

L'incidenza delle nuove infezioni è in riduzione?

Ruolo del trattamento universale e della PrEP

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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%
- ⦿ Rapporto orale ricettivo con eiaculazione: 0,02%
- ⦿ Rapporto anale insertivo: 0,06%
- ⦿ Rapporto vaginale insertivo: 0,082%

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.



Prevenzione dell'infezione da HIV

- ⦿ Prevenzione primaria: vaccino preventivo.
- ⦿ Prevenzione farmacologica (PLWHIV): TasP.
- ⦿ Prevenzione farmacologica: PEP.
- ⦿ Prevenzione farmacologica: PrEP.

TasP



HIV TREATMENT as **PREVENTION**

A HIGHLY EFFECTIVE STRATEGY TO PREVENT THE SEXUAL TRANSMISSION OF HIV



People living with HIV who take
**HIV medication daily
as prescribed**



and get and keep an
undetectable viral load



**have effectively no risk of
sexually transmitting HIV**
to their HIV-negative partners



MARCH 2019

LEARN MORE AT [HIV.GOV/TASP](https://www.hiv.gov/tasp)





Lancet. 2010 August 14; 376(9740): 532–539. doi:10.1016/S0140-6736(10)60936-1.

Expanded HAART Coverage is Associated with Decreased Population-level HIV-1-RNA and Annual New HIV Diagnoses in British Columbia, Canada

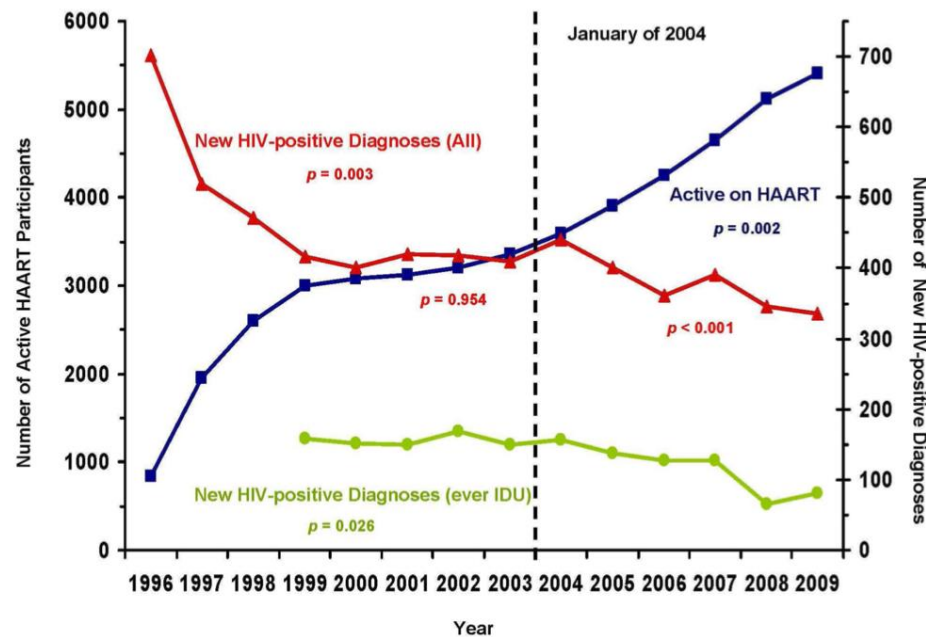
Julio S.G. Montaner^{1,2}, Viviane D. Lima^{1,2}, Rolando Barrios¹, Benita Yip¹, Evan Wood^{1,2}, Thomas Kerr^{1,2}, Kate Shannon^{1,2}, P. Richard Harrigan^{1,2}, Robert S. Hogg^{1,3}, Patricia Daly⁴, and Perry Kendall⁵

Abstract

Background—Cohort studies and mathematical models have suggested that expanded coverage with highly active antiretroviral therapy (HAART) could decrease HIV transmission. This study focuses on the HIV epidemic, stratified by injection drug use, in the province of British Columbia, Canada, and seeks to estimate the association between plasma HIV-1-viral load, HAART coverage and number of new cases of HIV at the population-level.

Methods—HAART use, plasma HIV-1-viral level determinations, and rates of reportable sexually transmitted infections, including HIV, are all recorded in province-wide registries allowing for temporal comparisons of these parameters. Trends of new HIV positive tests and number of individuals on HAART were modeled using generalized additive models. Poisson log-linear regression models were used to estimate the association between the outcome new HIV positive tests (per 100 population) and the covariates viral load (\log_{10} transformed), year, and number of individuals on HAART.

Conclusions—Our results demonstrate a strong association at the population-level between increasing levels of HAART coverage, decreased viral load and decreased new HIV diagnoses/year, against a background of increased HIV testing and increased rates of other STIs in the province. Our results support the proposed secondary benefit of HAART, used within current medical guidelines, on HIV transmission at a population level.



Active on HAART	837	1960	2597	2994	3079	3120	3211	3356	3585	3913	4255	4654	5123	5413
New HIV+ diagnoses (All)	702	519	471	416	400	420	418	408	441	400	361	391	346	338
New HIV+ diagnoses (ever IDU)	NA	NA	NA	159	152	149	168	149	156	137	128	128	65	80
HIV Tests done in BC (per 1000)	138	140	137	135	135	135	145	142	154	161	172	176	182	NA

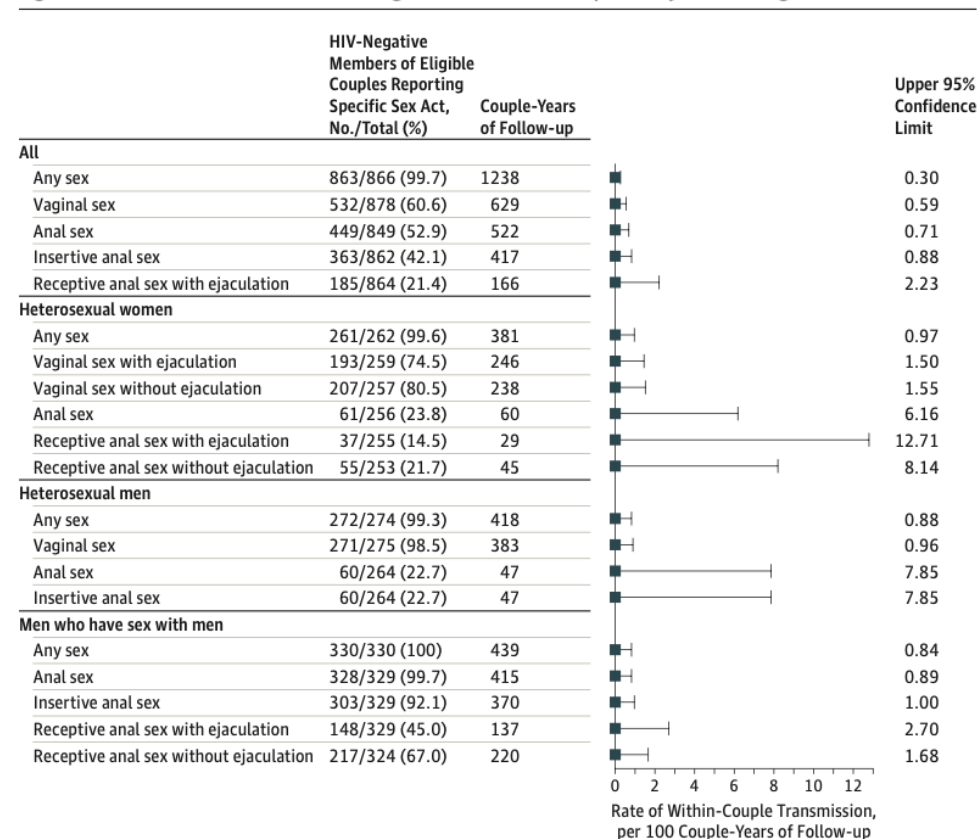


JAMA. 2016;316(2):171-181. doi:10.1001/jama.2016.5148
Last corrected on November 13, 2016.

Original Investigation

Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy

Figure 1. Rate of HIV Transmission According to Sexual Behavior Reported by the HIV-Negative Partner



IMPORTANCE A key factor in assessing the effectiveness and cost-effectiveness of antiretroviral therapy (ART) as a prevention strategy is the absolute risk of HIV transmission through condomless sex with suppressed HIV-1 RNA viral load for both anal and vaginal sex.

OBJECTIVE To evaluate the rate of within-couple HIV transmission (heterosexual and men who have sex with men [MSM]) during periods of sex without condoms and when the HIV-positive partner had HIV-1 RNA load less than 200 copies/mL.

DESIGN, SETTING, AND PARTICIPANTS The prospective, observational PARTNER (Partners of People on ART—A New Evaluation of the Risks) study was conducted at 75 clinical sites in 14 European countries and enrolled 1166 HIV serodifferent couples (HIV-positive partner taking suppressive ART) who reported condomless sex (September 2010 to May 2014). Eligibility criteria for inclusion of couple-years of follow-up were condomless sex and HIV-1 RNA load less than 200 copies/mL. Anonymized phylogenetic analysis compared couples' HIV-1 polymerase and envelope sequences if an HIV-negative partner became infected to determine phylogenetically linked transmissions.

EXPOSURES Condomless sexual activity with an HIV-positive partner taking virally suppressive ART.

MAIN OUTCOMES AND MEASURES Risk of within-couple HIV transmission to the HIV-negative partner

RESULTS Among 1166 enrolled couples, 888 (mean age, 42 years [IQR, 35-48]; 548 heterosexual [61.7%] and 340 MSM [38.3%]) provided 1238 eligible couple-years of follow-up (median follow-up, 1.3 years [IQR, 0.8-2.0]). At baseline, couples reported condomless sex for a median of 2 years (IQR, 0.5-6.3). Condomless sex with other partners was reported by 108 HIV-negative MSM (33%) and 21 heterosexuals (4%). During follow-up, couples reported condomless sex a median of 37 times per year (IQR, 15-71), with MSM couples reporting approximately 22 000 condomless sex acts and heterosexuals approximately 36 000. Although 11 HIV-negative partners became HIV-positive (10 MSM; 1 heterosexual; 8 reported condomless sex with other partners), no phylogenetically linked transmissions occurred over eligible couple-years of follow-up, giving a rate of within-couple HIV transmission of zero, with an upper 95% confidence limit of 0.30/100 couple-years of follow-up. The upper 95% confidence limit for condomless anal sex was 0.71 per 100 couple-years of follow-up.

CONCLUSIONS AND RELEVANCE Among serodifferent heterosexual and MSM couples in which the HIV-positive partner was using suppressive ART and who reported condomless sex, during median follow-up of 1.3 years per couple, there were no documented cases of within-couple HIV transmission (upper 95% confidence limit, 0.30/100 couple-years of follow-up). Additional longer-term follow-up is necessary to provide more precise estimates of risk.



Risk of HIV transmission through condomless sex in serodifferent gay couples with the HIV-positive partner taking suppressive antiretroviral therapy (PARTNER): final results of a multicentre, prospective, observational study

Alison J Rodger, Valentina Cambiano, Tina Bruun, Pietro Vernazza, Simon Collins, Olaf Degen, Giulio Maria Geretti, Apostolos Beloukas, Dorthe Raben, Pep Coll, Andrea Antinori, Nneka Nwokolo, Arm Rainer Weber, Arne Van Eeden, Norbert H Brockmeyer, Amanda Clarke, Jorge del Romero Guerrero, Francis Gilles Wandeler, Jan Gerstoft, Felix Gutiérrez, Kees Brinkman, Maria Kitchen, Lars Ostergaard, Agathe Leon, Matti Ristola, Heiko Jensen, Hans-Jürgen Stellbrink, Andrew N Phillips, Jens Lundgren, for the PARTNER Study Group*

Lancet 2019; 393: 2428–38

Summary

Background The level of evidence for HIV transmission risk through condomless sex in serodifferent gay couples with the HIV-positive partner taking virally suppressive antiretroviral therapy (ART) is limited compared with the evidence available for transmission risk in heterosexual couples. The aim of the second phase of the PARTNER study (PARTNER2) was to provide precise estimates of transmission risk in gay serodifferent partnerships.

Methods The PARTNER study was a prospective observational study done at 75 sites in 14 European countries. The first phase of the study (PARTNER1; Sept 15, 2010, to May 31, 2014) recruited and followed up both heterosexual and gay serodifferent couples (HIV-positive partner taking suppressive ART) who reported condomless sex, whereas the PARTNER2 extension (to April 30, 2018) recruited and followed up gay couples only. At study visits, data collection included sexual behaviour questionnaires, HIV testing (HIV-negative partner), and HIV-1 viral load testing (HIV-positive partner). If a seroconversion occurred in the HIV-negative partner, anonymised phylogenetic analysis was done to compare HIV-1 *pol* and *env* sequences in both partners to identify linked transmissions. Couple-years of follow-up were eligible for inclusion if condomless sex was reported, use of pre-exposure prophylaxis or post-exposure prophylaxis was not reported by the HIV-negative partner, and the HIV-positive partner was virally suppressed (plasma HIV-1 RNA <200 copies per mL) at the most recent visit (within the past year). Incidence rate of HIV transmission was calculated as the number of phylogenetically linked HIV infections that occurred during eligible couple-years of follow-up divided by eligible couple-years of follow-up. Two-sided 95% CIs for the incidence rate of transmission were calculated using exact Poisson methods.

Findings Between Sept 15, 2010, and July 31, 2017, 972 gay couples were enrolled, of which 782 provided 1593 eligible couple-years of follow-up with a median follow-up of 2.0 years (IQR 1.1–3.5). At baseline, median age for HIV-positive partners was 40 years (IQR 33–46) and couples reported condomless sex for a median of 1.0 years (IQR 0.4–2.9). During eligible couple-years of follow-up, couples reported condomless anal sex a total of 76 088 times. 288 (37%) of 777 HIV-negative men reported condomless sex with other partners. 15 new HIV infections occurred during eligible couple-years of follow-up, but none were phylogenetically linked within-couple transmissions, resulting in an HIV transmission rate of zero (upper 95% CI 0.23 per 100 couple-years of follow-up).

Interpretation Our results provide a similar level of evidence on viral suppression and HIV transmission risk for gay men to that previously generated for heterosexual couples and suggest that the risk of HIV transmission in gay couples through condomless sex when HIV viral load is suppressed is effectively zero. Our findings support the message of the U=U (undetectable equals untransmittable) campaign, and the benefits of early testing and treatment for HIV.

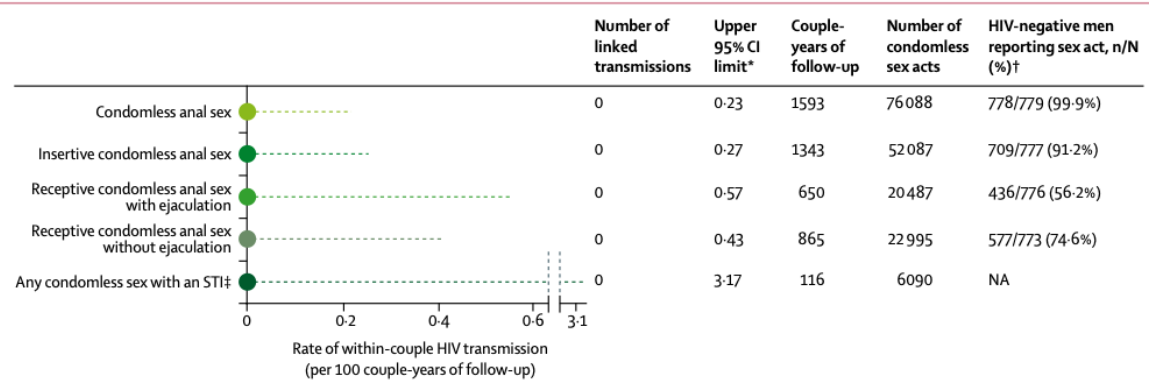


Figure 1: Rate of within-couple HIV transmission through condomless sex according to sexual behaviour reported by the HIV-negative partner. STI=sexually transmitted infection. NA=not applicable. *Estimated using the exact Poisson method. †Numerator is the number of HIV-negative men within the eligible couples ever reporting that specific sexual act and denominator is the group-specific number of HIV-negative participants who contributed eligible couple-years of follow-up. ‡Refers to STIs (excluding HIV) self-reported by the HIV-negative partner.

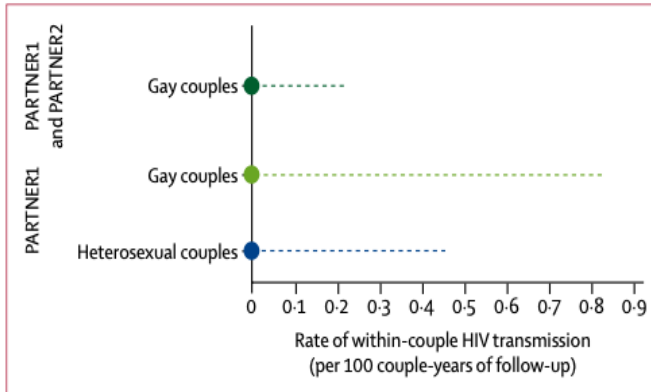


Figure 3: Upper 95% CI limit around estimated rate of zero HIV transmissions through penetrative sex (vaginal or anal) at the end of PARTNER1 and PARTNER2.



17:39

Mercoledì 19
Giugno 2019

OSPEDALE
SAN RAFFAELE



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

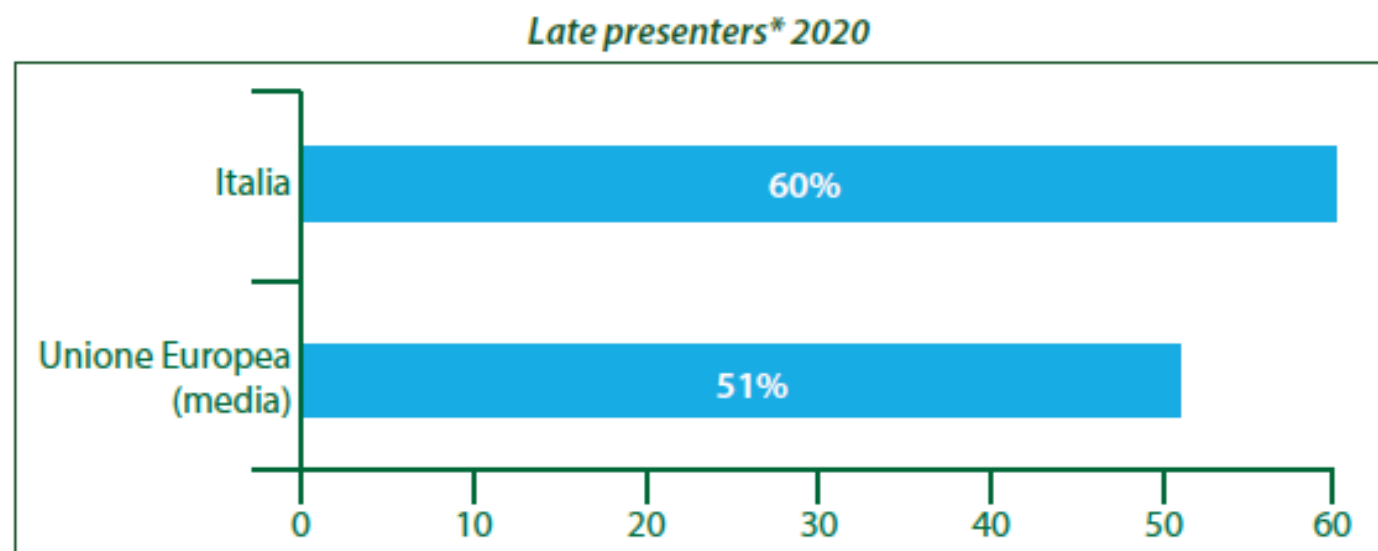
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artexe

NEC

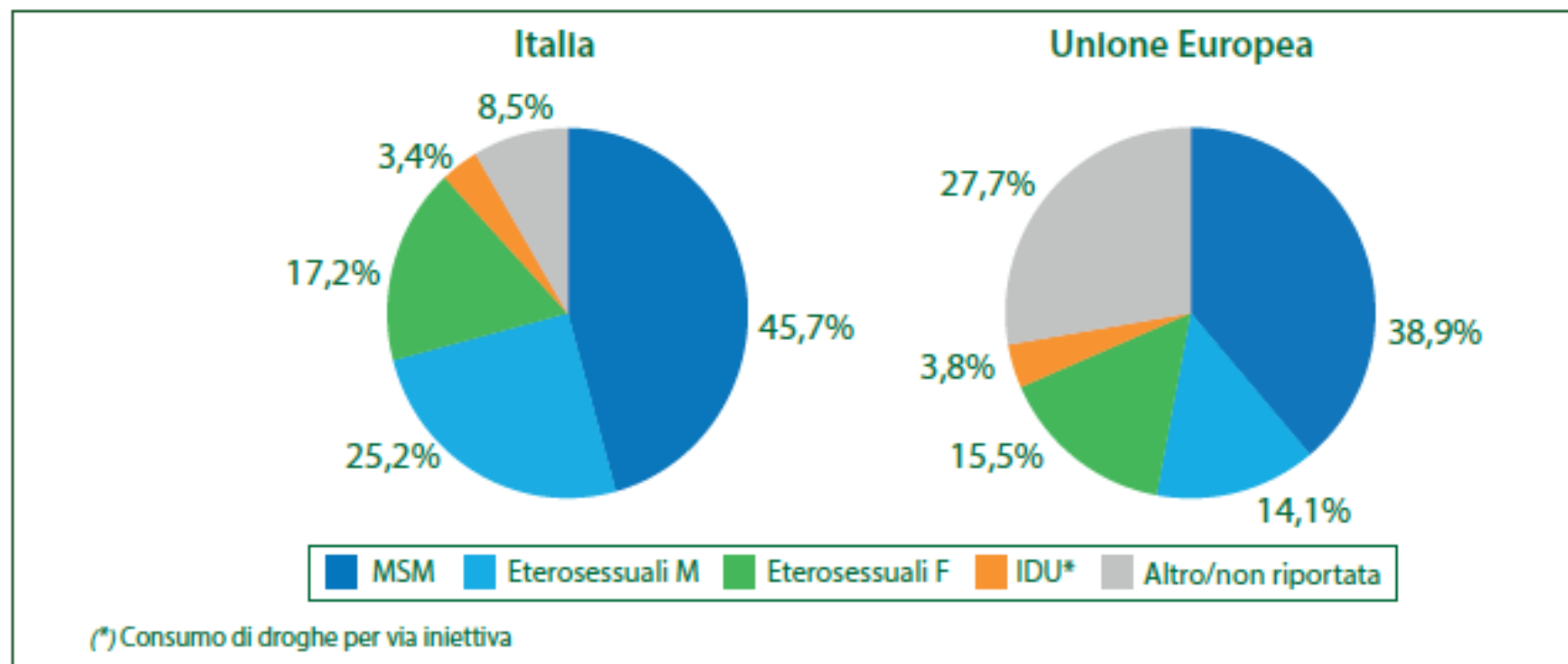


(*) *Late presenters*: nuove diagnosi di infezione da HIV con numero di linfociti CD4 < 350 cell/ μ l

Fonti: Sistema di Sorveglianza HIV nazionale, ECDC/WHO 2021 HIV/AIDS Surveillance in Europe 2021-2020 data (1)



Modalità di trasmissione 2020



Distribuzione percentuale delle nuove diagnosi di infezione da HIV per modalità di trasmissione 2020

Fonti: Sistema di Sorveglianza HIV nazionale, ECDC/WHO 2021 HIV/AIDS Surveillance in Europe 2021-2020 data (1)



CDC: Selecting Appropriate Candidates for PrEP

MSM	Heterosexual Women/Men	People Who Inject Drugs
<ul style="list-style-type: none">Any male sex partner in past 6 moNot in monogamous relationship with a recently tested, HIV-negative man <p><i>And ≥1 of These Criteria</i></p> <ul style="list-style-type: none">Any anal sex without a condom in past 6 moBacterial STI (syphilis, gonorrhea, or chlamydia) in <div>In any category, individual expected to be an adult or adolescent weighing >35 kg <i>without</i> acute or established HIV infection</div>	<ul style="list-style-type: none">Any sex with opposite sex partner in previous 6 moNot in monogamous relationship with a recently tested, HIV-negative partner <p><i>And ≥1 of These Criteria</i></p> <ul style="list-style-type: none">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 RNABacterial STI (syphilis, gonorrhea in females/males) in last 6 mo	<ul style="list-style-type: none">Any injection of drugs not prescribed by a clinician in past 6 mo <p><i>And ≥1 of These Criteria</i></p> <ul style="list-style-type: none">Any sharing of injection/drug preparation equipment in past 6 moRisk of sexual acquisition

Adapted from CDC. PrEP Guidelines. 2017.

Score di rischio



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	<input type="text"/>
Negli ultimi 3 mesi, numero partner:	7 >10	4 6-10	0 0-5		<input type="text"/>
Negli ultimi 3 mesi, partner sessuali HIV+ noti*	8 >1	4 1			<input type="text"/>
Negli ultimi 3 mesi, RR senza condom	10 1 o più	0 mai			<input type="text"/>
Negli ultimi 3 mesi, RI senza condom con HIV+ noti *	6 5 o più	0 0-4			<input type="text"/>
Negli ultimi 3 mesi, uso di meta-anfetamine/cocaina/LSD /cristalli	6 sì	0 no			<input type="text"/>
Negli ultimi 3 mesi, ti è stata diagnosticata una IST Quale? <u>clamidia</u> <u>sifilide</u> <u>gonorrea</u> <u>HPV</u> <u> </u>	6 sì	0 no			<input type="text"/>
Totale					<input type="text"/>

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 della 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.

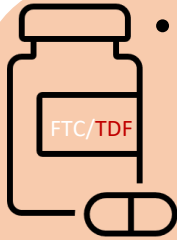
Summary of PrEP Eligibility by Regimen –EUROPE-



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

FTC/TAF PI. 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.

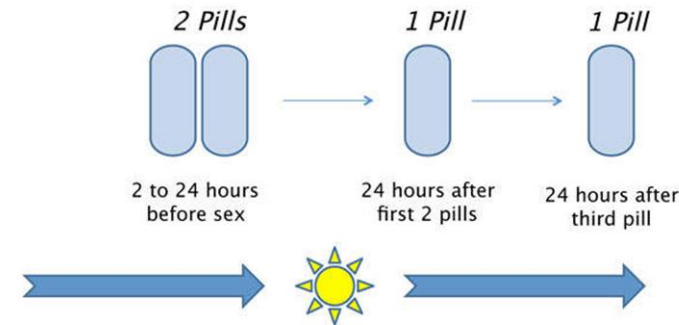
Selection of Oral PrEP Regimen: On-Demand FTC/TDF Dosing Options for MSM



- 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)

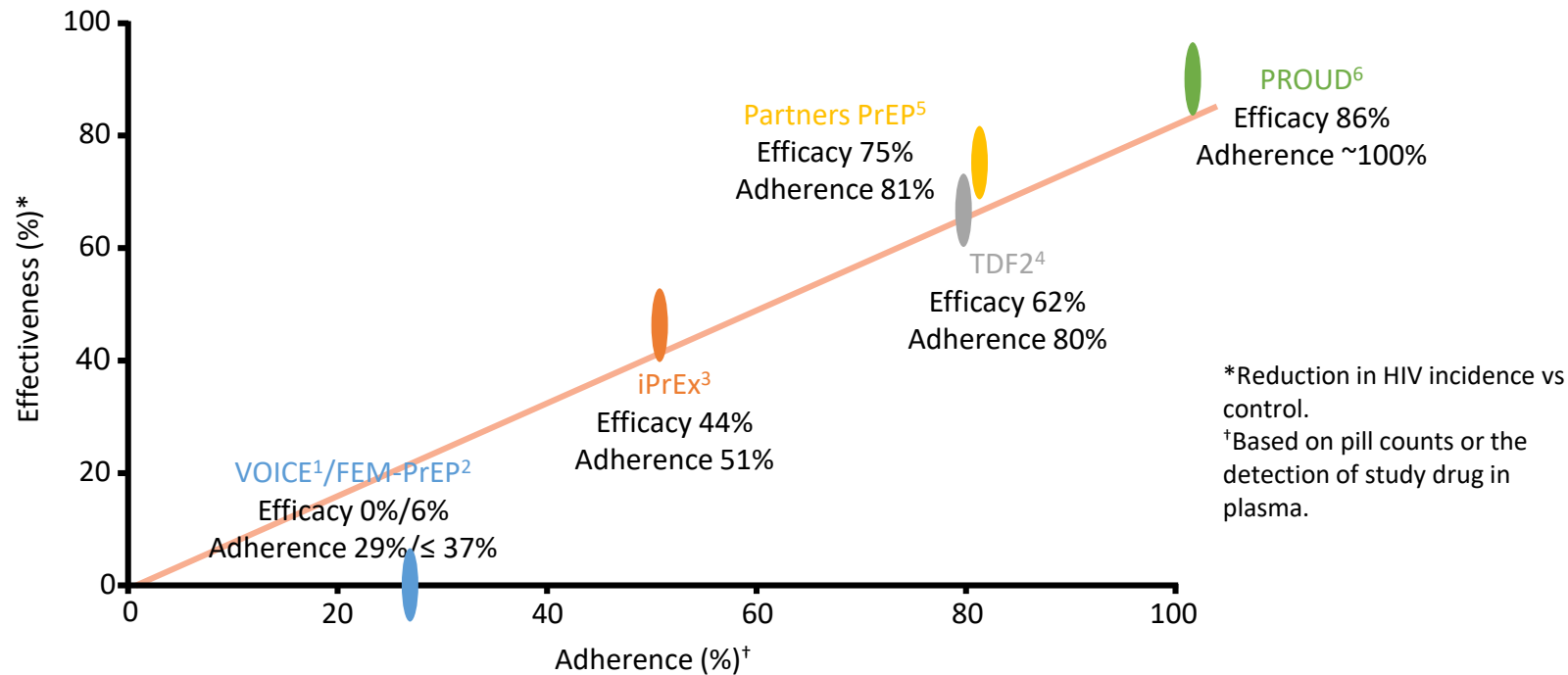
On-demand PrEP



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.

Select Daily Oral FTC/TDF PrEP Trials: Effectiveness Improves With Adherence



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



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

Population	Effectiveness Estimate	Source	Interpretation
<i>"Optimal or Consistent Use" ^a (Taking PrEP daily or at least 4 times per week)</i>			
Men who have sex with men (MSM)	~99%	Grant, 2014 Liu, 2015 McCormack, 2015 Volk, 2015 Marcus, 2017	When taking PrEP daily or consistently (<i>at least 4 times per week</i>), the risk of acquiring HIV is reduced by about 99% among MSM. While daily use is recommended in the U.S., taking PrEP consistently (<i>at least 4 times per week</i>) 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.

Clinical Monitoring During PrEP



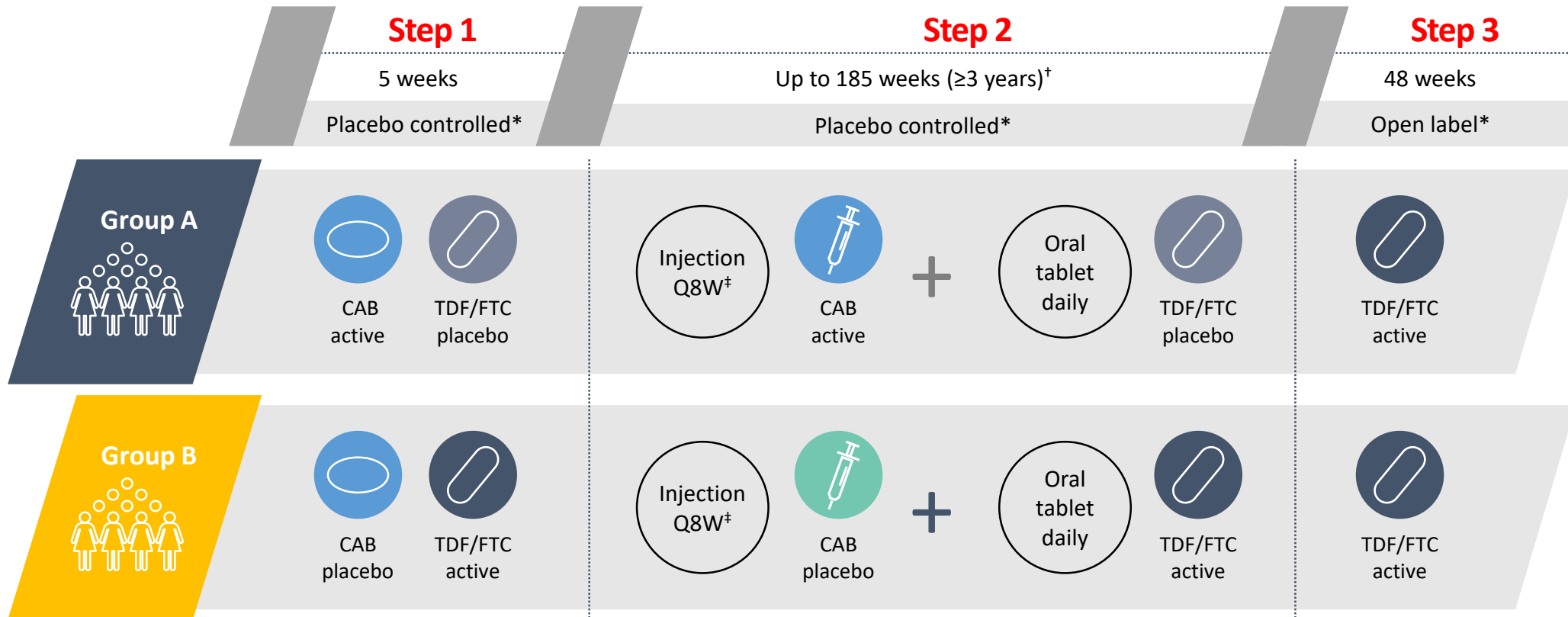
Assessment ¹	Initiation	At Least Every 3 Mo	At Least Every 6 Mo	At Least Every 12 Mo
HIV test: signs/symptoms of acute HIV	X	X		
Pregnancy test*	X	X		
STI assessment [†]	X	X		
STI testing [†]	X		X	
Hepatitis B serology	X			
Renal function [‡]	X		X	
Assess HIV risk and PrEP indication [§]	X			X
Counsel on adherence, behavioral risk reduction	X	X		

*Assess pregnancy intent and provide contraception to women who do not want to become pregnant. †Collect pharyngeal, rectal, and urine specimens in MSM. Vaginal specimens preferred for gonorrhea testing in women, but rectal specimens should be collected in women who report anal sex. ‡Guidelines from 2017 based only on FTC/TDF as PrEP. Prescribing information for FTC/TAF notes: at initiation and during use, assess renal function on a clinically appropriate schedule.² §Based on provider discretion, can be done more frequently.

HPTN 083 and HPTN 084: Study design



Studies to evaluate the safety and efficacy of CAB LA Q8W versus daily oral TDF/FTC for PrEP in HIV-uninfected MSM/TGW¹ or women²



HPTN 083
an HIV prevention clinical trial

HPTN 084
Long-acting Injectable For the Epidemic

*In Steps 1 and 2, the tablets and injections will look alike, so staff and participants will not know if they are getting the active or placebo products. In Step 3, all participants will be given active TDF/FTC

[†]3 years for HPTN 083 and 3.5 years for HPTN 084

[‡]In Step 2, the first 2 injections are 4 weeks apart and 8 weeks apart thereafter

E il condom?



Table 1 Behaviors among HIV-negative MSM, San Francisco, 2004–2017

	2004	2008	2011	2014	2017	χ^2, p
Behavioral classification, last 6 months						
No anal intercourse	287 (23.8)	114 (28.4)	84 (22.9)	62 (20.9)	84 (21.4)	1.8, 0.18
PrEP use ^a	0 (0.0)	0 (0.0)	5 (1.4)	29 (9.8)	169 (43.1)	559.4, 0.00
Consistent condom use	444 (36.8)	123 (30.6)	111 (30.2)	52 (17.5)	28 (7.1)	136.0, 0.00
Pure serosorting	283 (23.5)	100 (24.9)	109 (29.7)	106 (35.7)	84 (21.4)	2.6, 0.10
Condom serosorting	67 (5.6)	16 (4.0)	24 (6.5)	15 (5.1)	5 (1.3)	6.4, 0.01
Seropositioning	61 (5.1)	19 (4.7)	23 (6.3)	16 (5.4)	10 (2.6)	1.5, 0.22
Condom seropositioning	10 (0.8)	5 (1.2)	2 (0.5)	2 (0.7)	1 (0.3)	1.3, 0.25
No discernible strategy	53 (4.4)	25 (6.2)	9 (2.5)	15 (5.1)	11 (2.8)	1.5, 0.21
Behavioral classification without PrEP use, last 6 months						
No anal intercourse	287 (23.8)	114 (28.4)	84 (22.9)	62 (20.9)	84 (21.4)	1.8, 0.18
Consistent condom use	444 (36.8)	123 (30.6)	113 (30.8)	55 (18.5)	37 (9.4)	115.7, 0.00
Pure serosorting	283 (23.5)	100 (24.9)	110 (30.0)	120 (40.4)	169 (43.1)	71.1, 0.00
Condom serosorting	67 (5.6)	16 (4.0)	24 (6.5)	16 (5.4)	21 (5.4)	0.0, 0.96
Seropositioning	61 (5.1)	19 (4.7)	25 (6.8)	21 (7.1)	36 (9.2)	9.3, 0.00
Condom seropositioning	10 (0.8)	5 (1.2)	2 (0.5)	2 (0.7)	3 (0.8)	0.1, 0.72
No discernible strategy	53 (4.4)	25 (6.2)	9 (2.5)	21 (7.1)	42 (10.7)	15.4, 0.00



Key Take-Home Points

- ✧ TasP is the most effective prevention strategy.
- ✧ PrEP is a highly safe and effective HIV prevention option, and **clinicians have a key role to play in expanding access/uptake.**
- ✧ MSM also have the option of on-demand (2:1:1) oral FTC/TDF dosing or daily oral FTC/TAF.
- ✧ Expanding number/variety of PrEP regimens hoped to appeal to diverse populations.
- ✧ PrEP is a critical opportunity to engage people in comprehensive care, including but not limited to sexual health and mental health