PrEP: tra vecchie e nuove opportunità

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Il sottoscritto SILVIA NOZZA in qualità di Relatore del corso ECM consapevole che chiunque rilasci dichiarazioni mendaci è punito ai sensi del codice penale e delle leggi speciali in materia, ai sensi dell'art. 3.3 sul Conflitto di Interessi, pag. 17 del Reg. Applicativo dell'Accordo Stato-Regione del 5 novembre 2009

Dichiara

che negli ultimi due anni ha avuto i seguenti rapporti anche di finanziamento con soggetti portatori di interessi commerciali in campo sanitario:

VIIV HEALTHCARE
GILEAD SCIENCES
JANSSEN CILAG
MSD

Il rischio di trasmissione dell'HIV

- Rapporto anale ricettivo con eiaculazione: 1,43%
- Rapporto anale ricettivo senza eiaculazione: 0,65%
- Rapporto vaginale con eiaculazione: 0,1% (RR 2,14-3,63 in presenza di IST)
- Rapporto orale ricettivo con eiaculazione: 0,02%
- Rapporto anale insertivo: 0,06%
- Rapporto vaginale insertivo: 0,082%

Adattato da Linee Guida SIMIT

Table 2 Associations between STIs and HIV incidence rate

	Participants, n (%)	Total PY	HIV infections (n)	Incidence rate (per 100 PY)	95% CI
Rectal CT/GC or syphilis (key STI)	101 (39.4)	87.0	15	17.2	9.7 to 28.5
Syphilis	30 (11.7)	24.0	5	20.8	6.8 to 48.6
Rectal CT/GC	83 (32.4)	72.9	12	16.5	8.5 to 28.8
Rectal CT	56 (21.9)	49.8	8	16.1	6.9 to 31.6
Rectal GC	62 (24.2)	54.0	8	14.8	6.4 to 29.2
Excluding participants reporting rectal infection or syphilis					
Pharyngeal infection	25 (16.1)	23.5	0	0	0 to 15.7*
Urethral infection	33 (21.3)	30.6	1	3.3	0.08 to 18.2

*One sided, 97.5% CI.
GC, gonorrhoea CT, chlamydia; PY, person-years.

CDC: Selecting Appropriate Candidates for PrEP

MSM	Heterosexual Women/Men	People Who Inject Drugs
▪ Any male sex partner in past 6 mo ▪ Not in monogamous relationship with a recently tested, HIV-negative man *And ≥1 of These Criteria* ▪ Any anal sex without a condom in past 6 mo ▪ Bacterial STI (syphilis, gonorrhea, or chlamydia) in	▪ Any sex with opposite sex partner in previous 6 mo ▪ Not in monogamous relationship with a recently tested, HIV-negative partner *And ≥1 of These Criteria* ▪ Infrequent condom use with ≥1 partner(s) with unknown HIV status at substantial risk of HIV infection (PWID or MSM) ▪ Is in ongoing relationship with HIV-positive partner with unsuppressed HIV-1 RNA ▪ Bacterial STI (syphilis, gonorrhea in females/males) in last 6 mo	▪ Any injection of drugs not prescribed by a clinician in past 6 mo *And ≥1 of These Criteria* ▪ Any sharing of injection/drug preparation equipment in past 6 mo ▪ Risk of sexual acquisition

In any category, individual expected to be an adult or adolescent weighing >35 kg *without* acute or established HIV infection

Indicazione alla PrEP

Calcolo dello score per la valutazione del rischio per esposizione sessuale negli MSM (adattato da Smith DK [12])

Età:	5 18-28	8 29-40	2 41-48	0 >49	|__|
Negli **ultimi 3 mesi**, numero partner:	7 >10	4 6-10	0 0-5		|__|
Negli **ultimi 3 mesi**, partner sessuali **HIV+ noti***	8 >1	4 1			|__|
Negli **ultimi 3 mesi**, **RR** senza condom	10 1 o più	0 mai			|__|
Negli **ultimi 3 mesi**, **RI** senza condom con **HIV+ noti** *	6 5 o più	0 0-4			|__|
Negli **ultimi 3 mesi**, uso di meta-anfetamine/cocaina/LSD /cristalli	6 sì	0 no			|__|
Negli **ultimi 3 mesi,** ti è stata diagnosticata una IST ***Quale?*** |*clamidia*| |*sifilide*| |*gonorrea*||*HPV*| |_____ *epatite A*|	6 sì	0 no			|__|
Totale					|__|
Se il punteggio è 10 o superiore proporre la PrEP (>15 cost-effective).					
* NB: lo score è stato calcolato su persone arruolate in studi condotti fra il 1998 ed il 2001; pertanto non è stato valutato il ruolo dalla terapia cART o della carica virale, ma si può supporre che l'esposizione fosse a partner non in soppressione virologica. RR: rapporto recettivo; RI: rapporto insertivo; IST: infezione sessualmente trasmissibile.					

Clinical Approach to Initiating PrEP

- Documented HIV-negative test (antigen/antibody test preferred) within 1 wk of initiating PrEP
- No signs/symptoms of acute HIV infection in preceding month or on day of evaluation
- Renal function requirements
  - FTC/TDF: CrCl >60 mL/min
  - FTC/TAF: CrCl >30 mL/min (or CrCl <15 mL/min if receiving chronic hemodialysis)
- Documented HBV infection and vaccination status: vaccinate if susceptible
- Test for HCV infection and link patients with HCV infection to HCV care provider
- Screen for STIs; offer HAV and HPV vaccination

CDC. PrEP Guidelines. 2017. FTC/TAF PI. FTC/TDF PI.

Summary of PrEP Eligibility by Regimen

Risk Group	Daily FTC/TDF	On-Demand (2:1:1) FTC/TDF	Daily FTC/TAF	I.M. CAB
MSM	Approved, guideline recommended	Off-label, guideline recommended	Approved, guideline recommended	Approved, guideline recommended
TG women	Approved, guideline recommended	Off-label, not recommended	Approved, guideline recommended	Approved, guideline recommended
Heterosexual women	Approved, guideline recommended	Off-label, not recommended	Off-label, not recommended, **studies underway**	Approved, guideline recommended
Heterosexual men	Approved, guideline recommended	Off-label, not recommended	Approved, guideline recommended	N.A.
TG men	Approved, guideline recommended	Off-label, not recommended	Off-label, not recommended (unless risk from anal sex only)	Approved, guideline recommended
PWID	Approved, guideline recommended	Off-label, not recommended	Off-label, not recommended	N.A.

ANRS IPERGAY: On-Demand Oral FTC/TDF PrEP in MSM at High Risk for HIV Infection

- Double-blind, randomized study of on-demand FTC/TDF vs placebo as PrEP*

Study Phase	N	Total Follow-up, PY	Median Pills/Mo	Risk Reduction, %	*P* Value
Placebo controlled, randomized[1]	400	431.3	15	86	.002
Open-label extension[2]	361	518	18	97	NR

On-demand regimen for each sexual intercourse[3]

- 2 FTC*/TDF tablets 2-24 hr before sex; 1 FTC*/TDF tablet 24 hr after the first drug intake, and 1 FTC*/ TDF tablet 24 hr later

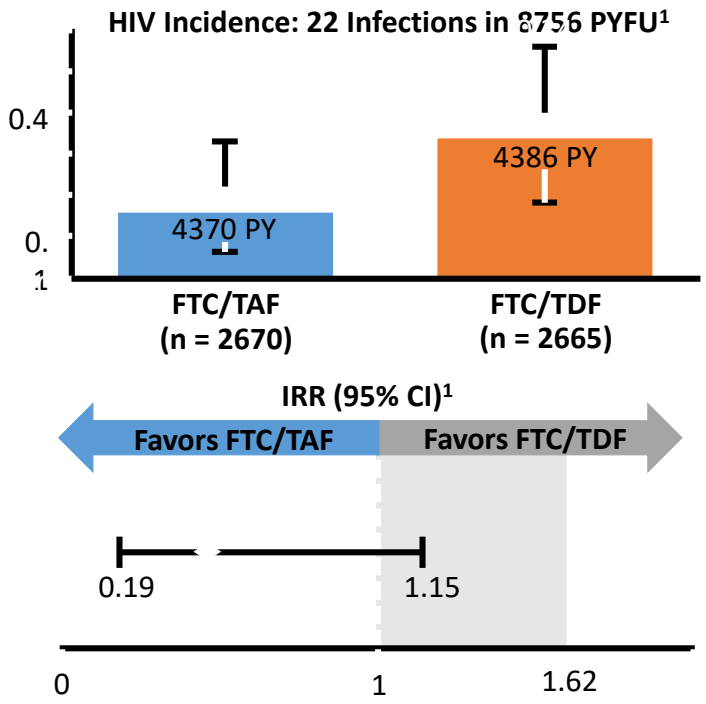
In case of multiple subsequent sexual intercourses[3]

- 1 FTC*/TDF tablet per day until the last sexual intercourse, then 1 FTC*/TDF tablet per day for 2 further days

- AMPrEP study: when MSM offered both daily and on-demand options, they choose both and they alternate between them depending on their circumstances[4]
- On-demand FTC/TDF should not be used for heterosexual men and women, TG men and women, or those with HBV infection[3]

1. Molina. NEJM. 2015;373:2237. 2. Molina. Lancet HIV. 2017;4:e402.
3. WHO. apps.who.int/iris/bitstream/handle/10665/325955/WHO-CDS-HIV-19.8-eng.pdf. 4. Hoornenborg. Lancet HIV. 2019;6:e447.

DISCOVER: Daily Oral FTC/TAF Noninferior to Daily Oral FTC/TDF for HIV Prevention in MSM and TG Women



- Primary analysis conducted when 100% completed Wk 48, 50% completed Wk 96[1]
- Noninferiority of FTC/TAF maintained:
  - In sensitivity analysis excluding 5 suspected baseline infections[1]
    - IRR: 0.55 (95% CI: 0.20-1.48)
  - Through Wk 96 analysis[2]
    - IRR: 0.54 (95% CI: 0.23-1.26)

1. Mayer. Lancet. 2020;396:239. 2. Ogbuagu. Lancet HIV. 2021;8:e397.

DISCOVER: Wk 96 Safety With Daily Oral FTC/TAF vs Daily Oral FTC/TDF

- FTC/TAF and FTC/TDF were well tolerated
  - Discontinuations due to AEs: 1% to 2%
- Significantly better bone and renal safety outcomes with FTC/TAF vs FTC/TDF (*P* <.001)
  - Median percent Δ from baseline to Wk 96 in ratios of proximal tubular proteins (retinol-binding protein and β_2-macroglobulin) to creatinine significantly lower with FTC/TAF vs FTC/TDF (*P* <.001)
  - In bone safety substudy (n = 375), hip and spine BMD Δ significantly more favorable with FTC/TAF vs FTC/TDF (*P* <.001)

Outcome	FTC/TAF	FTC/TDF
Median body weight Δ, kg		
▪ Wk 48	+1.0	+0.0
▪ Wk 96	+1.7*	+0.5
Median BMI		
Baseline	25.3	25.3
Wk 48	25.6	25.3
Wk 96	25.9*	25.4

**P* <.001 vs FTC/TDF.

Ogbuagu. CROI 2020. Abstr 92. Ogbuagu. Lancet HIV. 2021;8:e397.

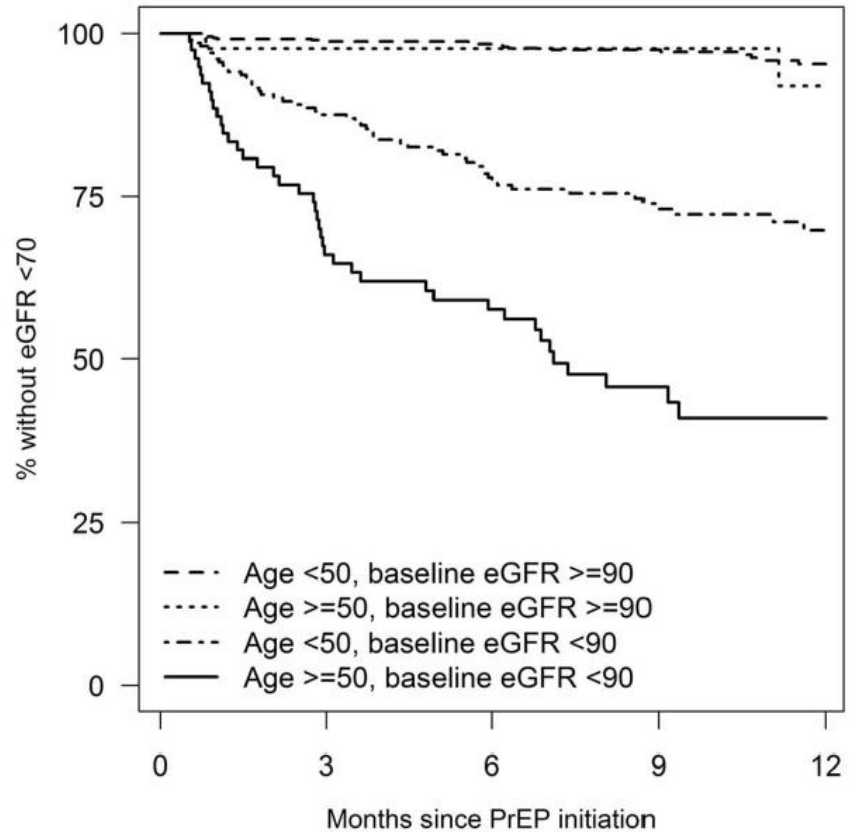


FIGURE 1.

Cumulative incidence of eGFR <70 mL·min^{-1}·1.73 m^{-2} during the first year of preexposure prophylaxis use. Differences across strata of age and baseline eGFR were statistically significant at $P < 0.001$ by log-rank test.

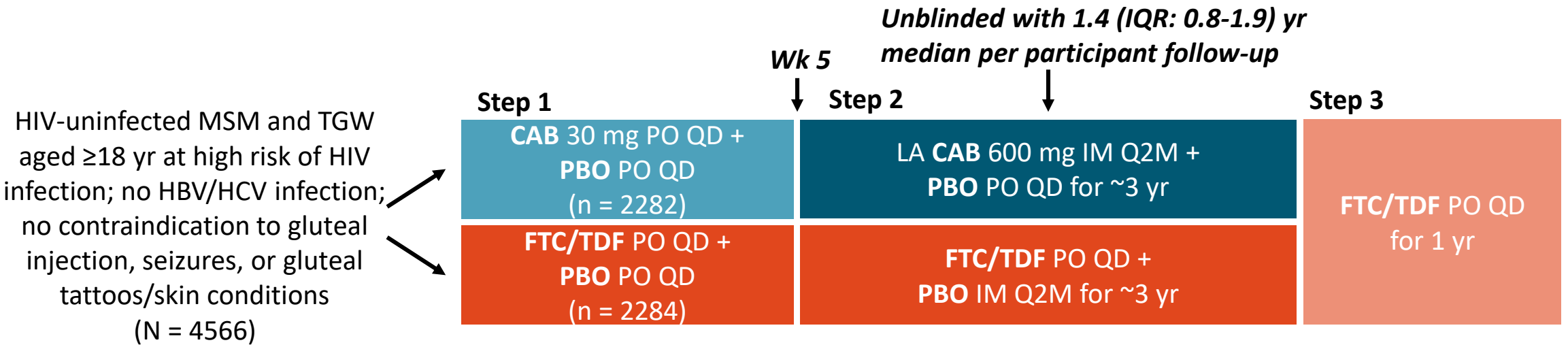
HPTN 083: Background

- HPTN 083: ongoing phase IIb/III randomized controlled trial of long-acting injectable cabotegravir in HIV-uninfected MSM and TGW at increased risk of HIV infection
  - Efficacy and safety previously reported (both prespecified and post hoc analyses of the blinded period)[1-4]
  - Combined with results from HPTN 084,[5] data show LA CAB superior to daily oral FTC/TDF for HIV PrEP
- Current analysis: efficacy and safety of an additional yr of follow-up during the unblinded period in HPTN 083[6]

1. Landovitz. AIDS 2020. Abstr OAXLB0101. 2. Landovitz. NEJM. 2021;385:595. 3. Marzinke. CROI 2021. Abstr 153.
4. Marzinke. J Infect Dis. 2021;224:1581. 5 Delany-Moretlwe. HIVR4P 2021. Abstr HY01-02. 6. Landovitz. CROI 2022. Abstr 96.

HPTN 083 Updated Safety and Efficacy: LA CAB for PrEP

- International, randomized, double-blind phase IIb/III study[1,2]

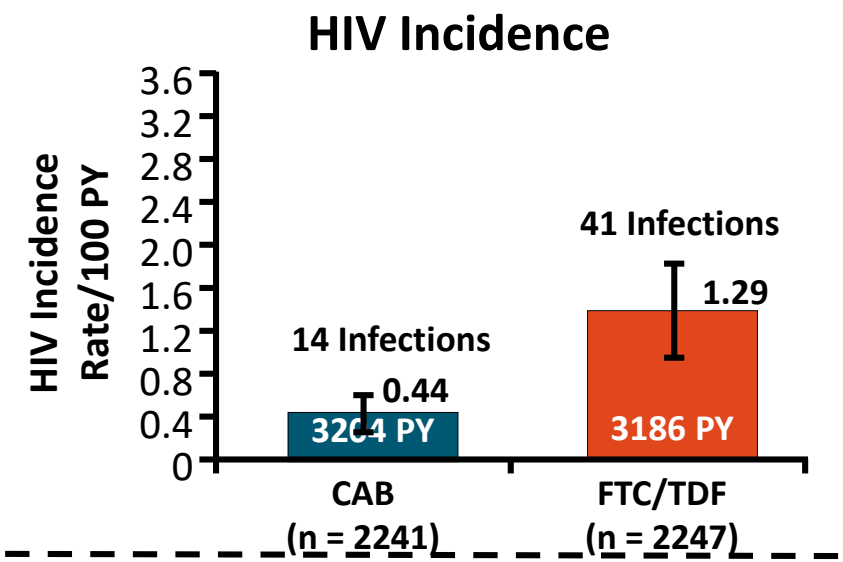


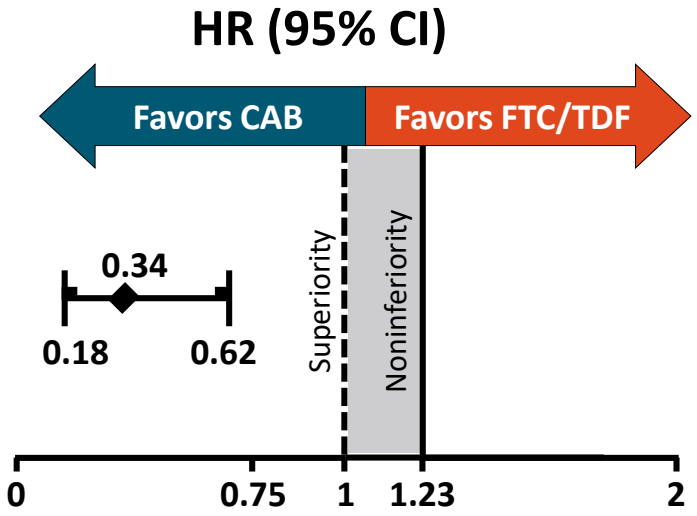
- Previously reported **13 incident infections** with CAB vs 39 with FTC/TDF; 1 incident CAB infection was later readjudicated to a BL infection (updated HR: 0.32; 95% CI: 0.16-0.58)[2]
- Current analysis of additional infections after 1 yr of follow-up after unblinding[3]

1. Landovitz. NEJM. 2021;385:595. 2. Landovitz. AIDS 2020. Abstr OAXLB0101. 3. Landovitz. CROI 2022. Abstr 96.

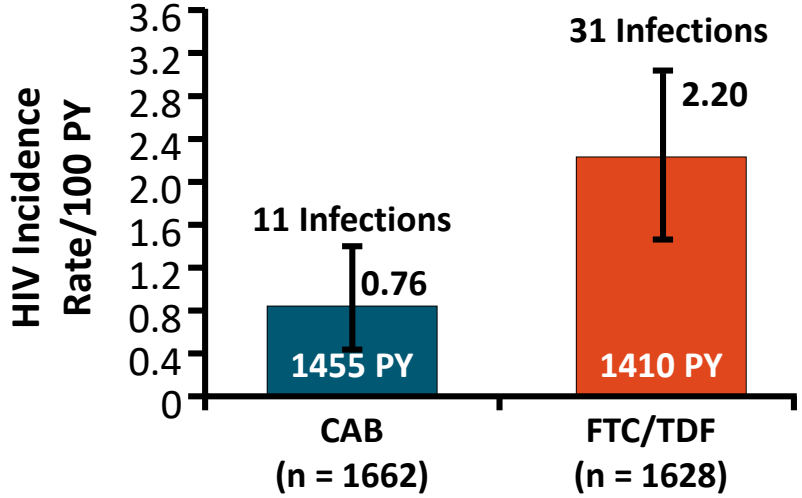
HPTN 083: Updated HIV Incidence During Primary Blinded Phase and 1 Yr Unblinded Phase

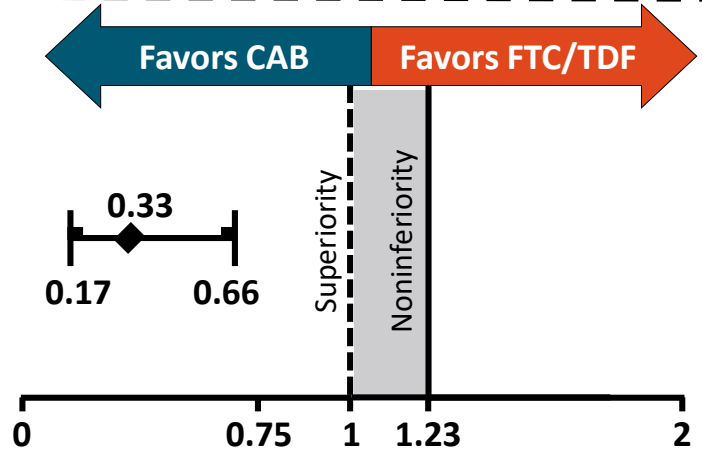
Primary Blinded Phase





1 Yr Unblinded Phase





Landovitz. CROI 2022. Abstr 96. Reproduced with permission.

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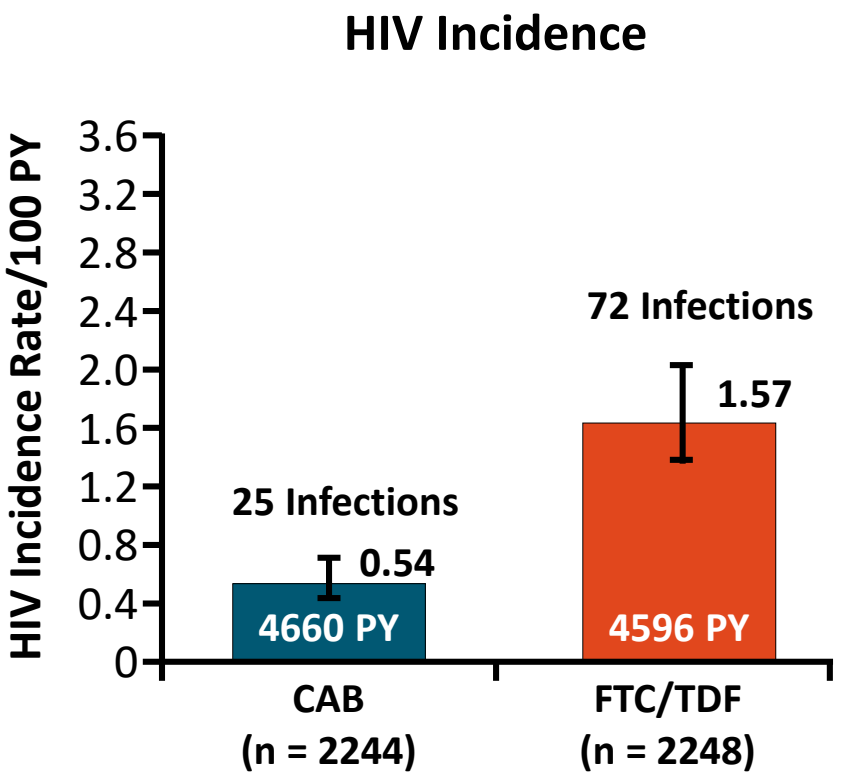
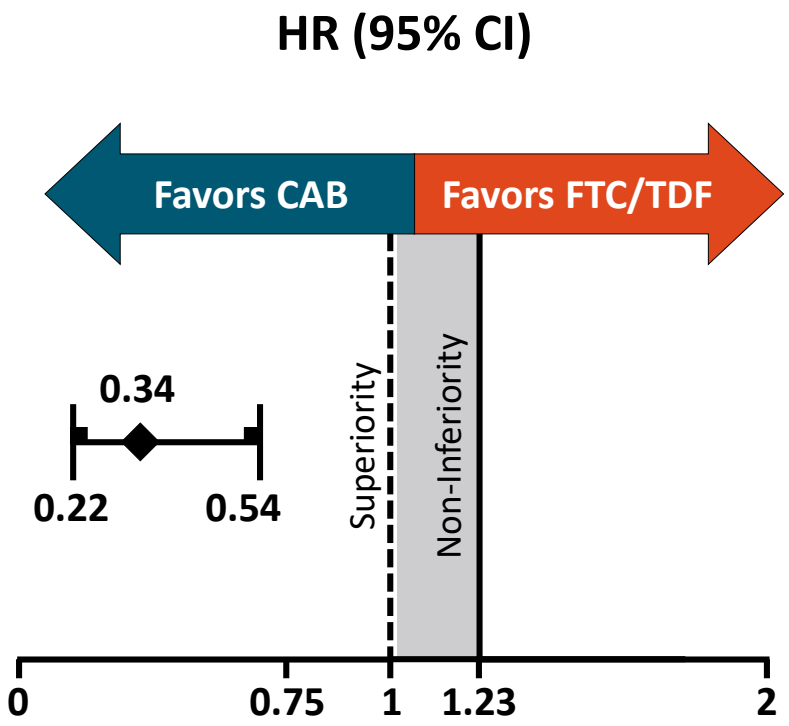
HPTN 083: HIV Incidence in Combined Efficacy Analysis





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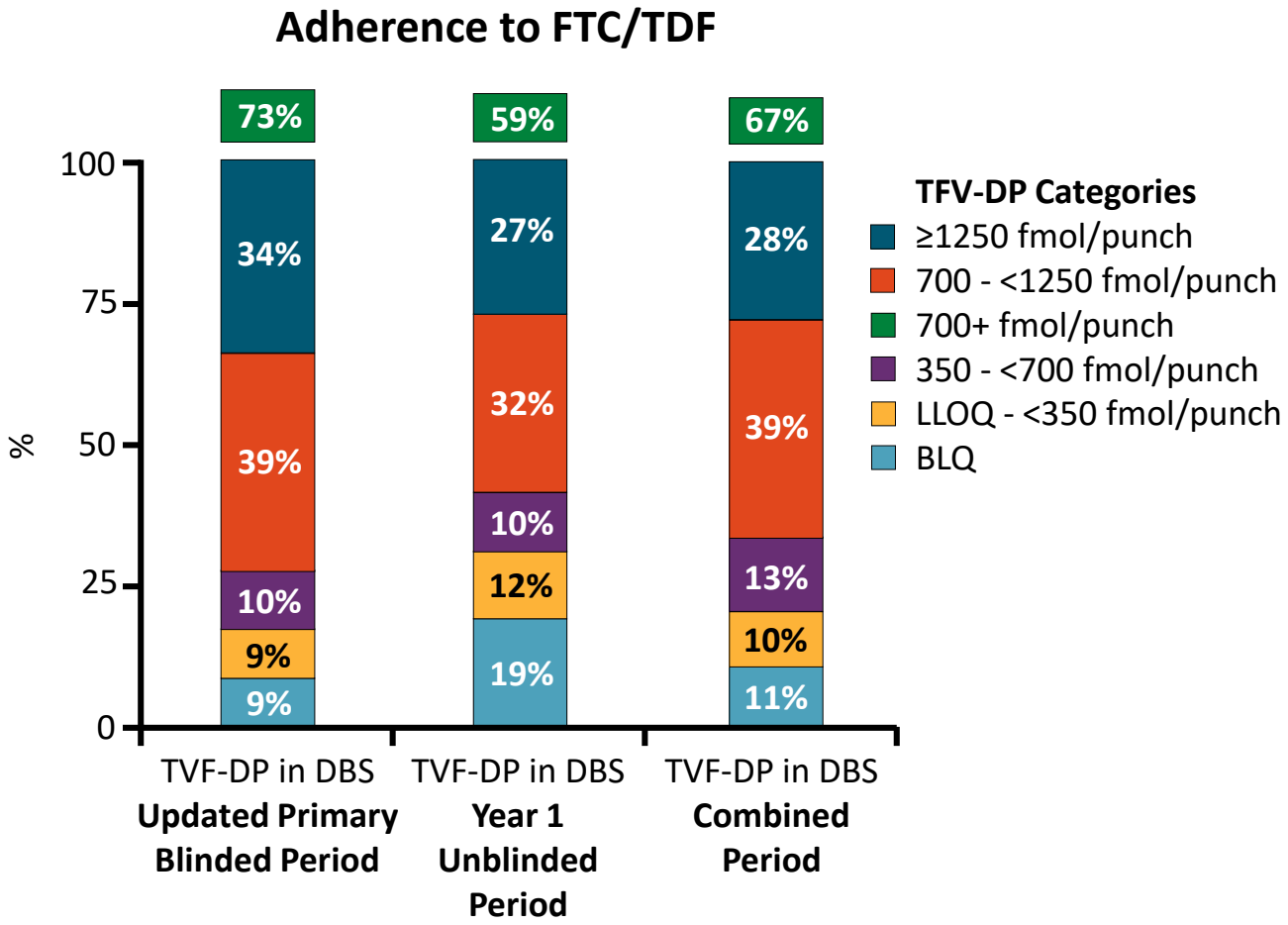
HPTN 083: Adherence by TFV-DP Dried Blood Spots and Person-Time by Region



Person-Time by Region, %	Primary Blinded Phase	Yr 1 Unblinded Phase
US	47	22
Latin America	32	54
Asia	18	20
Africa	3	3

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Oral Daily Pre-Exposure Prophylaxis (PrEP)[†] for HIV-Negative Persons

Population	Effectiveness Estimate	Source	Interpretation
"Optimal or Consistent Use" [a] (Taking PrEP daily or at least 4 times per week)			
Men who have sex with men (MSM)	~99%	Grant, 2014 Liu, 2015 McCormack, 2015 Volk, 2015 Marcus, 2017	When taking PrEP daily or consistently (*at least 4 times per week*), the risk of acquiring HIV is reduced by about 99% among MSM. While daily use is recommended in the U.S., taking PrEP consistently (*at least 4 times per week*) appears to provide similar levels of protection among MSM. The effectiveness of oral PrEP is highly dependent on PrEP adherence. When taking oral PrEP daily or consistently, HIV acquisition is extremely rare and has not been observed in any of the studies described below. In clinical practice, a few cases of new HIV infections have been confirmed while HIV-negative individuals were on PrEP with verified adherence.
Heterosexual Men and Women	~99%	*N/A*	There is evidence for the effectiveness of PrEP when used recently[b] (based on detecting TFV in plasma), which is estimated to be 88 – 90% as described below. There is no effectiveness estimate of PrEP when taken daily or consistently among heterosexuals; however, it is likely to be greater than the estimates corresponding to recent use and similar to what has been observed for MSM. The effectiveness of oral daily PrEP is highly dependent on PrEP adherence, with maximum effectiveness when taking PrEP daily and lower effectiveness when not taken consistently.
Persons Who Inject Drugs (PWIDs)	74 – 84%	Choopanya, 2013 Martin, 2015	PWID face HIV risks from both injecting and sex behaviors. Studies on the effectiveness of PrEP when taken daily among PWID are limited. However, when taking PrEP consistently, the risk of acquiring HIV is reduced by an estimated 74 – 84% among PWID. These estimates are based on tenofovir alone and among a subset of PWID taking PrEP consistently, as verified by directly observed therapy or daily diary plus monthly pill count. The effectiveness of two-drug oral therapy has not been assessed among PWID but may be higher. The effectiveness of oral daily PrEP is highly dependent on PrEP adherence, with maximum effectiveness when taking PrEP daily and lower effectiveness when missing doses.

CONCISE COMMUNICATION

Rising rates of recent preexposure prophylaxis exposure among men having sex with men newly diagnosed with HIV: antiviral resistance patterns and treatment outcomes

Nicolò Girometti[a], Sheena McCormack[a,b], Victoria Tittle[a], Alan McOwan[a], Gary Whitlock[a], on behalf of the 56 Dean Street Collaborative Group

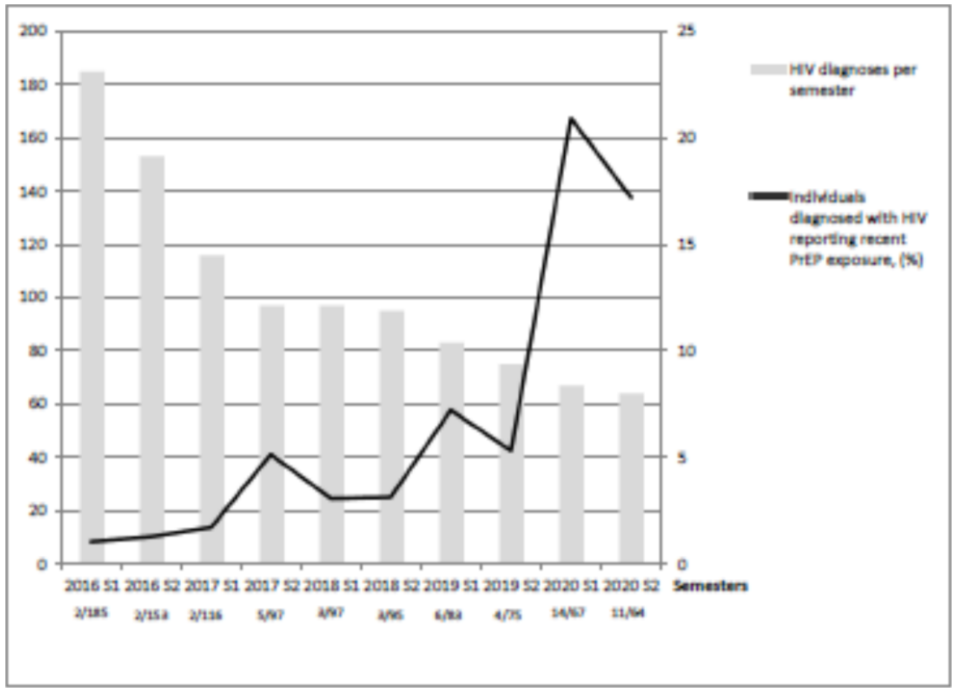
AIDS 2022, **36**:561–566

1030 individuals (986 MSM, 96%): 52/1030 (5%) of the HIV positive individuals reported recent PrEP.

-36/52 (69%) daily PrEP; 16/52 (31%) were taking event-based dosing

-33/52 (63%) were sourcing PrEP outside a clinical setting

Reasons for failure:
-24/52 (46%) reported inadequate adherence (11 on a daily regimen, 13 on EBD),
-9/52 (17%) had issues with PrEP supply resulting in its discontinuation,
-5/52 (10%) interrupted PrEP after starting a monogamous relationship,
-3/52 (6%) did not plan to have sex,
-3/52 (6%) chose to interrupt PrEP
-1/52 (2%) was taking raltegravir
-7/52 (13%) no reseason identified



Baseline characteristics	HIV+ reporting recent PrEP exposure, n=52	HIV+ with no recent PrEP exposure, n=978	p
Age, years (IQR)	34 (28-42)	32 (27-40)	0.52
MSM, n (%)	51 (98)*	935 (95)	0.42
White ethnicity, n (%)	34 (65)	644 (66)	0.54
UK-born, n (%)	18 (35)	326 (33)	0.88
Baseline HIV viral load, log_{10} n (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, n (%)	10 (19)	32 (3)	<0.01
Genotypic resistance test at baseline, n (%) - Not performed - Unable to amplify viral DNA - Performed, with DNA amplification	0 9/52 (17) 43/52 (83)	41 (4) 27/939 (3) 912/939 (97)	<0.01
PrEP-related NRTI mutations, n (%) - M184V/I - K65R Other NRTI mutations, n (%) - L74V - M41L and/or L210W and/or T215Y/F - D67N and/or K70R and/or K219Q/E/R/N	13 (30) 0 1 (2) 1 (2) 0	5 (1) 1 (<1) 0 4 (<1) 7 (1)	<0.01
NNRTI mutations, n (%) - K103N/S - V108V/I - E138A - G190A/S/E	3 (7) 1 (2) 0 1 (2)	29 (3) 8 (1) 26 (3) 0	0.54
PI mutations, *n (%)* -M461/L -L90M	0 0	6 (1) 18 (2)	0.62

Real-world effectiveness of pre-exposure prophylaxis in men at high risk of HIV infection in France: a nested case-control study

Hugo Jourdain, Sophie Billioti de Gage, David Desplas, Rosemary Dray-Spira

Lancet Public Health 2022;
7: e529–36

Added value of this study

We found that PrEP use was associated with an overall 60% reduction in the risk of HIV infection, reaching 93% for a high amount of PrEP consumption, and 86% if excluding periods after PrEP discontinuation. PrEP effectiveness appeared to be reduced in individuals who were younger than 30 years and who were socioeconomically deprived, both of which groups showed low amounts of PrEP consumption and high rates of PrEP discontinuation. Thus, our findings suggest that PrEP effectiveness is substantially lower in real-world conditions than is reported in clinical trials, as a result of frequent suboptimal PrEP consumption and interruptions of treatment supply.

Implications of all the available evidence

These findings, by providing new insights on the degree and determinants of PrEP effectiveness in the real world, are important in the current context of worldwide PrEP scale up. Strengthening efforts such as enhanced counselling or SMS-based support to improve the monitoring of PrEP compliance will be essential to ensure PrEP effectiveness, especially among young and socioeconomically deprived recipients.

Methods

- Observational study.
- From 2018 to 2021, out of **827 PLWH enrolled in the cohort** with known data on previous use or not of PrEP.
- 9 (1.1%) were PrEP users.

Characteristics

	Age	PrEP Regimen	HIVRNA	GRT
A19-FNFL41_21	40	ON DEMAND	841	RT: M184V
B02-93GC2015	27	ON DEMAND	113000	PR: K20I, M36I, H69K, L89M; INT: L74I
E08-DS684	35	ON DEMAND	102339	RT: M184V; PR: L10I, M36I, L89M
F00-FM230492	28	DAILY	46641	WT
F16-MAGIM180591	30	DAILY	64000	N.A.
B02-94RG2124	26	DAILY	29700	K103N/R
E10-LM1205	37	DAILY	12224	N.A
B00-SDM847N	25	ON DEMAND	378000	WT
B00-NP848N	31	ON DEMAND	1938	RT: M184V

Follow up

	ART REGIMEN	HIVRNA	CD4	MONTHS TO VS
A19-FNFL41_21	FTC,TAF,BIC	841	929	4,6
B02-93GC2015	FTC,TAF,DRV,DTG,cob	113000	467	5,2
E08-DS684	FTC,TAF,DRV,cob	102339	357	7,1
F00-FM230492	FTC,TAF,BIC	46641	624	10,5
F16-MAGIM180591	3TC,DTG	64000	783	9,4
B02-94RG2124	FTC,TAF,DRV,DTG,cob	29700	469	2,1
E10-LM1205	FTC,TAF,DTG	12224	464	1,1
B00-SDM847N	FTC,TAF,BIC	378000	512	3,2
B00-NP848N	DRV,cob,DTG,DOR	1938	949	0,8

EACS European AIDS Clinical Society

Regimen	Main requirements	Additional guidance (see footnotes)
Recommended regimens		
2 NRTIs + INSTI		
ABC/3TC + DTG ABC/3TC/DTG	HLA-B*57:01 negative HBsAg negative	I (ABC: HLA-B*57:01, cardiovascular risk) II (Weight increase (DTG))
TAF/FTC/BIC		II (Weight increase (BIC, TAF))
TAF/FTC or TDF/XTC + DTG		II (Weight increase (DTG, TAF)) III (TDF: prodrug types. Renal and bone toxicity. TAF dosing)
TAF/FTC or TDF/XTC + RAL qd or bid		II (Weight increase (RAL, TAF)) III (TDF: prodrug types. Renal and bone toxicity. TAF dosing) IV (RAL: dosing)
1 NRTI + INSTI		
XTC + DTG or 3TC/DTG	HBsAg negative HIV-VL < 500,000 copies/mL Not recommended after PrEP failure	II (Weight increase (DTG)) V (3TC/DTG not after PrEP failure)
2 NRTIs + NNRTI		
TAF/FTC or TDF/XTC + DOR or TDF/3TC/DOR		II (Weight increase (TAF)) III (TDF: prodrug types. Renal and bone toxicity. TAF dosing) VI (DOR: caveats, HIV-2)

BMJ Open

Characteristics of HIV pre-exposure prophylaxis users at first PrEP counselling visit: the CSL-PrEP cohort

Silvia Nozza ,[1] Angelo Roberto Raccagni ,[2] Riccardo Lolatto,[1] Daniele Ceccarelli,[1] Laura Galli,[1] Francesca Alberton,[2] Elena Bruzzesi,[2] Diana Canetti,[1] Martina Strano,[2] Marco Ripa,[1,2] Costanza Bertoni,[2] Antonella Castagna[1,2]

Nozza S, *et al. BMJ Open* 2022;**12**:e067261. doi:10.1136/bmjopen-2022-067261

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Individuals attending our centre for pre-exposure prophylaxis (PrEP) are followed in a dedicated clinic, with detailed investigations on risk factors, previous and current sexually transmitted infections, PrEP regimen choice, laboratory, serologic and virologic data; this process may guarantee the acquisition of complete data on PrEP users recorded into the Centro San Luigi (CSL)-PrEP cohort.
- ⇒ This is a monocentric, cross-sectional study on a single cohort of people with no control group.
- ⇒ The type of PrEP-regimen chosen at baseline might have changed over time; changes over time will be recorded and evaluated in future studies.
- ⇒ The cohort includes cisgender-men who have sex with men only and no other key population who might benefit from PrEP access.

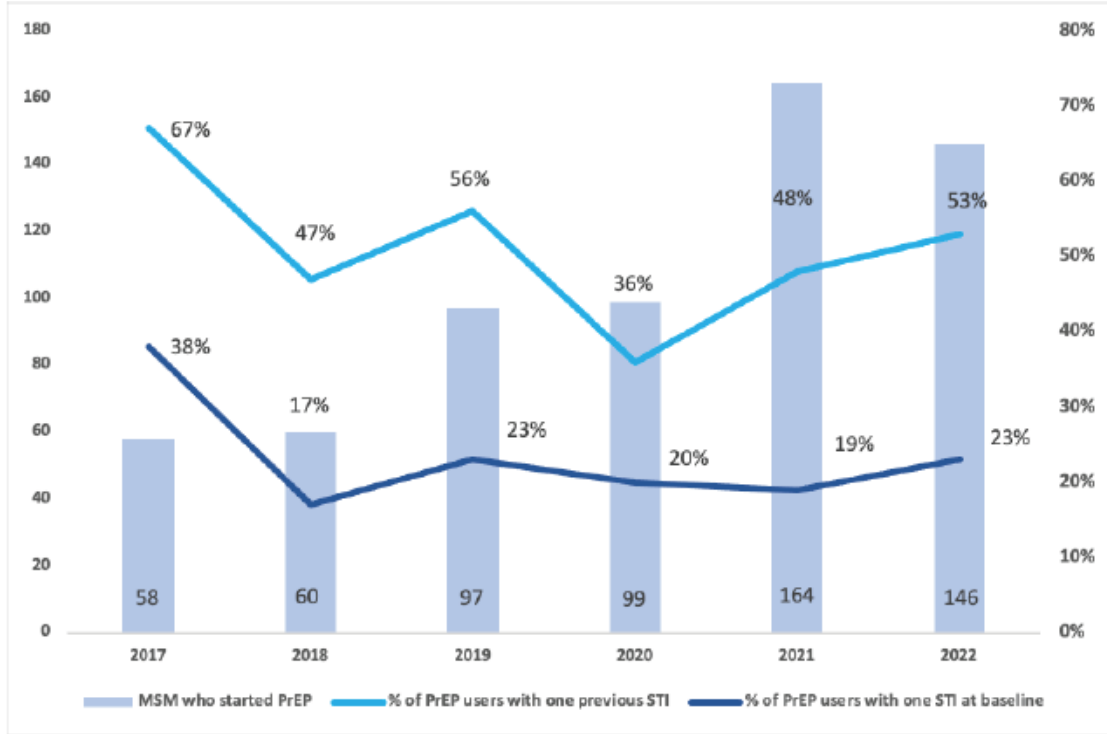
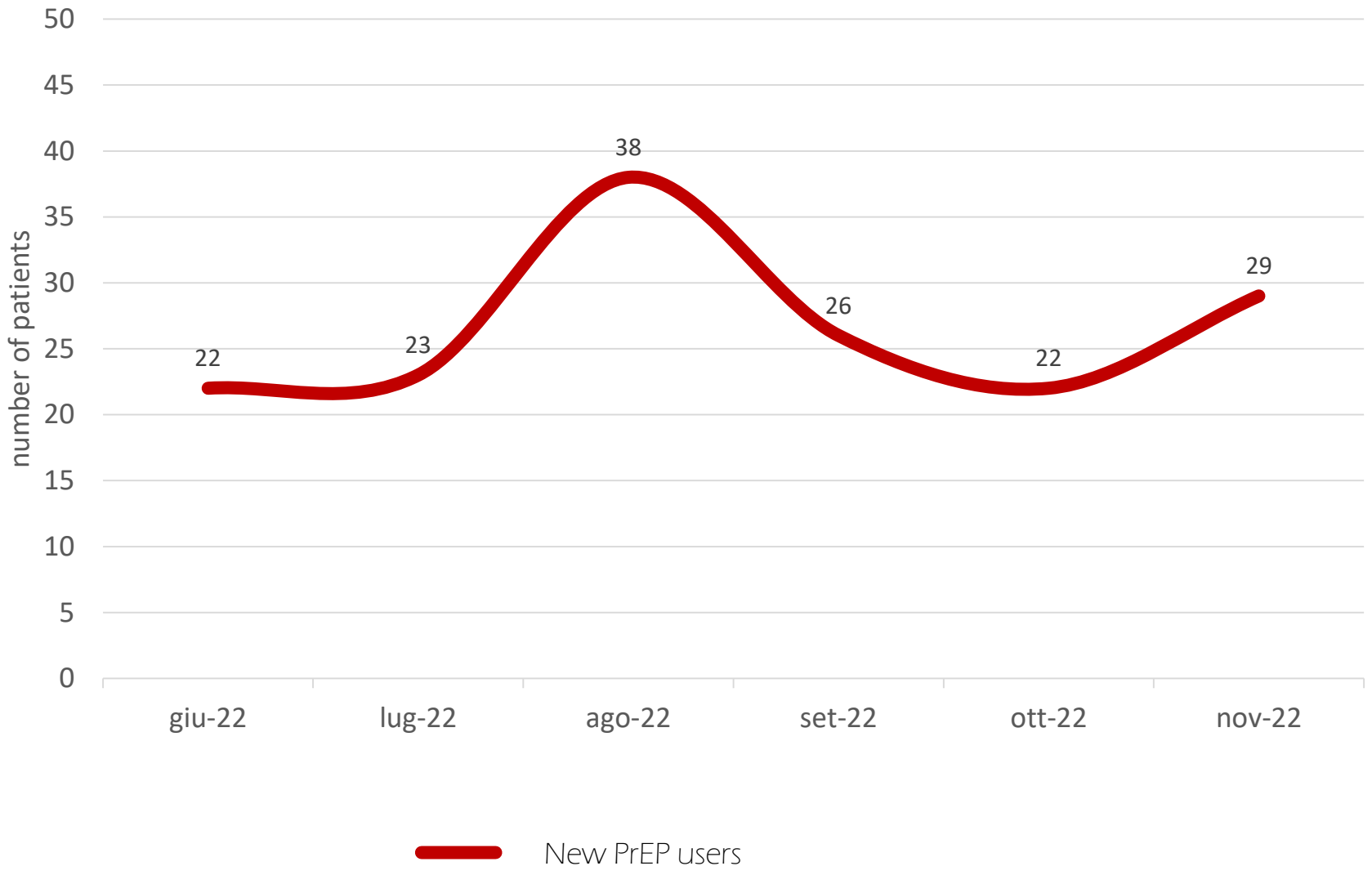


Figure 1 PrEP beginning and STIs diagnosis over years. MSM, men who have sex with men; PrEP, pre-exposure prophylaxis; STI, sexually transmitted infection.

Table 1 Individuals' characteristics at BL by PrEP regimen

Characteristics	Overall (n=624)	Event-based (n=344)	Daily-based (n=280)	P value
BL age (years; median (IQR))*	34.5 (30.1; 40.2)	34.2 (30.6; 39.7)	34.8 (29.8; 41.2)	0.665
Ethnicity†‡				0.09
Caucasian	606 (97.1%)	338 (98.3%)	268 (95.7%)	
Non-Caucasian	18 (2.9%)	6 (1.7%)	10 (3.6%)	
Chemsex¶§†	258 (41.3%)	137 (39.8%)	121 (43.2%)	0.439
Number of sexual partners†§				0.221
0–9	261 (41.8%)	143 (41.6%)	118 (42.1%)	
10-19	204 (32.7%)	121 (35.2%)	83 (29.6%)	
20–49	125 (20.0%)	66 (19.2%)	59 (21.1%)	
>50	34 (5.45%)	14 (4.07%)	20 (7.14%)	
Previous STI**†	313 (50.2%)	165 (48.0%)	148 (52.9%)	0.256
HIRI-MSM†	67 (10.7%)	35 (10.2%)		0.881
10-19	337 (54.0%)	187 (54.4%)	32 (11.4%)	
20–29	220 (35.3%)	122 (35.5%)	150 (53.6%)	
>30			98 (35.0%)	
Education†				0.993
Middle school	13 (2.08%)	7 (2.03%)	6 (2.14%)	
Upper school	215 (34.5%)	119 (34.6%)	96 (34.3%)	
University	396 (63.5%)	218 (63.4%)	178 (63.6%)	
Year of BL visit†				<0.001
2017	58 (9.29%)	3 (0.87%)	55 (19.6%)	
2018	60 (9.62%)	20 (5.81%)	40 (14.3%)	
2019	97 (15.5%)	40 (11.6%)	57 (20.4%)	
2020	99 (15.9%)	57 (16.6%)	42 (15.0%)	
2021	164 (26.3%)	111 (32.3%)	53 (18.9%)	
2022	146 (23.4%)	113 (32.8%)	33 (11.8%)	

New PrEP users



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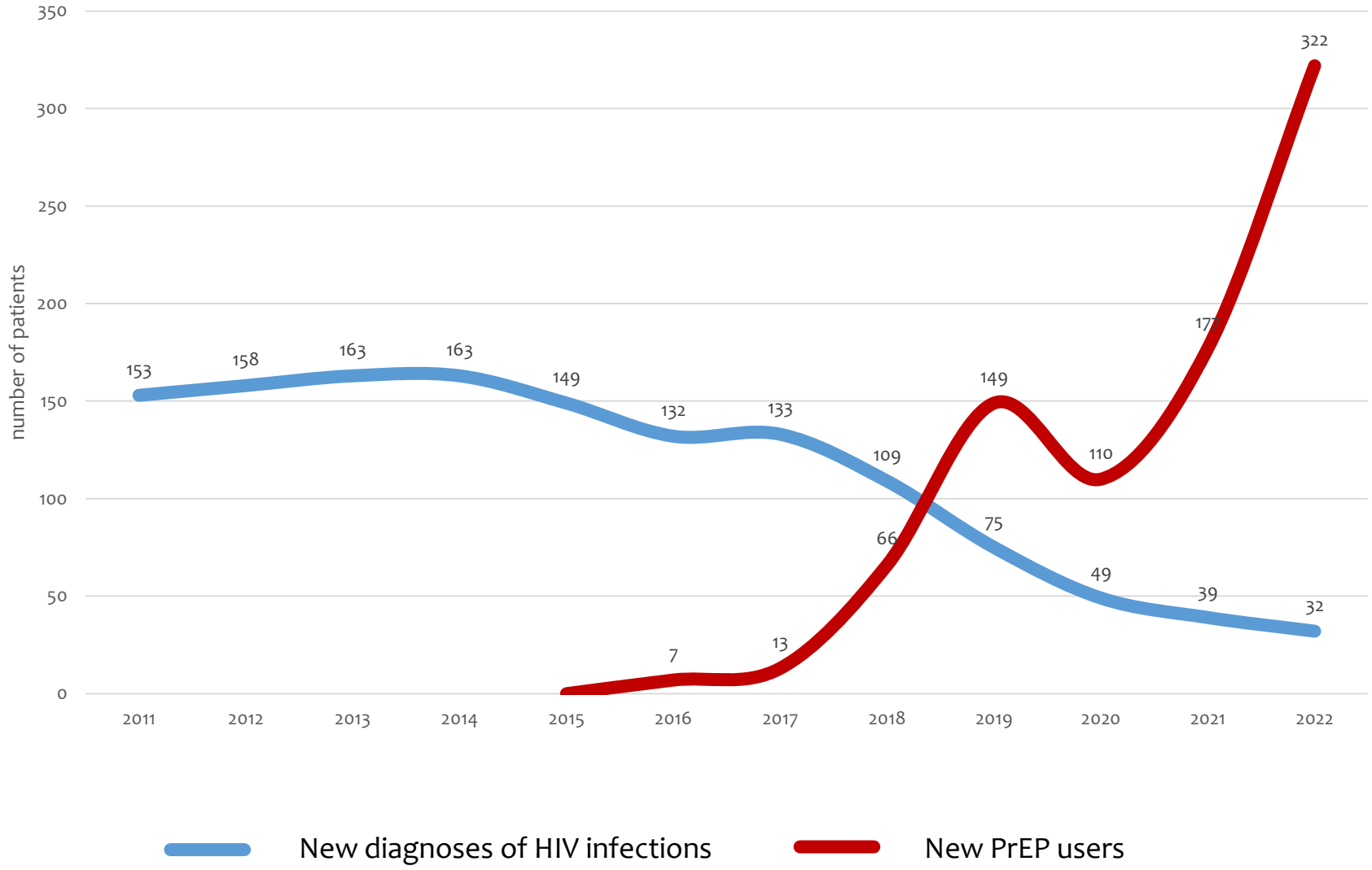
OSR Real world data



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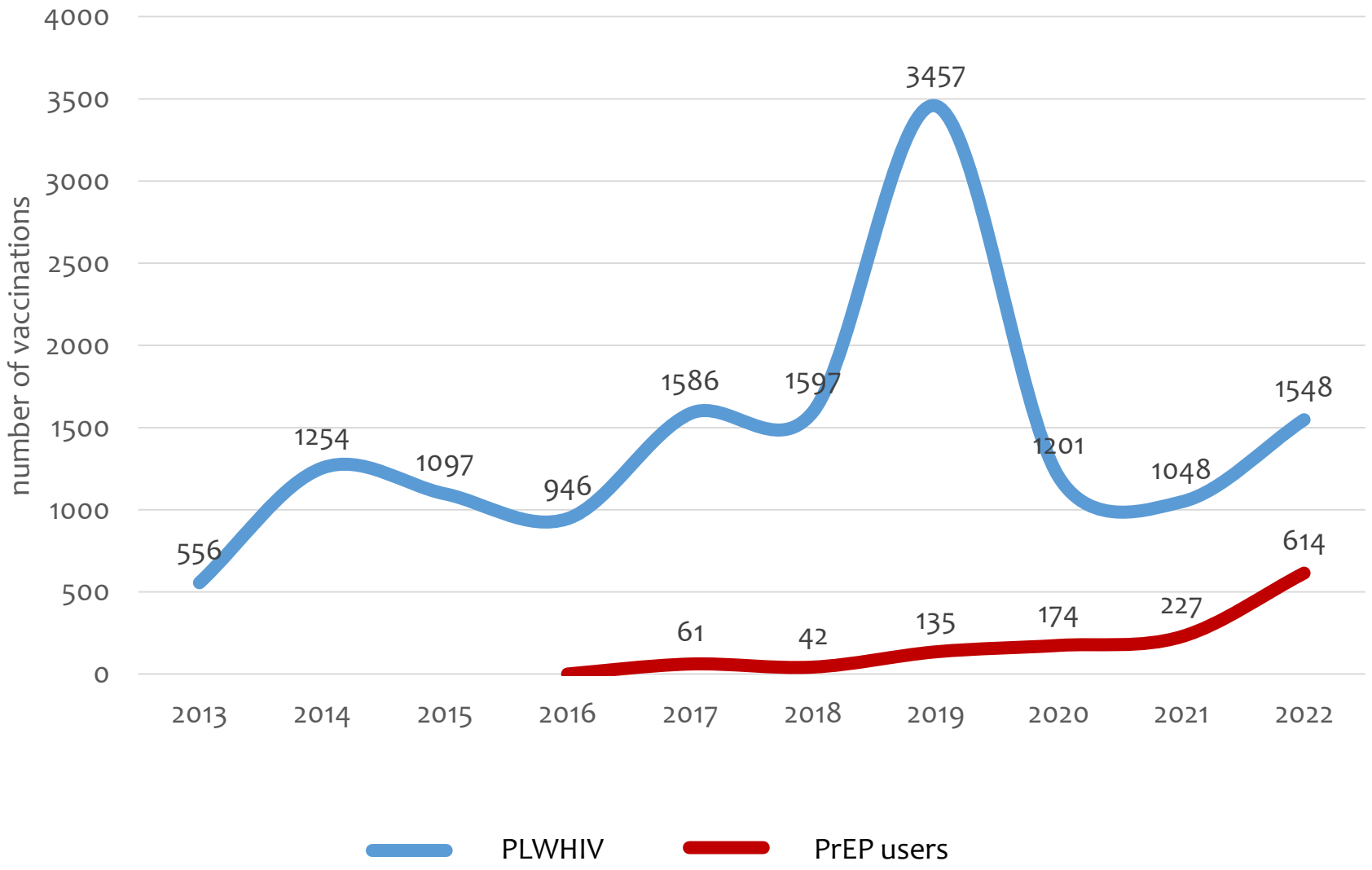
Vaccinations



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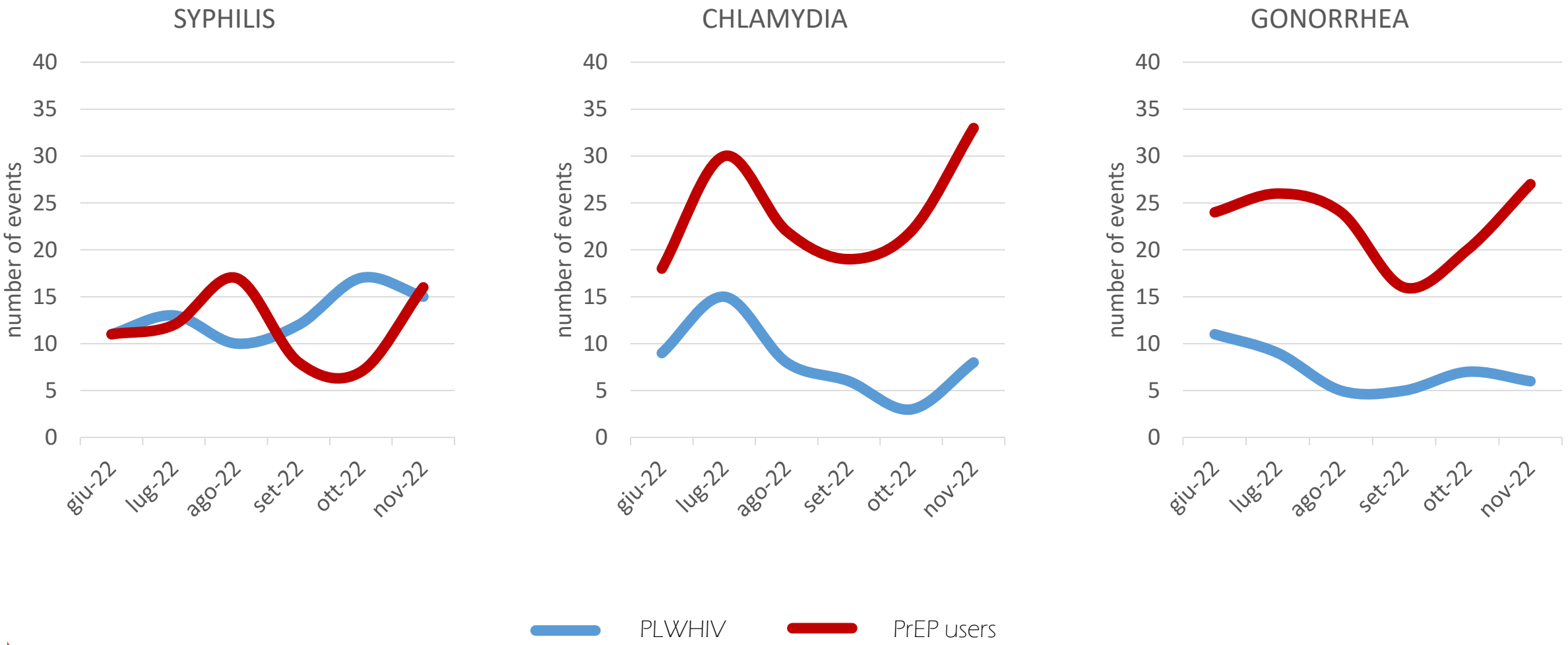
IST



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Gruppo San Donato

DISCUSSION- Barriers to PrEP access

- HIV acquisition is uncommon when PrEP is used correctly.

- Suboptimal awareness or acceptance of PrEP among some individuals at risk for acquiring HIV and their **care providers.**
- Lack of **retention** in PrEP care due to individual and structural barriers.
- **Stigma**, which may keep people who would benefit from PrEP from using it.
- Disparities in access to PrEP among populations at high risk of HIV acquisition, including transgender women, women, and people who inject drugs.