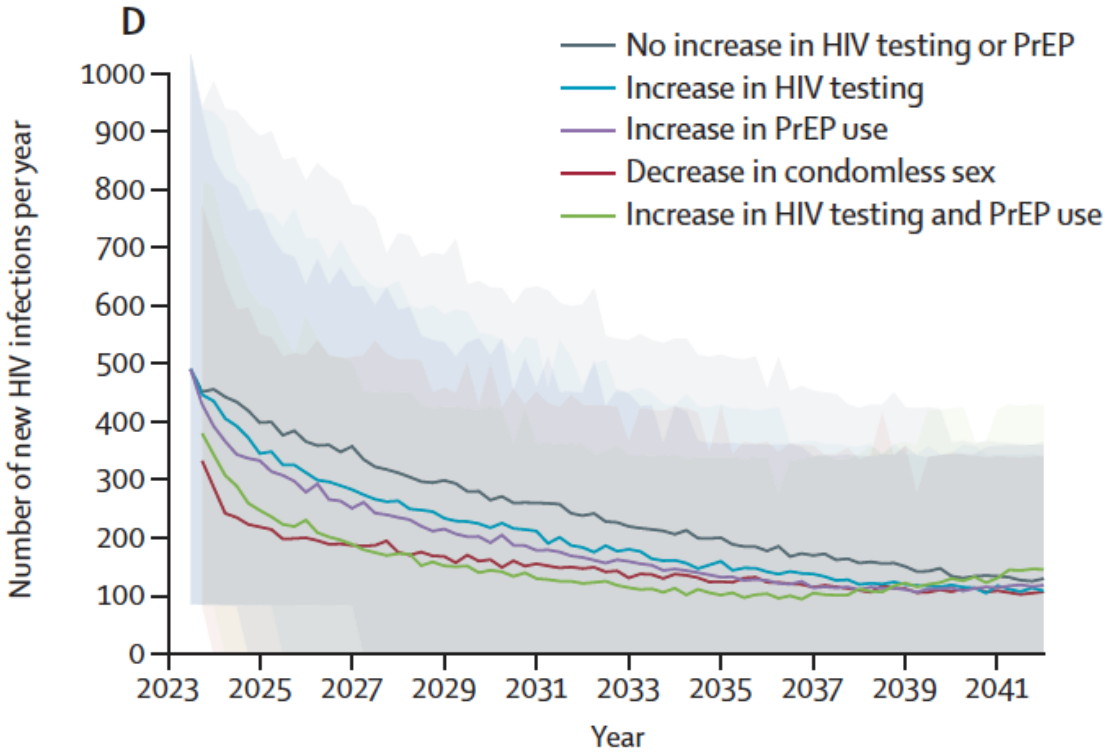


Grulich. IAS 2023. Plenary PL05.

Combination prevention, including PrEP, played a major role in the reduction in HIV incidence observed so far in the UK among GBMSM.

A dynamic, individual-based, stochastic simulation model, the HIV Synthesis Model, to multiple sources of data on HIV among GBMSM aged 15 years or older in the UK. Primarily these were routine HIV surveillance data collected by the UK Health Security Agency. We compared HIV incidence in 2022 with the counterfactual incidence: if HIV testing rates stopped increasing in 2012 and the policy of antiretroviral therapy (ART) at diagnosis was not introduced in mid-2015; if pre-exposure prophylaxis (PrEP) was not introduced; if condom use was low from 2012 in all GBMSM, at levels similar to those observed in 1980; and in the first and second scenario combined.





Cambiano V, et al. Lancet HIV 2023; 10: e713–22

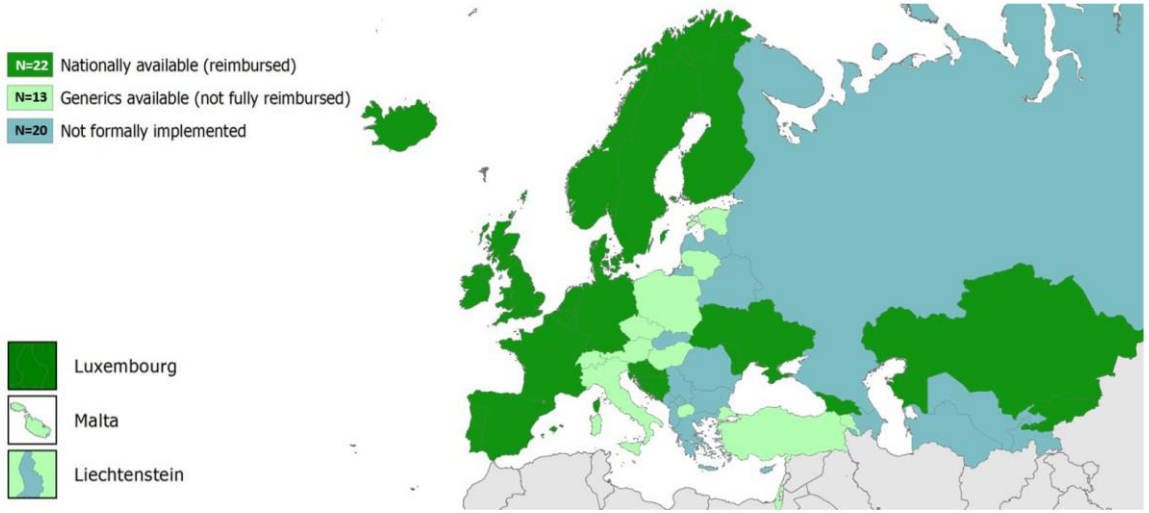
ECDC EVIDENCE BRIEF

Pre-exposure prophylaxis for HIV prevention in Europe and Central Asia

Monitoring implementation of the Dublin Declaration on Partnership to fight HIV/AIDS in Europe and Central Asia – 2020/2021 progress report

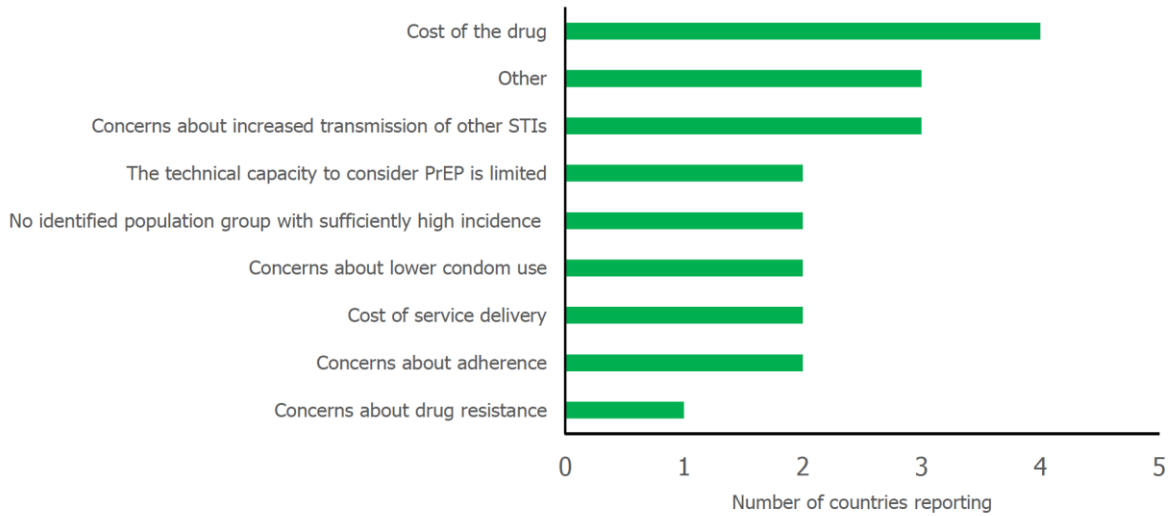
July 2022

Figure 1. Status of the formal implementation of PrEP in the WHO European Region, 2021



Source: European Centre for Disease Prevention and Control. Monitoring implementation of the Dublin Declaration. Stockholm: ECDC; 2021 (unpublished data)

Figure 2. Issues preventing or limiting PrEP implementation across Europe and Central Asia (n=11)



11 Maggio 2023

SERIE GENERALE

Spediz. abb. post. - art. 1, comma 1
Legge 27-02-2004, n. 46 - Filiale di Roma

Anno 164° - Numero 115

GAZZETTA UFFICIALE

DELLA REPUBBLICA ITALIANA

PARTE PRIMA — Roma - Giovedì, 18 maggio 2023 — SI PUBBLICA TUTTI I GIORNI NON FESTIVI

DETERMINA 8 maggio 2023.

Regime di rimborsabilità e prezzo, a seguito di nuove indicazioni terapeutiche, del medicinale per uso umano «Emtricitabina/Tenofovir Disoproxil Mylan». (Determina n. 349/2023).

Indicazione autorizzata:

Emtricitabina/Tenofovir disoproxil Mylan è indicato in combinazione con pratiche sessuali sicure per la profilassi pre-esposizione al fine di ridurre il rischio di infezione da HIV-1 sessualmente trasmessa in adulti e adolescenti ad alto rischio.

Indicazione rimborsata SSN:

Emtricitabina/Tenofovir disoproxil Mylan è rimborsato nell'indicazione della profilassi pre-esposizione di HIV unicamente in soggetti adulti ad alto rischio di acquisizione di HIV per via sessuale come definito nei seguenti criteri di rimborsabilità

Emtricitabina/tenofovir disoproxil deve essere utilizzato per la profilassi pre-esposizione solo come parte di una strategia globale di prevenzione dell'infezione da HIV-1, incluso l'uso di altre misure di prevenzione dell'HIV-1 (per es., l'uso costante e corretto del preservativo, la conoscenza dello stato HIV-1, l'analisi regolare per altre malattie sessualmente trasmesse) e nell'ambito del programma di gestione e implementazione della PrEP predisposto dal Ministero della Salute.

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 siero-stato 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*).

La persona candidata alla PrEP non deve presentare nessuno dei seguenti criteri di esclusione:

- Persone con infezione da HIV;

Valutazione clinica e monitoraggio ^

	Prima prescrizione	Ogni 3 mesi	Ogni 6 mesi
Visita clinica generale (raccolta dati demografici, clinici e sui comportamenti sessuali a rischio)	X		
Definizione dei criteri di eleggibilità	X		
Counseling sui comportamenti a rischio	X	X	X
Test HIV Ab/Ag (4° generazione o superiore)	X	X	X
Test per HBV (HBsAg, HBsAb e HBcAb)	X		X*
Sierologia per epatite C (HCV Ab)	X		X§
Sierologia per epatite A (HAV Ab)	X		X*
Screening per MST (sierologia per sifilide; tampone oro-faringeo, ano-rettale e raccolta urine spot per Chlamydia, Neisseria gonorrhoeae)	X	X	X
Determinazione della creatinina sierica e stima GFR	X		X
Misurazione dell'aderenza alla PrEP e interventi di supporto		X	X
Valutazione degli eventi avversi		X	X

^ Procedure definite in accordo al Documento sulla profilassi pre-esposizione per l'infezione da HIV (PrEP) redatto dalle Sezioni L e M per la lotta contro l'AIDS del Comitato Tecnico-Sanitario del Ministero della Salute.

* nei soggetti con sierologia negativa precedente, non vaccinati o non *responder* alla vaccinazione;

§ nei soggetti con sierologia negativa precedente.

AGGIORNAMENTO DELLE NUOVE DIAGNOSI DI INFEZIONE DA HIV E DEI CASI DI AIDS IN ITALIA AL 31 DICEMBRE 2022

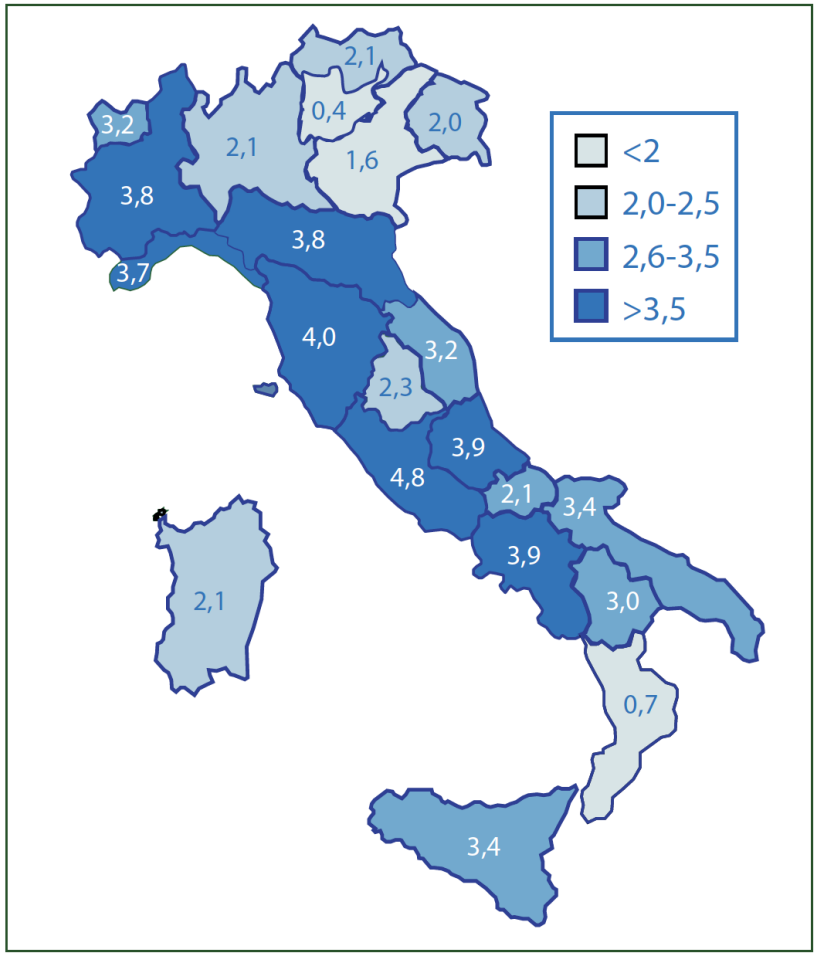


Figura 3 - Incidenza delle nuove diagnosi di infezione da HIV (per 100.000 residenti) per Regione di residenza (2022)

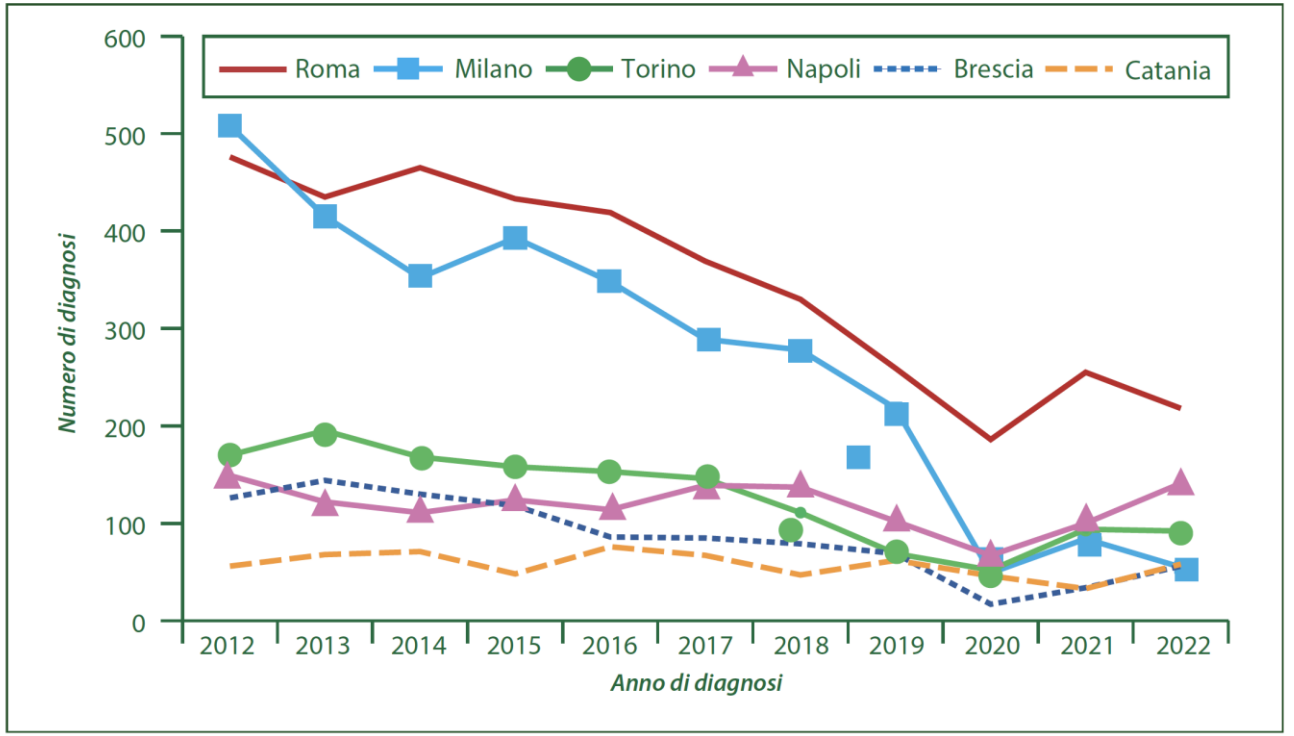
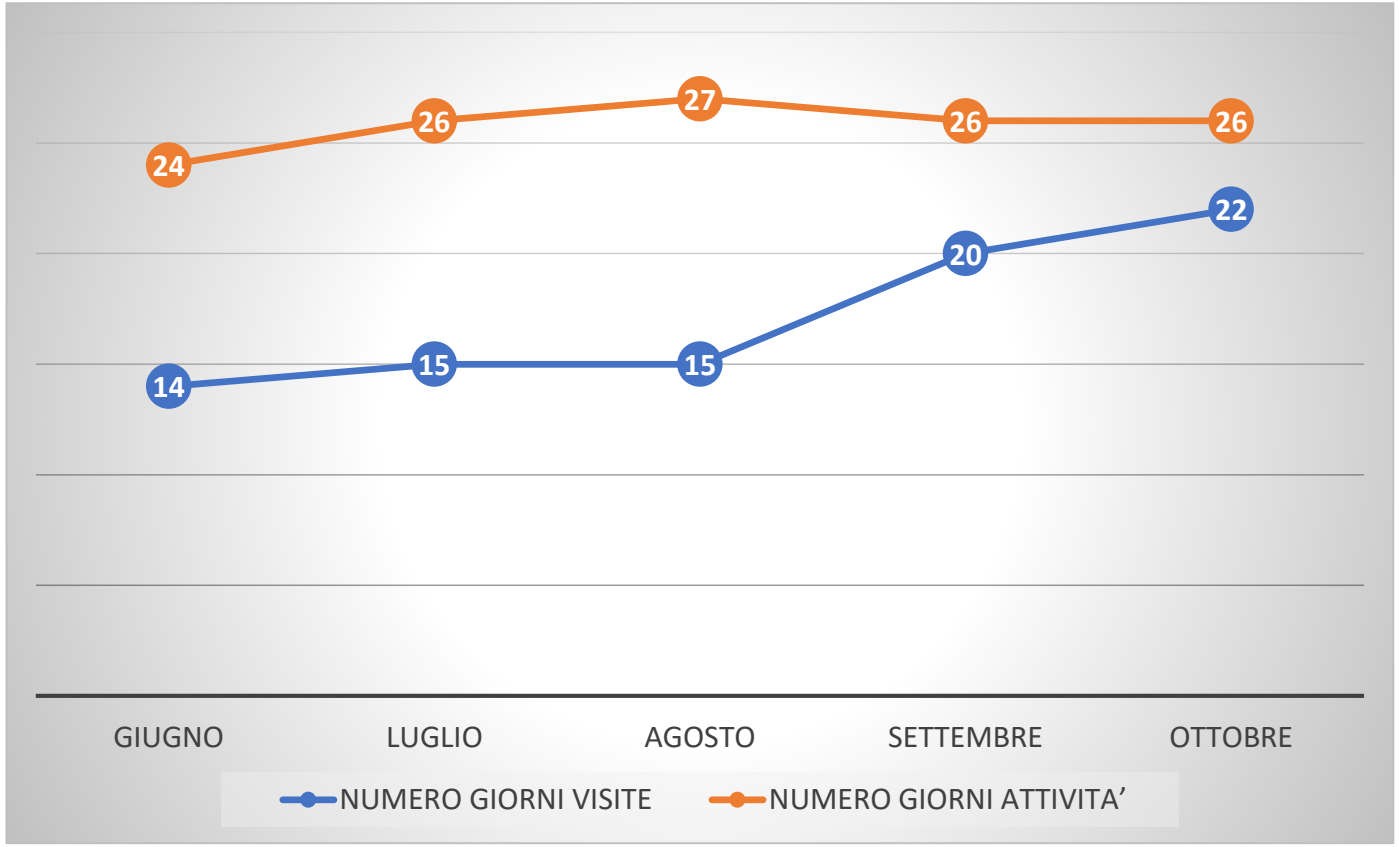


Figura 4 - Nuove diagnosi di infezione da HIV nelle Province con il maggior numero di diagnosi per anno (2012-2022)

Increasing the outpatient offer of the PrEP/STD Ambulatory Service at INMI (2023)

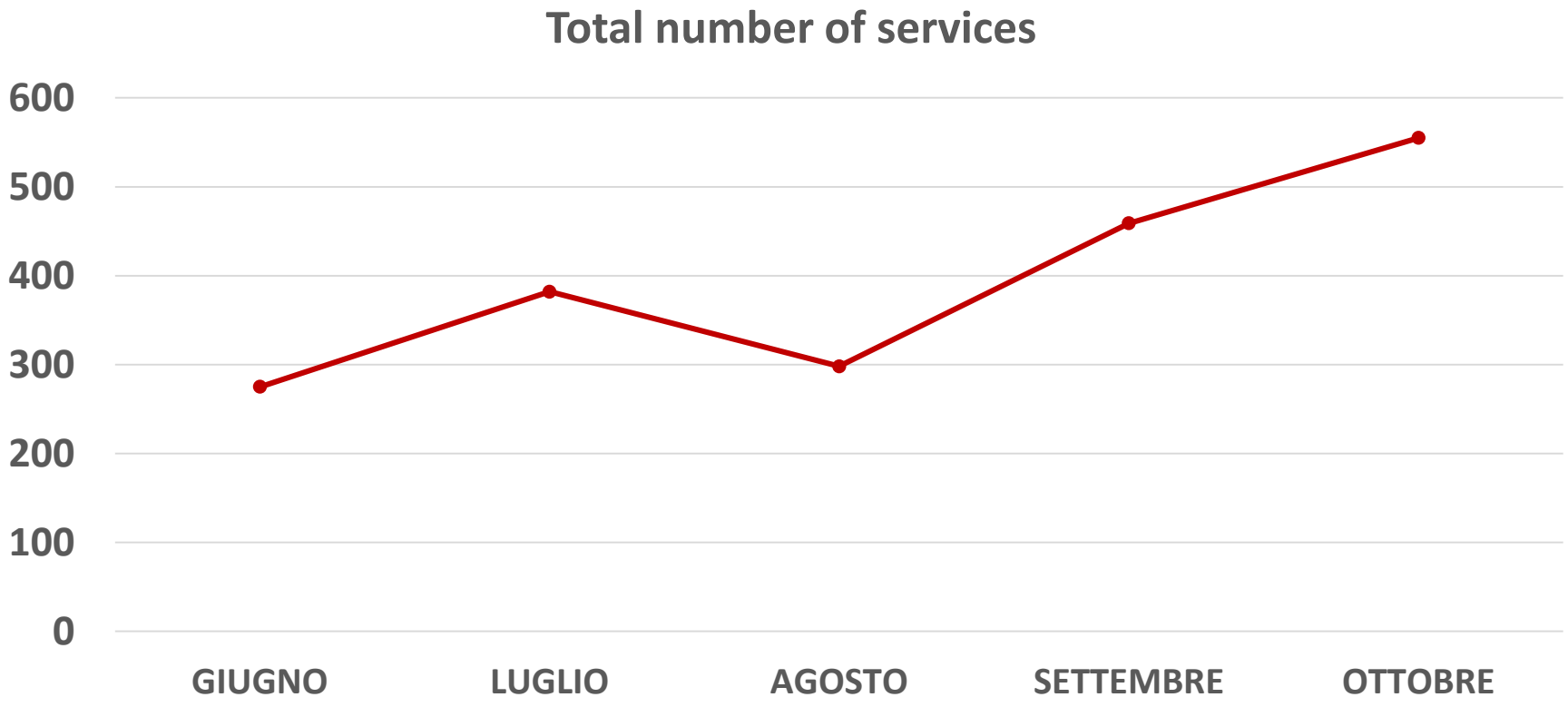
- The PrEP/STD outpatient clinic was upgraded at INMI from June to October 2023 in a phased manner, tailoring the offer to the number of bookings and waiting lists
- It is currently open every morning from Monday to Friday
- The outpatient clinic is currently open also on Saturdays with a nursing shift only



Number of users and total number of services provided.

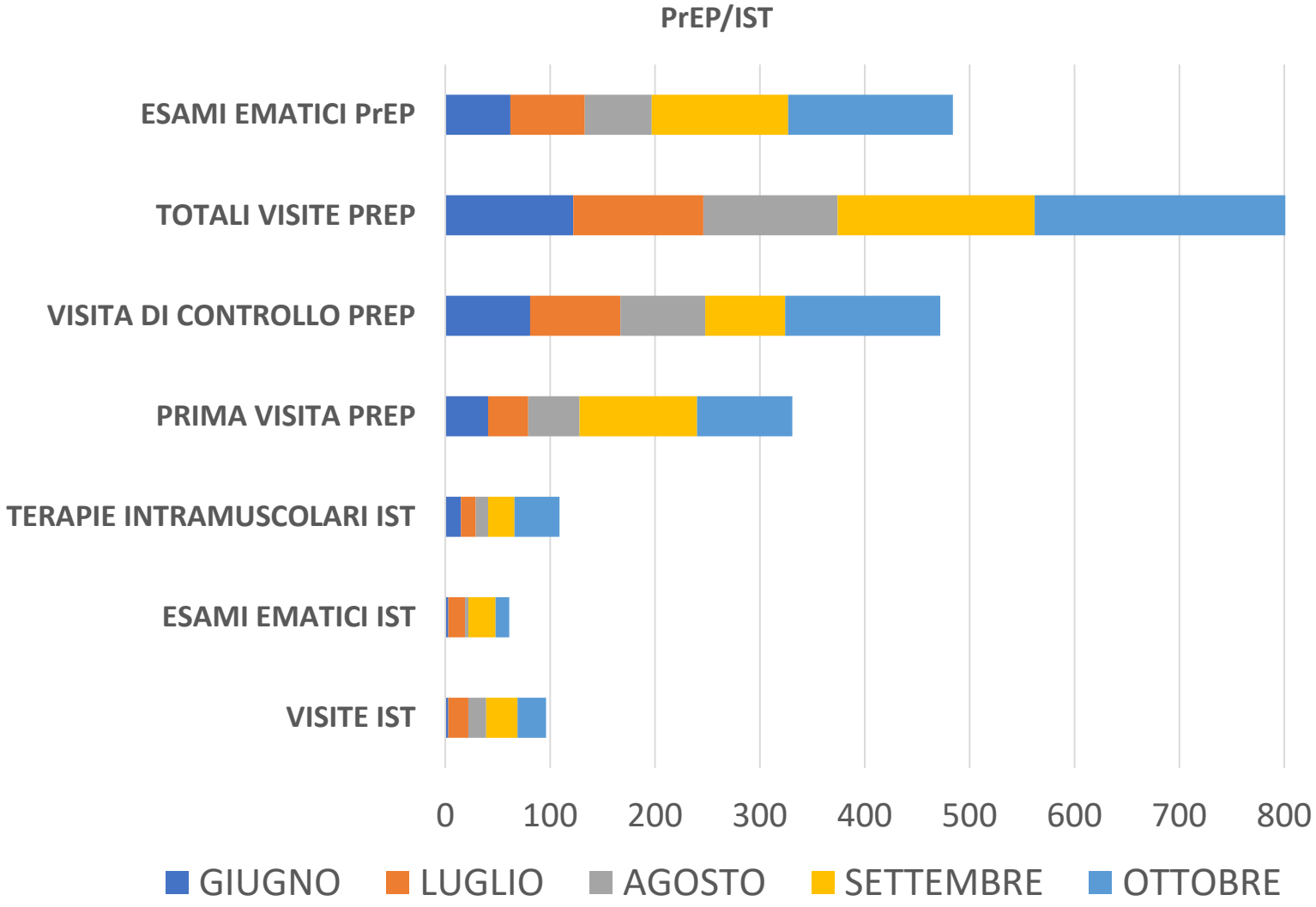
June 1, 2023 - October 31, 2023

The number of HIV-negative people at risk included in the INMI PrEP programme as of January 2024 is approximately 1,500



TOTAL SERVICES
from 1/6 to 31/10
N=1969

List of activities at INMI PrEP/STD Ambulatory service



Other 2023 activities

Mpox outpatient clinic

- 298 suspected mpox cases (80% of total suspected cases Lazio Region
- 135 notified cases of confirmed mpox (with diagnosis by RT-PCR test) (82% of total cases notified Lazio Region,

Mpox vaccination program

- 161 vaccinated (3,460 from August 2022 to December 2023)

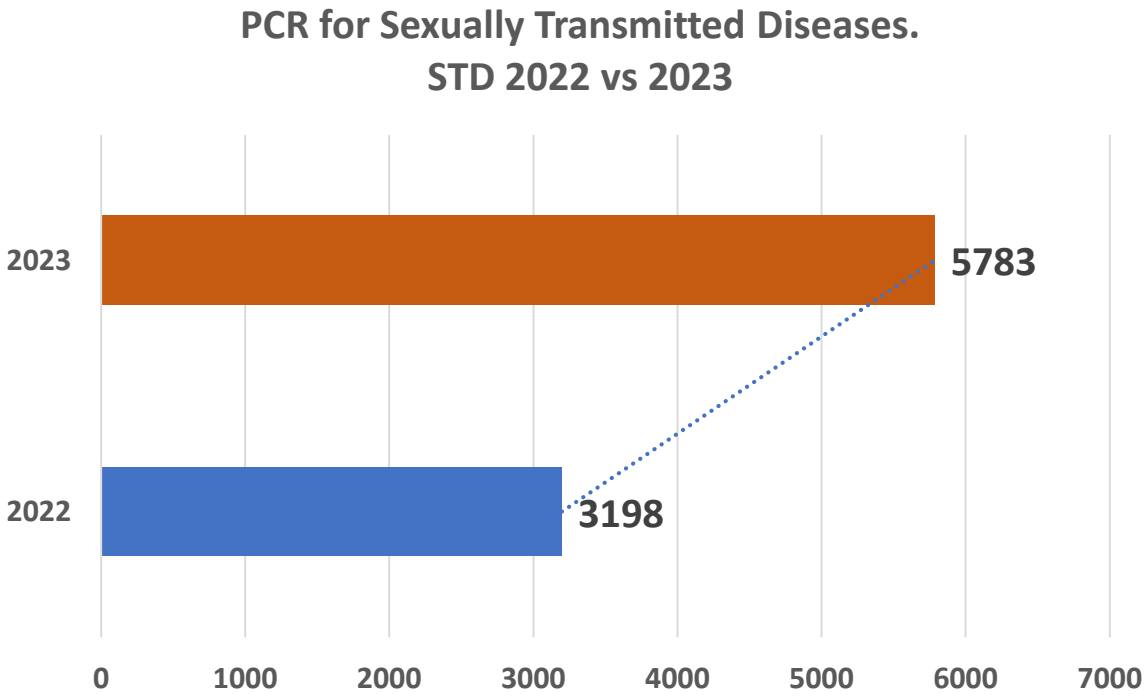
Clinical studies

- 410 follow-up visits

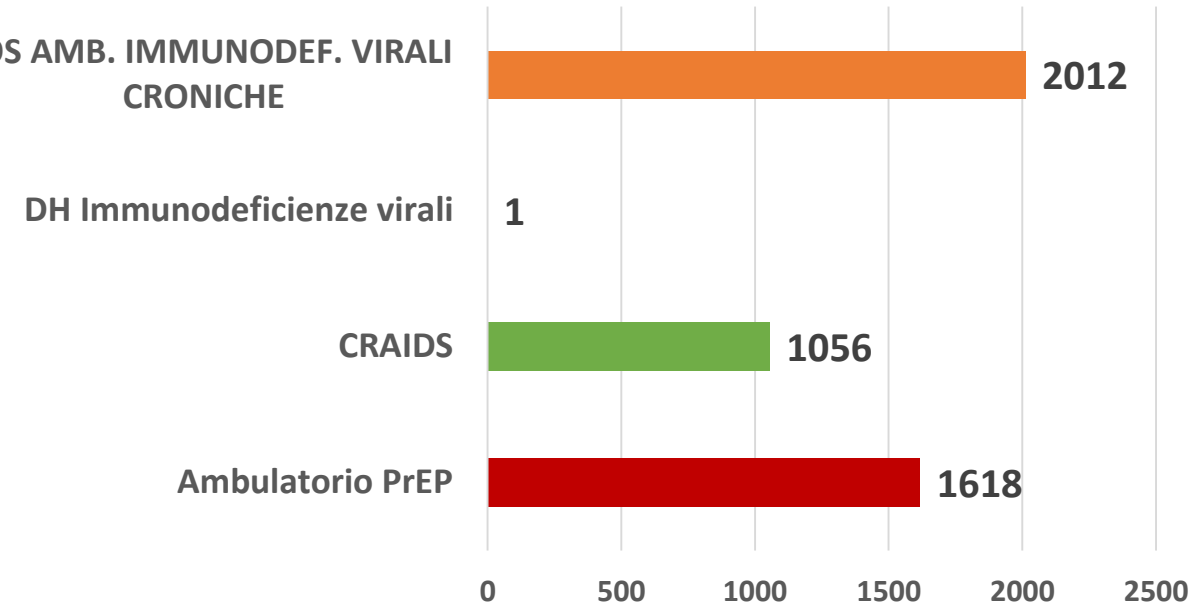
Other vaccinations

- HAV, HBV, HPV, MenB

STD monitoring. Comparison 2022 vs 2023



In 2023, 55% increase over 2022



Requests for STD diagnostic tests per service.
Data year 2023

ITAPrEP

Main characteristics and HIV/STI events among 1,919 Italian PrEP users

HIV-seroconversions	**5**
Incidence Rate HIV*	**2.2 x 1000 PYFU**

*IR placebo Ipergay Trial = 6.6 x 100 PYFU

C. trachomatis pos tests after first visit	**551**
Incidence Rate C. trachomatis	**250 x 1000 PYFU**

N. gonorrhoeae pos test after first visit	**424**
Incidence Rate N. gonorrhoeae	**201 x 1000 PYFU**

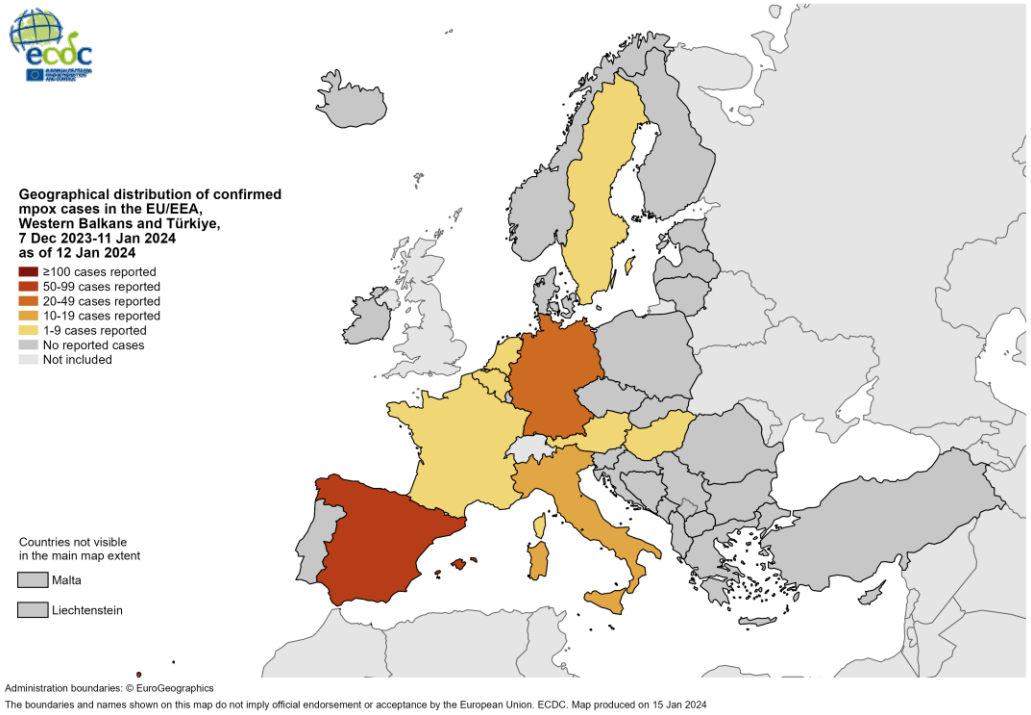
Syphilis pos test after first visit	**321**
Incidence Rate Syphilis	**192 x 1000 PYFU**

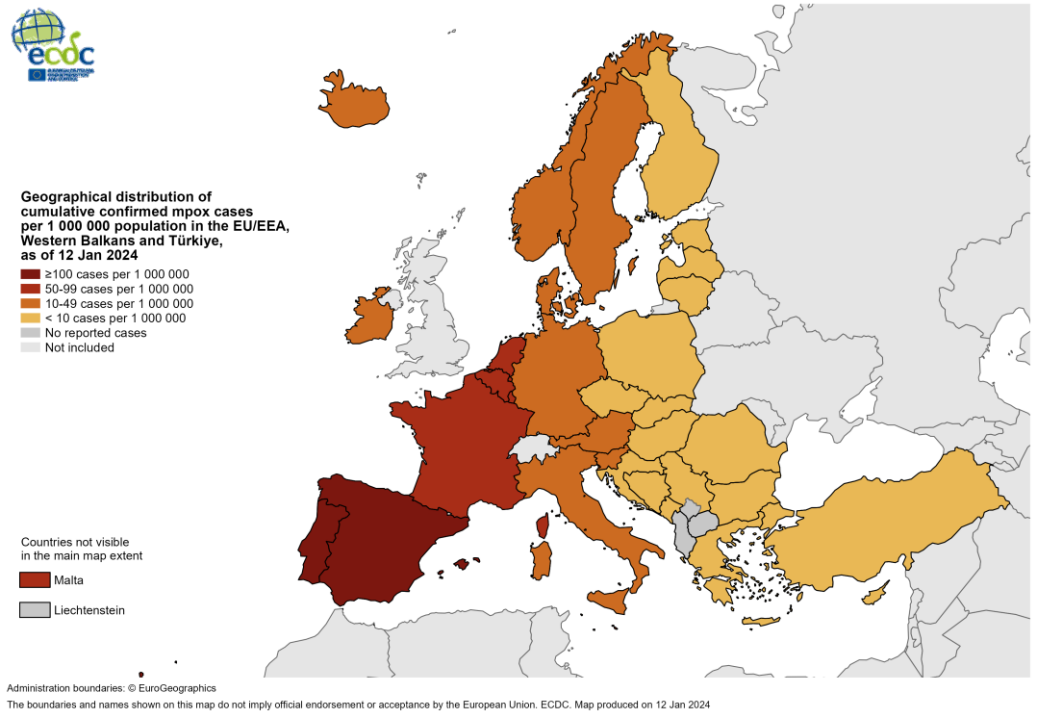
	Ita-PrEP users (N=1,919)	%
Age, Median (IQR)	36	31-44
<30	380	19,8
30-40	**781**	**40,7**
>40	**758**	**39,5**
Gender		
F	24	1,25
M	**1.873**	**97,6**
MtF	22	1,15
Sexual Orientation		
Bisexual	125	6,55
Heterosexual	46	2,41
MSM	**1.738**	**91,04**
Italian	**1585**	**82,6**
University	**1126**	**58,6**
Job		
Not-employed	223	11,6
Employed	**1476**	**76,9**
Sex worker	67	3,5
STIs baseline	**433**	**22,6**
Chemsex baseline	**333**	**17,3**
PEP baseline	**295**	**15,4**

Joint ECDC-WHO Regional Office for Europe Mpox Surveillance Bulletin

Surveillance summary

A total of 26,703 cases of mpox (formerly named monkeypox) have been identified through IHR mechanisms, official public sources and TESSy up to 14 January 2024, 14:00, from 45 countries and areas throughout the European Region. **Since the last report, in the last three months, 472 cases have been reported from 19 countries and areas. Over the past 4 weeks, 138 cases of mpox have been identified from 11 countries and areas.**





ECDC-WHO. Produced on 12 January 2024

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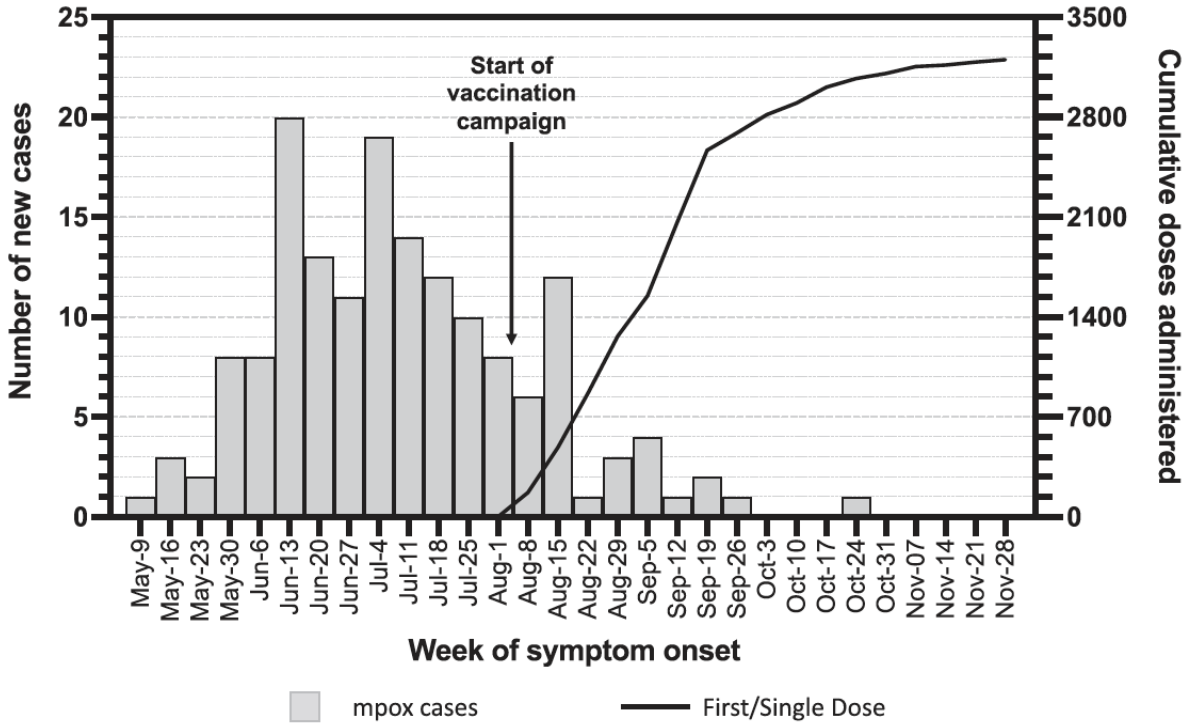
journal homepage: www.elsevier.com/locate/ijid

The possible effect of sociobehavioral factors and public health actions on the mpox epidemic slowdown

Francesco Vairo[1], Sara Leone[1], Valentina Mazzotta[1,*], Pierluca Piselli[1], Gabriella De Carli[1], Simone Lanini[1], Fabrizio Maggi[1], Emanuele Nicastri[1], Roberta Gagliardini[1], Serena Vita[1], Andrea Siddu[2], Giovanni Rezza[2], Alessandra Barca[3], Francesco Vaia[1], Andrea Antinori[1], Enrico Girardi[1]

[1] National Institute for Infectious Diseases 'Lazzaro Spallanzani' (IRCCS), Rome, Italy
[2] Directorate General of Health Prevention, Ministry of Health, Rome, Italy
[3] Unit of Health Promotion and Prevention, Directorate of Health and integration, Lazio Region, Italy



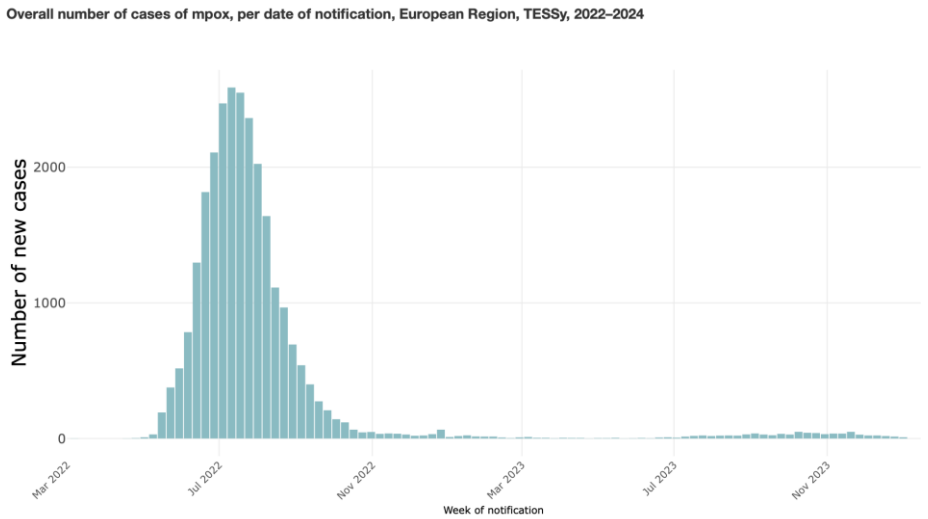


Table 1
Poisson segmented regression model of the impact of communication and vaccination campaign on the weekly number of monkeypox cases in one Italian region (Lazio) from May 9, 2022 to November 30, 2022.

Time/period	Incidence rate ratio (95% confidence interval)
Scale-up of public and media communication (June 13-19)[a]	0.971 (0.800-1.179)
Prescale-up of communication trend	**1.661 (1.549-1.781)**
Postscale-up-of mass communication trend	**0.926 (0.899-0.952)**
Vaccination (August 22-28)[a]	**0.452 (0.331-0.618)**
Post- vaccination trend	**0.734 (0.673-0.801)**
End of study period[a]	**0.018 (0.007-0.047)**
Slope change following scale-up of communication	**0.557 (0.519-0.598)**
Slope change following vaccination	**0.793 (0.725-0.868)**

[a] Compared with counterfactual.

REGIONE/PA	LAZIO
data inizio della campagna vaccinale (prime somministrazioni)	08/08/2022
data rilevazione (comprende tutte le vaccinazioni effettuate fino a tale data a partire dall'inizio della campagna vaccinale)	31/12/2023
Ambulatori attivi	**Ambulatorio Vaccinazione MPOX INMI Lazzaro Spallanzani IRCCS, Roma**
numero totale di dosi somministrate	5975
numero totale di dosi somministrate SC	636
numero totale di dosi somministrate ID	5339
numero totale prime dosi	2688
numero prime dosi SC	528
numero prime dosi ID	2160
numero totale seconde dosi	2537
numero seconde dosi SC	1
numero seconde dosi ID	2536
numero totale richiami (vaccinati Vaiolo)	750
numero richiami SC	107
numero richiami ID	643
distribuzione dei vaccinati per genere	
M	3412
Altro Genere (donne transgender)	48
numero totale di persone che hanno ricevuto almeno una dose	**3460**
distribuzione delle dosi somministrate per fasce di età	
< 25 anni	130
25-59 anni	3215

Immunogenicity and reactogenicity of modified vaccinia Ankara pre-exposure vaccination against mpox according to previous smallpox vaccine exposure and HIV infection: prospective cohort study

eClinicalMedicine
2024;68: 102420

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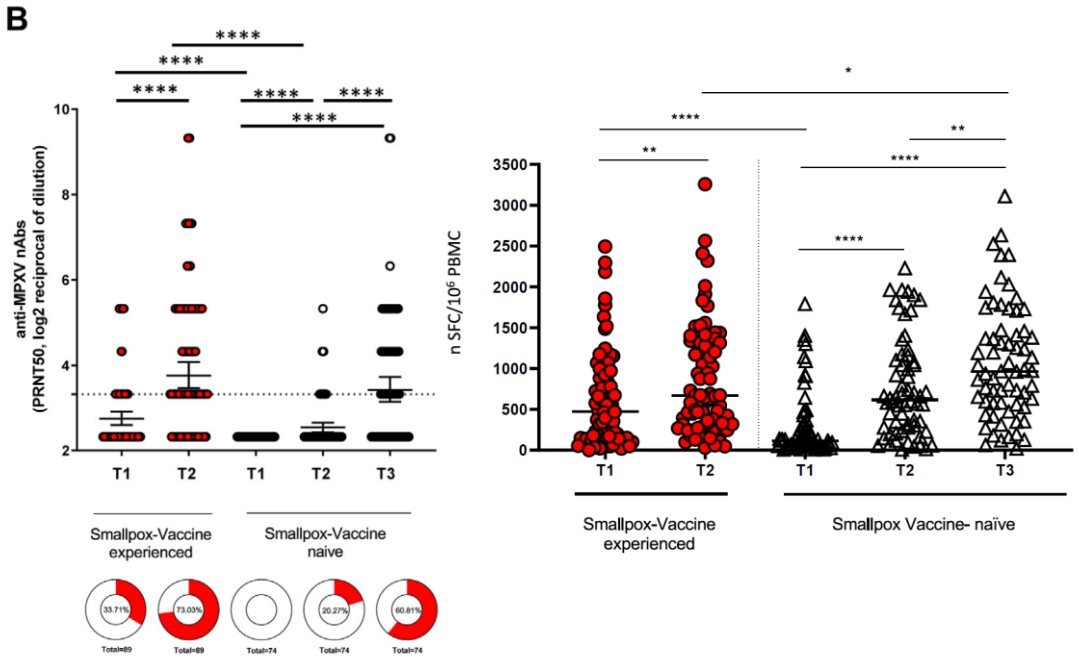

vaccines

MDPI

Article

Risk Awareness as a Key Determinant of Early Vaccine Uptake in the Mpox Vaccination Campaign in an Italian Region: A Cross-Sectional Analysis

Giulia Del Duca [1], Alessandro Tavelli [2], Ilaria Mastrorosa [1,*], Camilla Aguglia [1,3], Simone Lanini [1], Anna Clelia Brita [1], Roberta Gagliardini [1], Serena Vita [1], Alessandra Vergori [1], Jessica Paulicelli [1], Giorgia Natalini [1], Angela D'Urso [1], Pierluca Piselli [4], Paola Gallì [5], Vanessa Mondillo [5], Claudio Mastroianni [6], Enrica Tamburrini [7], Loredana Sarmati [3], Christof Stingone [8], Miriam Lichtner [9], Emanuele Nicastri [1], Massimo Farinella [10], Filippo Leserri [11], Andrea Siddu [12], Fabrizio Maggi [13], Antonella d'Arminio Monforte [2], Francesco Vairo [4], Alessandra Barca [14], Francesco Vaia [12], Enrico Girardi [15], Valentina Mazzotta [1,†] and Andrea Antinori [1,†]

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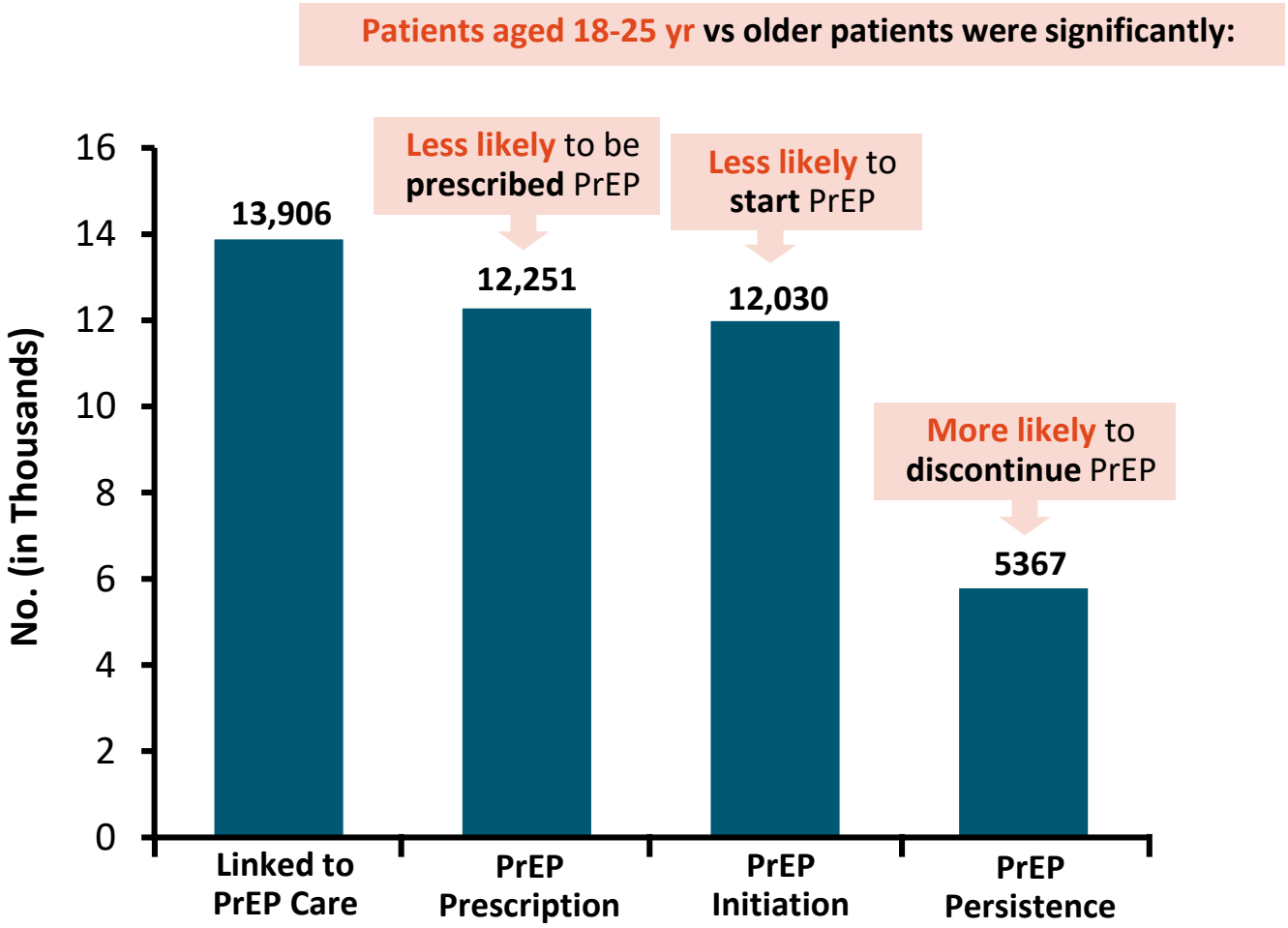
Table 3. Odds ratio (OR) and adjusted OR (AOR) of being vaccinated in the first 30 days of the mpox vaccination campaign in the Latium region (early acceptance), using logistic regression analysis.

	OR	95%CI	*p*	AOR *	95%CI	*p*
HIV/PrEP status						
HIV−/No PrEP	1			1		
HIV+	1.23	0.98–1.53	0.07	1.24	0.99–1.57	0.064
HIV−/On PrEP	2.11	1.49–2.99	<0.001	1.97	1.37–2.82	<0.001
N. main partners, per 1 more	1.07	1.03–1.11	0.001	1.07	1.03–1.11	0.001
Use of Drugs/Chems, yes (vs. no)	1.54	1.18–2.01	0.002	1.49	1.11–2.00	0.007
Sex under the influence of drugs or alcohol						
No	1			1		
Yes	1.67	1.3–2.15	<0.001	1.78	1.36–2.34	<0.001
Unknown	2.04	1.3–3.22	0.002	2.04	1.18–3.53	0.01

PrEP Continuum of Care in Kaiser Permanente Cohort

- Individuals linked to PrEP care 2012-2019: N = 13,906
  - Male: 95%
  - Race/ethnicity: 49% White, 22% Hispanic, 15% Asian, 7% Black
  - **Discontinued PrEP at least once: 52%**
    - **60% of those who discontinued restarted**



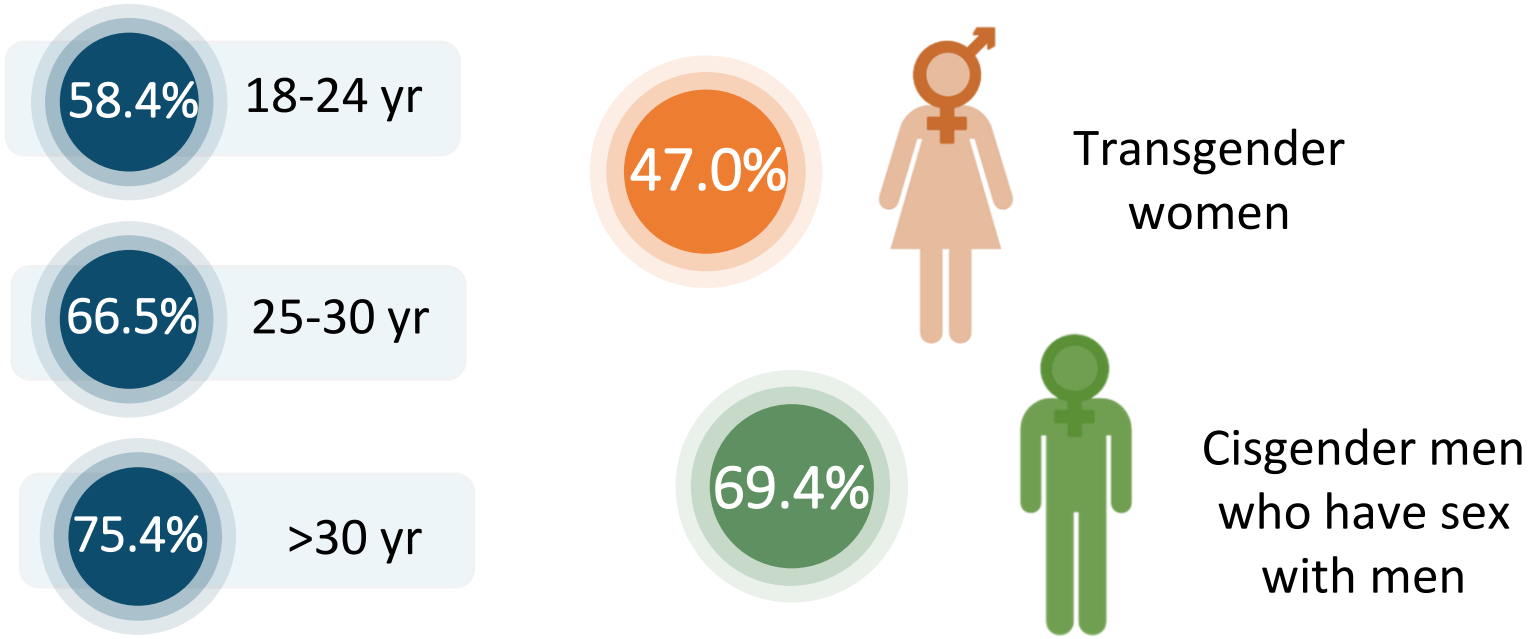
Hojilla. JAMA Netw Open. 2021;4:e2122692.

ImPrEP: Adherence

- **Adherence measured by MPR*:**

MPR = No. of FTC/TDF pills dispensed during the study / No. of days between enrollment and last visit → MPR ≥0.6 = 4 pills/wk

Percentage of People With an MPR ≥0.6



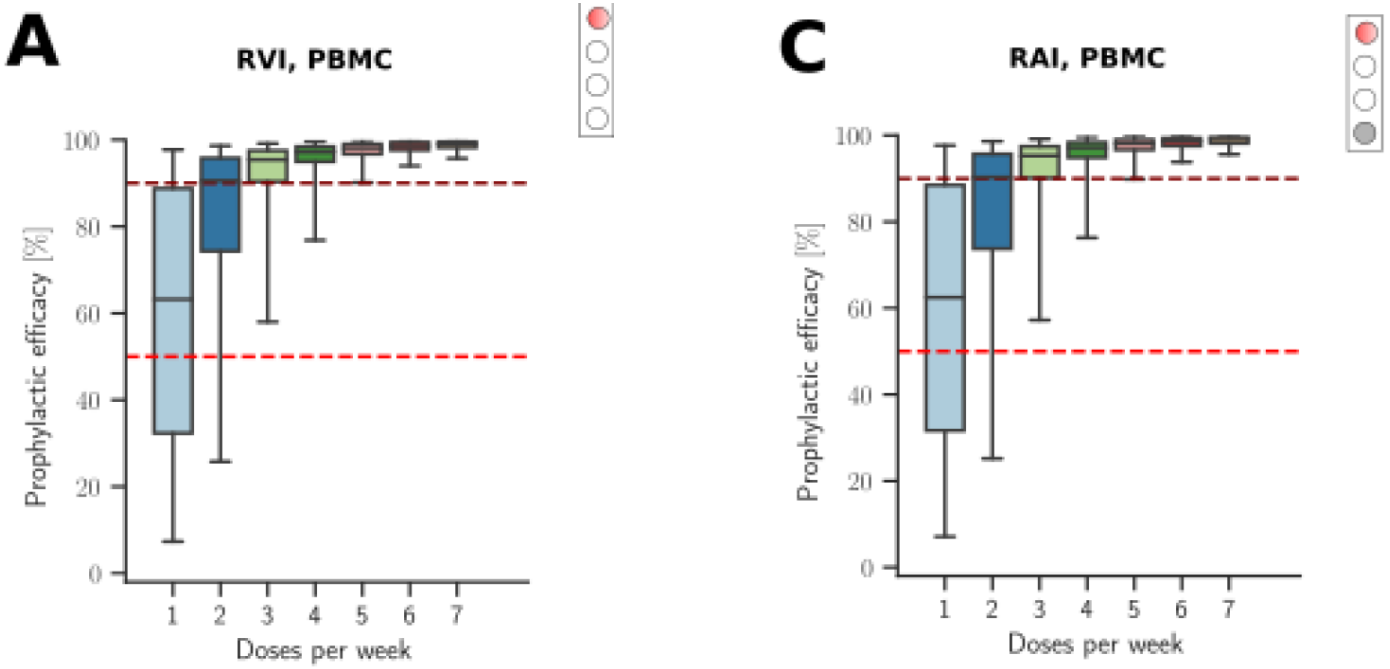
- Transgender women had **decreased** odds of **PrEP adherence**

*MPR, medication possession ratio

Veloso. Lancet HIV. 2023;10:e84.

PrEP 90% protection was achieved when women took some product (three doses per week)

Mechanistic models utilizing pharmacokinetics in PBMCs predict oral prophylactic efficacy, without regard for colon–vaginal differences. If this was also the case for MSM, then adherence requirements between women and MSM may not be different and observed MSM versus women differences in PrEP effectiveness could rather be related to specific adherence (pill-taking) behavior in cis women in these studies.



In panels A and C, PBMCs pharmacokinetics were considered the surrogate marker for effect-site concentrations.

Zhang L, et al. Nature Medicine | Volume 29 | November 2023 | 2753–2762

Interventions to Support PrEP Persistence

Delivery	Support	Regimen
▪ Provision of PrEP in settings: – People are already frequenting – That are youth friendly – Outside of medical settings ▪ Integration and colocation of PrEP with other services: – OB/GYN for cisgender women – **FHT for transgender women** – Treatment of OUD for people who use drugs	▪ **Enhanced and peer-based support and navigation** ▪ Computer- and phone-based counseling ▪ Text messages	▪ **Offer PrEP modality and dosing options** ▪ Offer extended pill supplies

Calabrese. J Acquir Immune Defic Syndr. 2019;81:395. Lama. JMIR Res Protoc. 2019;8:e14091.
Lama. JMIR Res Protoc. 2019;8:e14091. Reback. AIDS Behav. 2021;25:40. Velloza. AIDS. 2021;35:463.

HPTN 083 and 084: LA IM CAB Q2M vs Daily Oral FTC/TDF for PrEP

- International, randomized, double-blind phase IIb/III (083) and phase III (084) trials
- LA IM CAB met criteria for **superiority** vs daily oral FTC/TDF in both trials

HPTN 083[1]

- 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)**

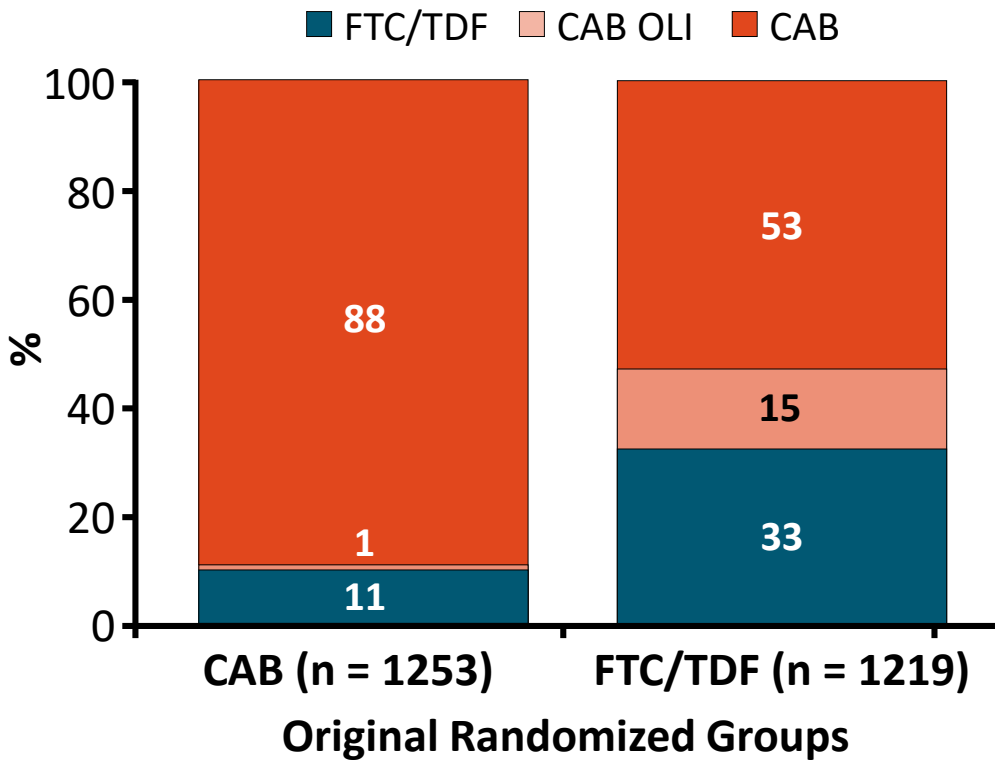
HPTN 084[2]

- 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)**

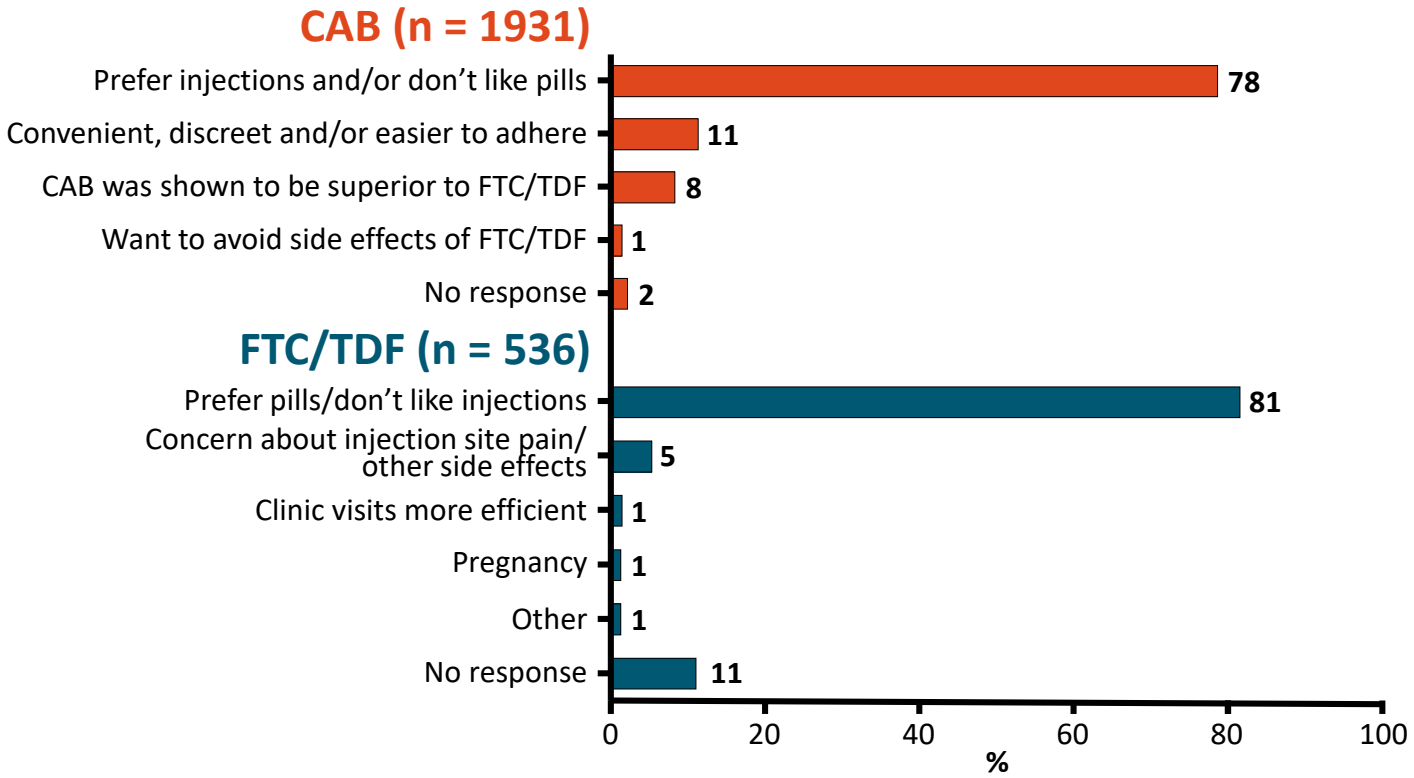
1. Landovitz. NEJM. 2021;385:595. 2. Delany-Moretlwe. Lancet. 2022;399:1779.

HPTN 084 Open-Label Extension: PrEP Product Choice

- **78% of participants chose CAB**



- Reasons for PrEP product choice



- **Participants who chose CAB were less likely to live with partners and more likely to have experienced recent physical intimate partner violence and to have been paid for sex**

Delany-Moretlwe. IAS 2023. Abstr OALBX0203.

IAS-USA Recommendations for PrEP by Population and Transmission Risk Behavior

Population and Risk Behavior	Oral TDF/FTC		Oral QD TAF/FTC	IM CAB
	QD	2:1:1		
Cisgender men/women				
▪ Insertive sex (vaginal/anal)	Yes	Yes	Yes	Yes
▪ Receptive anal sex	Yes	Yes	Yes	Yes
▪ Receptive vaginal sex	Yes	Insufficient data	Insufficient data	Yes
▪ Injection drug use	Yes	Insufficient data	Insufficient data	Insufficient data
Transgender women				
▪ Insertive sex (vaginal/anal)	Yes	Yes	Yes	Yes
▪ Receptive anal sex	Yes	Yes	Yes	Yes
▪ Receptive (neo) vaginal sex	Yes	Insufficient data	Insufficient data	Yes
▪ Injection drug use	Yes	Insufficient data	Insufficient data	Insufficient data
Transgender men				
▪ Receptive anal sex	Yes	Yes	Yes	Yes
▪ Receptive vaginal (“front hole”) sex	Yes	Insufficient data	Insufficient data	Yes
▪ Injection drug use	Yes	Insufficient data	Insufficient data	Insufficient data

Gandhi. JAMA. 2023;329:63.

Monitoring During PrEP

Laboratory Testing Timing	Oral PrEP	Injectable PrEP
HIV Ag/Ab and HIV-1 RNA testing	Every 3 mo	Every 1 mo with first 2 injections, then every 2 mo
Serum creatinine	▪ **Every 6 mo** if age ≥50 yr or eCrCl <90 mL/min at initiation ▪ **Every 12 mo** if age <50 yr and eCrCl ≥90 mL/min at initiation ▪ Persons with CrCl <60 mL/min should not take FTC/TDF for PrEP	Not required
Lipid panel	Every 12 mo (FTC/TAF only)	Not required
STI testing	Every 3 mo*	Every 4 mo*
Hepatitis B serology	Baseline only	Not required
Hepatitis C serology	Every 12 mo+	Not required

*Men who have sex with men and transgender women
+Men who have sex with men, transgender women, and people who inject drugs

cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 July 2023
EMA/327881/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Apretude

cabotegravir

On 20 July 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Apretude, intended for prevention of sexually acquired HIV-1 in combination with safer sex practices. The applicant for this medicinal product is ViiV Healthcare B.V.

Apretude will be available as a 30 mg film-coated tablet and a 600 mg prolonged-release suspension for injection. The active substance of Apretude is cabotegravir, an antiviral for systemic use (ATC code: J05AJ04). Cabotegravir is an integrase inhibitor of HIV-1 which inhibits HIV integrase by binding to the integrase active site and blocking the strand transfer step of retroviral DNA integration, which is essential for the HIV replication cycle.

The benefit of Apretude was a demonstrated superiority of injections every 2 months over a daily oral regimen of tenofovir disoproxil fumarate plus emtricitabine (TDF/FTC) in preventing acquisition of HIV-1 infection, with a 69% and an 90% risk reduction, as shown in two double-blind safety and efficacy studies. The most common side effects are injection site reactions, headache, diarrhoea, and increased transaminase levels.

The full indication is:

> Apretude is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in high-risk adults and adolescents, weighing at least 35 kg (see sections 4.2, 4.4 and 5.1).

Apretude should be prescribed by physicians experienced in the treatment of HIV.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

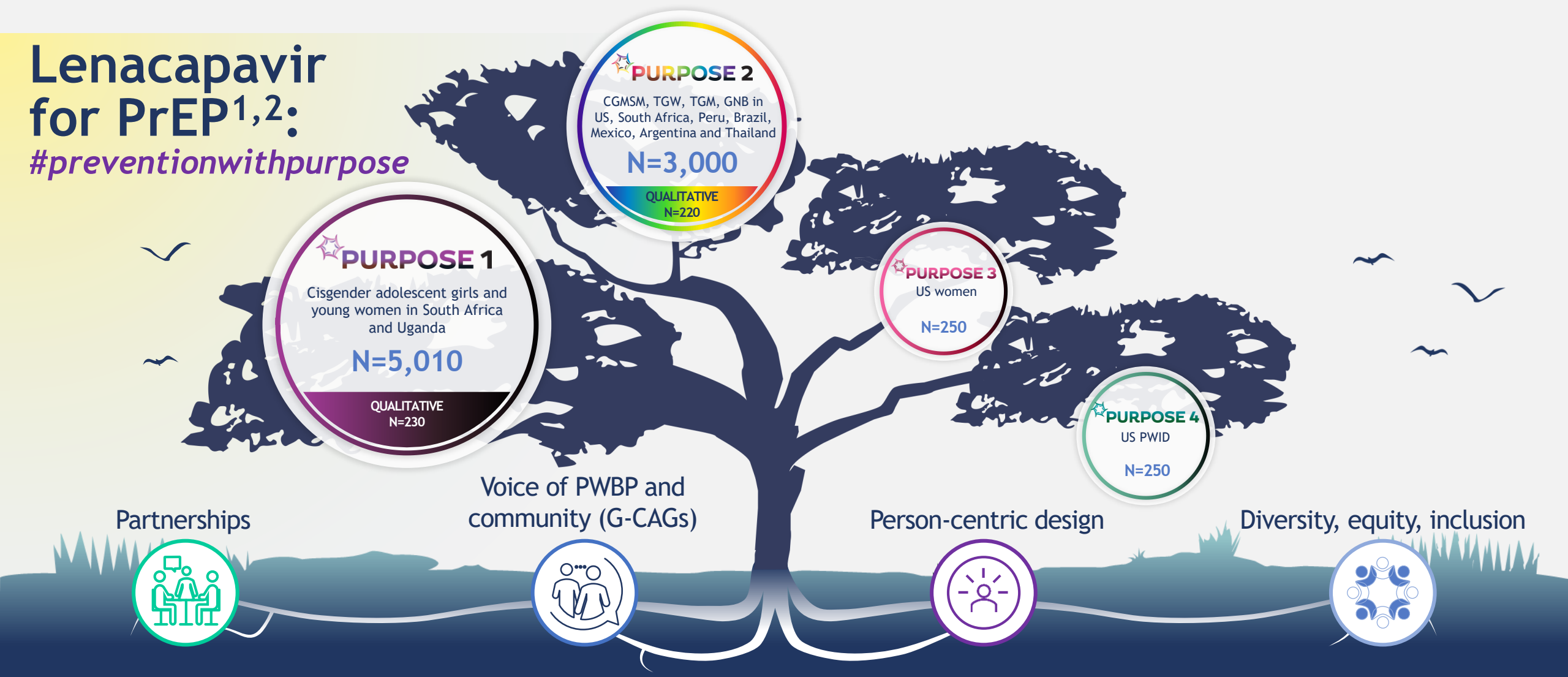
Authorisation details

Product details	
Name	Apretude
Agency product number	EMEA/H/C/005756
Active substance	Cabotegravir
International non-proprietary name (INN) or common name	cabotegravir
Therapeutic area (MeSH)	HIV Infections
Anatomical therapeutic chemical (ATC) code	J05AJ04

Publication details	
Marketing-authorisation holder	ViiV Healthcare B.V.
Date of issue of marketing authorisation valid throughout the European Union	15/09/2023

Lenacapavir for PrEP[1,2]:

#preventionwithpurpose

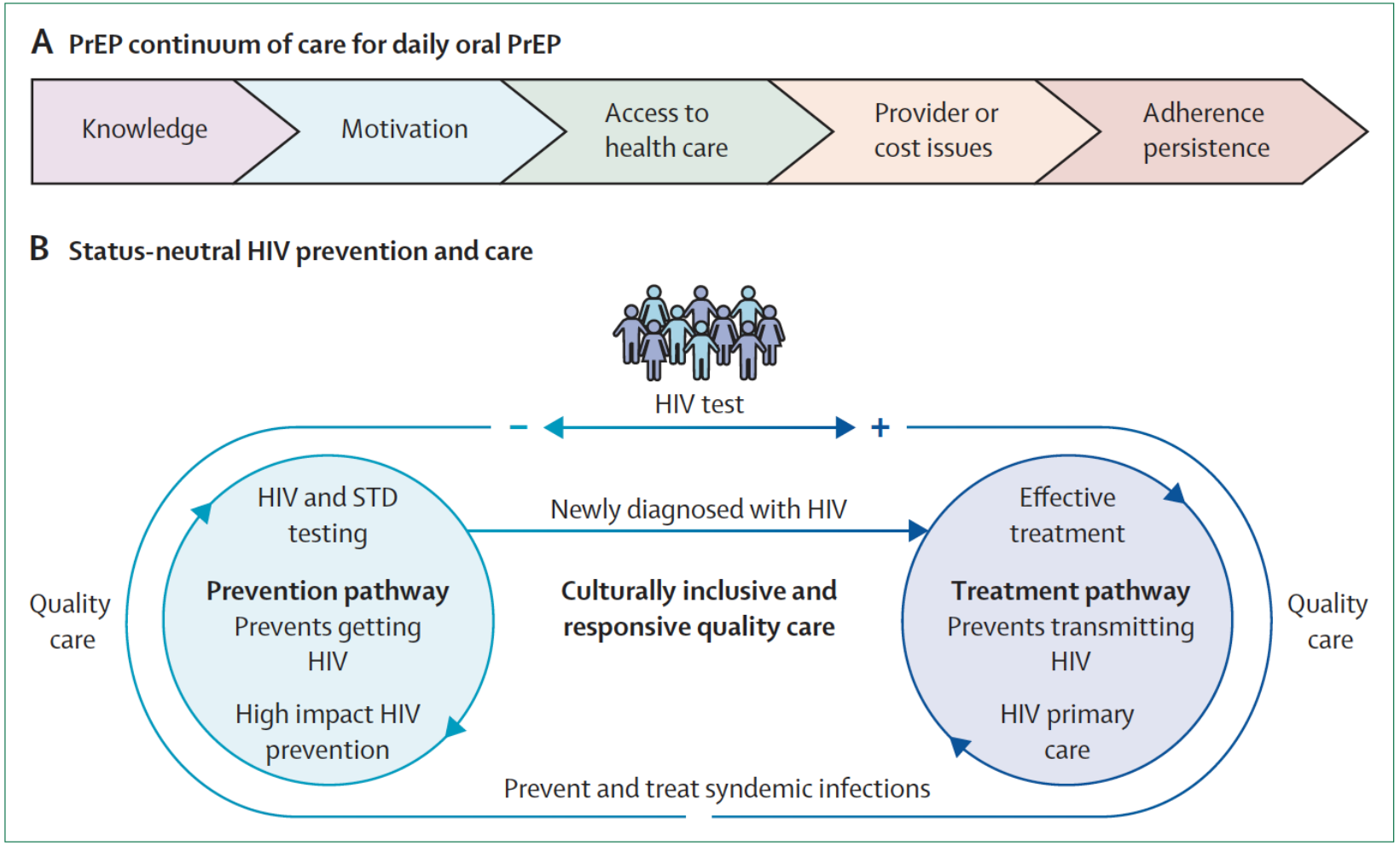


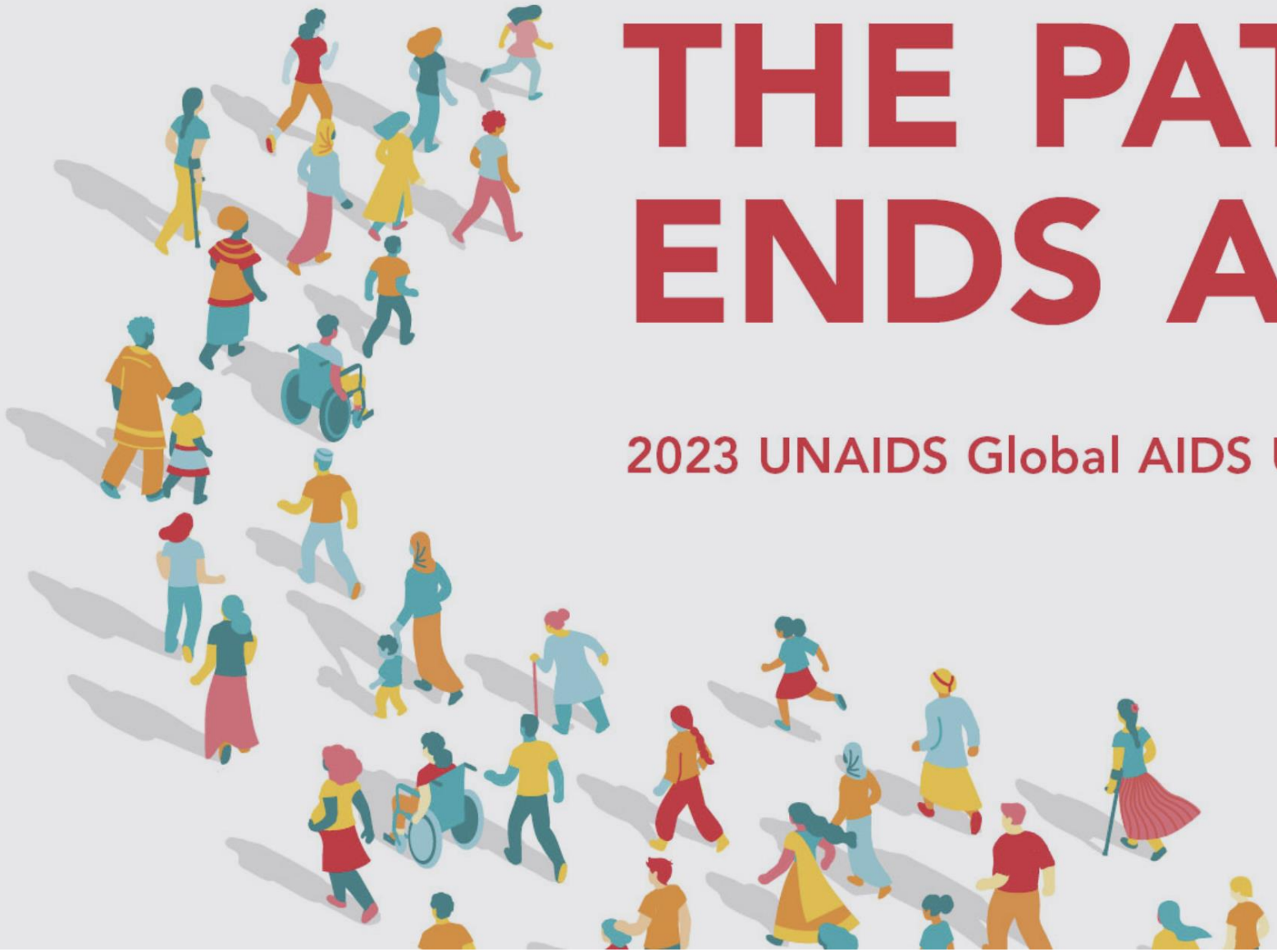
Proof of concept that capsid inhibitors prevent SHIV in nonhuman primates[3-5]; Robust pharmacokinetic and safety database in persons with[6-10] and without HIV[11]

PURPOSE 1 NCT identifier: NCT04994509; PURPOSE 2 NCT identifier: NCT04925752.CGMSM, cisgender men who have sex with men; G-CAG, Global Community Advisory Group; GNB, gender nonbinary individuals; MDR, multidrug-resistant; PWBP, people who would benefit from PrEP; PWID, people who inject drugs; SHIV, simian-human immunodeficiency virus; TGM, transgender men; TGW, transgender women; Tx, treatment.1. Das et al, et al. IAS 2023, Symposium SY05; 2. Das et al, et al. IAS 2023, Satellite SAT050; 3.Bekerman E, et al, vCROI, 2021, Oral/Poster 717; 4. Bekerman E, et al, vIAS, 2021, PECLB24; 5. Swanstrom A, et al, CROI 2022, Poster 860; 6. Segal-Maurer S, et al, vCROI, 2021, Oral 127; 7. Molina JM, et al. vIAS, 2021, OALX01LB02; 8. Stellbrink H-J, et al. EACS, 2021, PE2/69; 9. Margot N, et al, EACS, 2021, OS1/1; 10. Gupta S, et al. vIAS, 2021, OALB0302; 11. Begley R, et al, AIDS, 2020, PEB0265

Purpose Studies. https://www.purposestudies.com/ (accessed July 31, 2023)

The PrEP continuum of care model (A) and the HIV serostatus-neutral model (B)





THE PATH THAT ENDS AIDS

2023 UNAIDS Global AIDS Update