

Innovation & New Prevention of HIV (&STDs)



ศ พญ ธันยวีร์ ภูษนกิจ¹
ภาควิชาการเวชศาสตร์

คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

25 สิงหาคม 2566

People living with HIV

38.4 million [33.9 million–43.8 million]

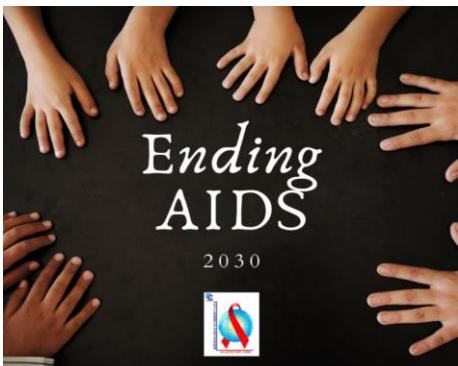
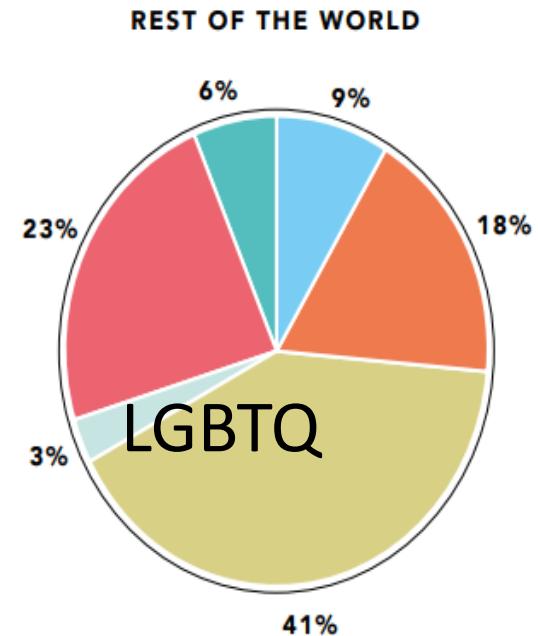
New HIV infections in 2021

1.5 million [1.1 million–2.0 million]

4000 new HIV infections a day
1/3 in young people 15–24 years

Deaths due to AIDS in 2021

650 000 [510 000–860 00]



2030 goal of ending AIDS
as a global health threat

- SEX WORKERS
- PEOPLE WHO INJECT DRUGS
- GAY MEN AND OTHER MEN WHO HAVE SEX WITH MEN
- TRANSGENDER WOMEN
- CLIENTS OF SEX WORKERS AND SEX PARTNERS OF KEY POPULATIONS
- REMAINING POPULATION

Source: UNAIDS special analysis, 2022 (see Annex on Methods).

Young people have a right to sexual and reproductive health care that meets their needs



Empower youth to protect their health with comprehensive sex education



Invest in high quality, youth-friendly health services



Combat stigma as a barrier to care

- Prevention tools
- Access to sexual reproductive health care: on-line outreach
- Youth-friendly health services

Q1 ท่านเคยให้การป้องกันการติดเชื้อเอชไอวีหรือไม่?

A. เคย

B. ไม่เคย

C. ไม่แน่ใจ

Q2 ในการทำงานของท่าน ท่านได้พบกับ AYA

Adolescent and Young Adult 15-24 ปี เพียงใด?

A. < 10%

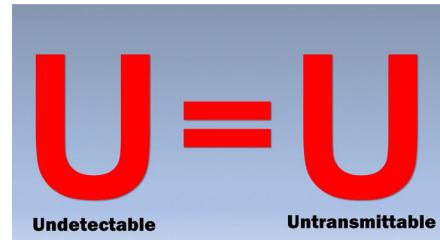
B. 10-25%

C. 25-50%

D. 50-75%

E. >75%

Treatment as Prevention



- Risk of transmission
 - Undetectable (HIV RNA < 200 c/ml) = zero transmission
 - Suppressed (HIV RNA 200-1000 c/ml) = almost zero, negligible risk
 - Unsuppressed (HIV RNA > 1000 c/ml) = can transmit

The risk of sexual transmission of HIV in individuals with low-level HIV viraemia: a systematic review



Laura N Broyles, Robert Luo, Debi Boeras, Lara Vojnov

Published online July 23, 2023 [https://doi.org/10.1016/S0140-6736\(23\)00877-2](https://doi.org/10.1016/S0140-6736(23)00877-2)

7762 serodiscordant couples across 25 countries.

- VL < 200 c/mL = no transmission
- VL 200-1000 c/ml = 2 events (long intervals 50,53 days)
- VL > 1000 c/ml = 321 events



HIV testing strategy including HIV-ST

New recommendation

HIV self-testing may be offered as an additional option for testing at facilities (*conditional recommendation, low-certainty evidence*).

New recommendation

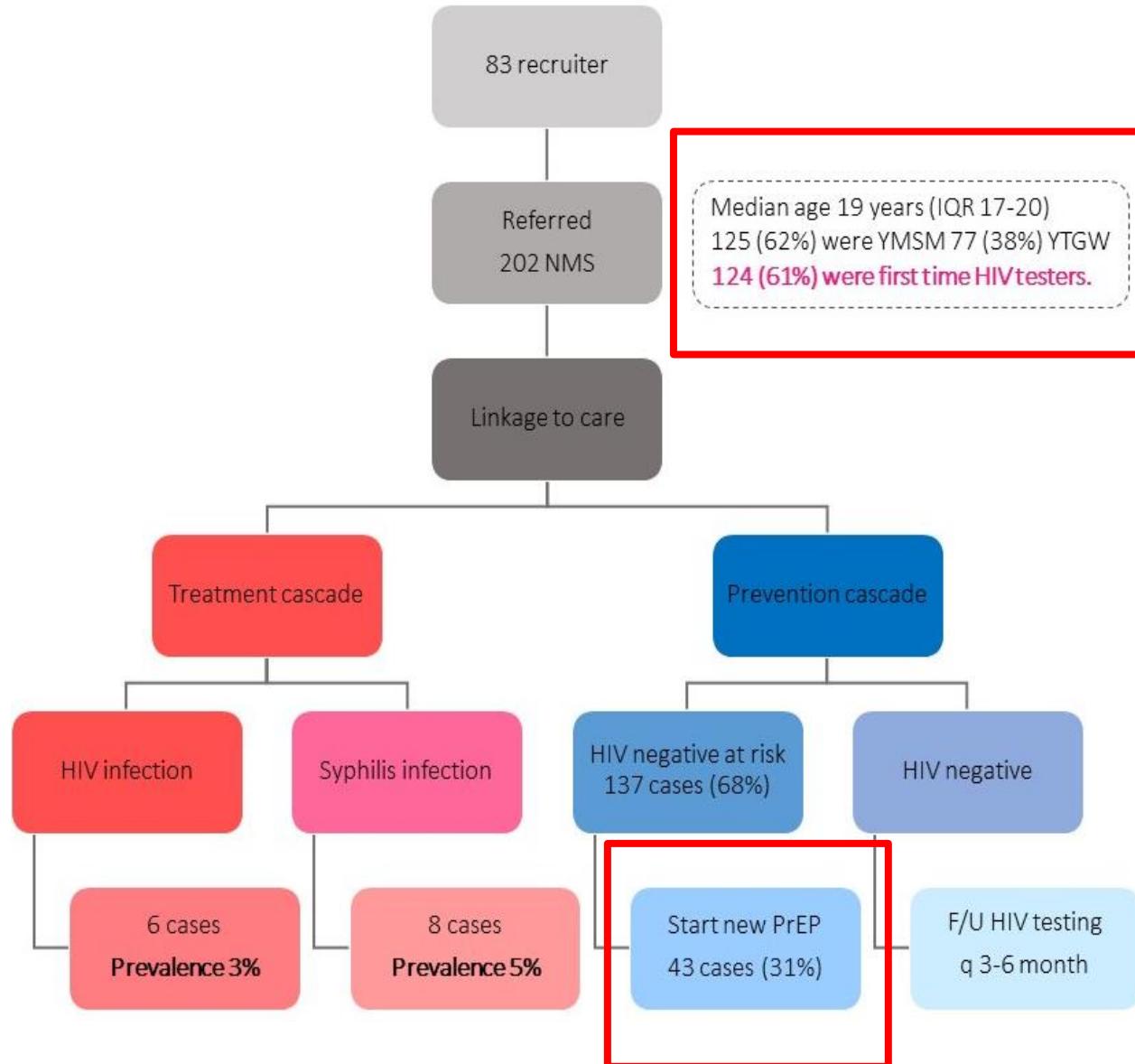
HIV self-testing may be used to deliver pre-exposure prophylaxis, including for initiation, re-initiation and continuation (*conditional recommendation, low-certainty evidence*).

New recommendation

Social network testing approaches may be offered as an additional approach to HIV testing as part of a comprehensive package of care and prevention (*conditional recommendation, low-certainty evidence*).



Adolescent empowerment: Social network strategy



- ◆ HIV negative
- ◆ HIV negative on PrEP
- ◆ HIV positive
- * First time tester
- S Syphilis
- MSM
- TGW
- ◇ Bisexual

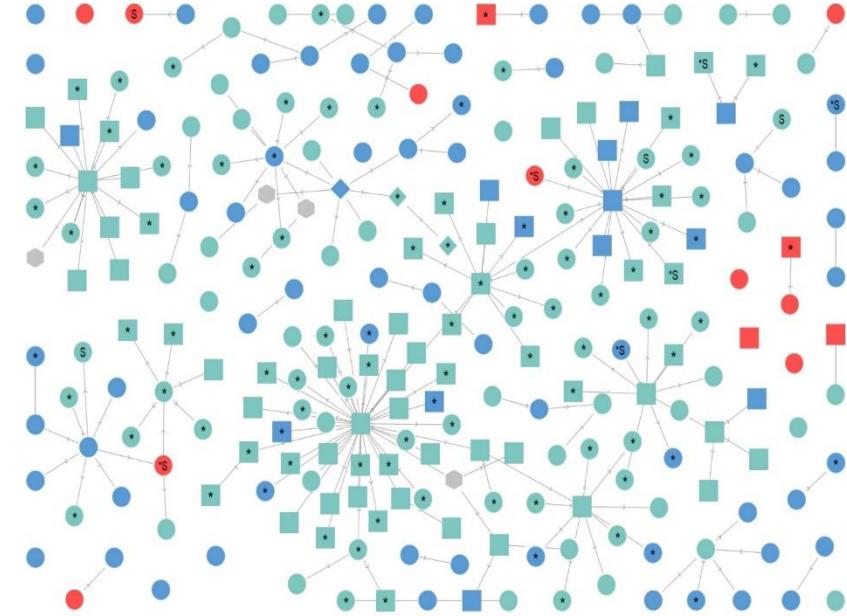


Figure: Social mapping showing recruitment pattern of social network strategy

61% first-time HIV testers

1 out of 3 of those HIV at risk, immediately linked to HIV prevention.

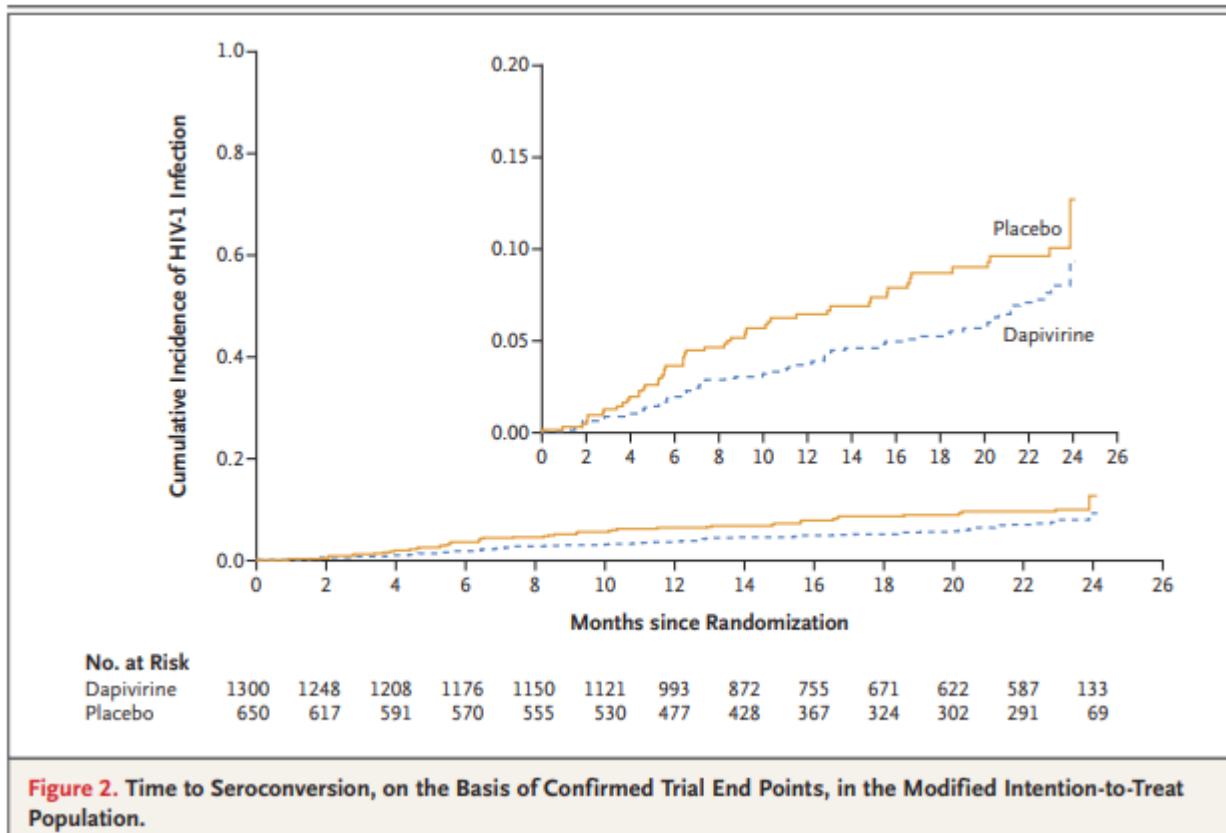
New technology Biomedical HIV intervention



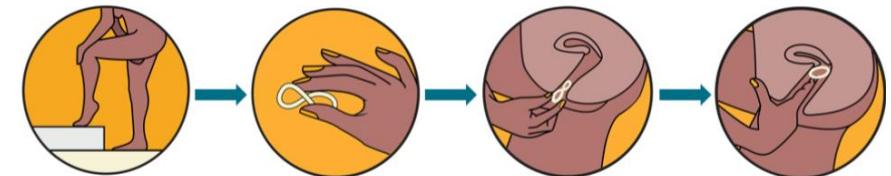
Dapvirine vaginal ring

Ring study (SA, Uganda)

Dapvirine = 6.1 per 100 person-year
Placebo = 4.1 per 100 person-year



Dapivirine 25 mg
Self inserted vaginal ring every 4 weeks



Ring insertion and placement



Oral pill for PrEP

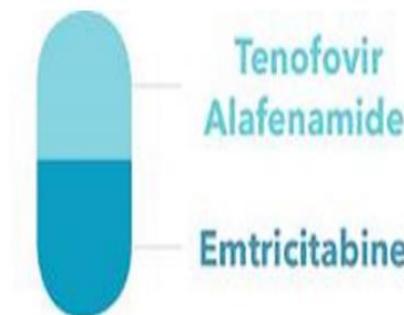
Daily PrEP

For risk > 2 times per week, unpredictable sex

TDF/FTC



TAF/FTC



On-Demand 2-1-1

2 pills



2 to 24 hours
before sex



1 pill



24 hours
after first 2 pills

1 pill



24 hours
after 3rd pill

1. On-demand dosing: If you have sex once a week

BEFORE SEX

2 PrEP tablets at least 2 hours &
ideally 24 hours before sex



AFTER SEX

1 PrEP 24 hours* after the 1st 2
1 PrEP 48 hours* after the 1st 2
= total of 2 tablets after sex

*2 hours before or after planned time is OK

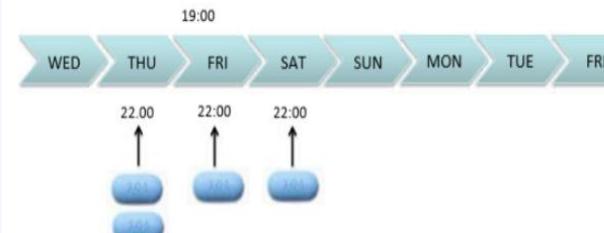
2. On-demand dosing: Sex several times over a few days

BEFORE SEX

2 PrEP tablets at least 2 hours & not
more than 24 hours before sex

1 PrEP 24 hours* after the 1st 2
Take Truvada every 24 hours* until 2
doses after your last sex

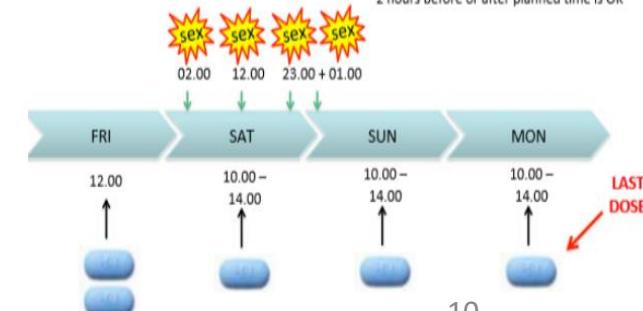
*2 hours before or after planned time is OK



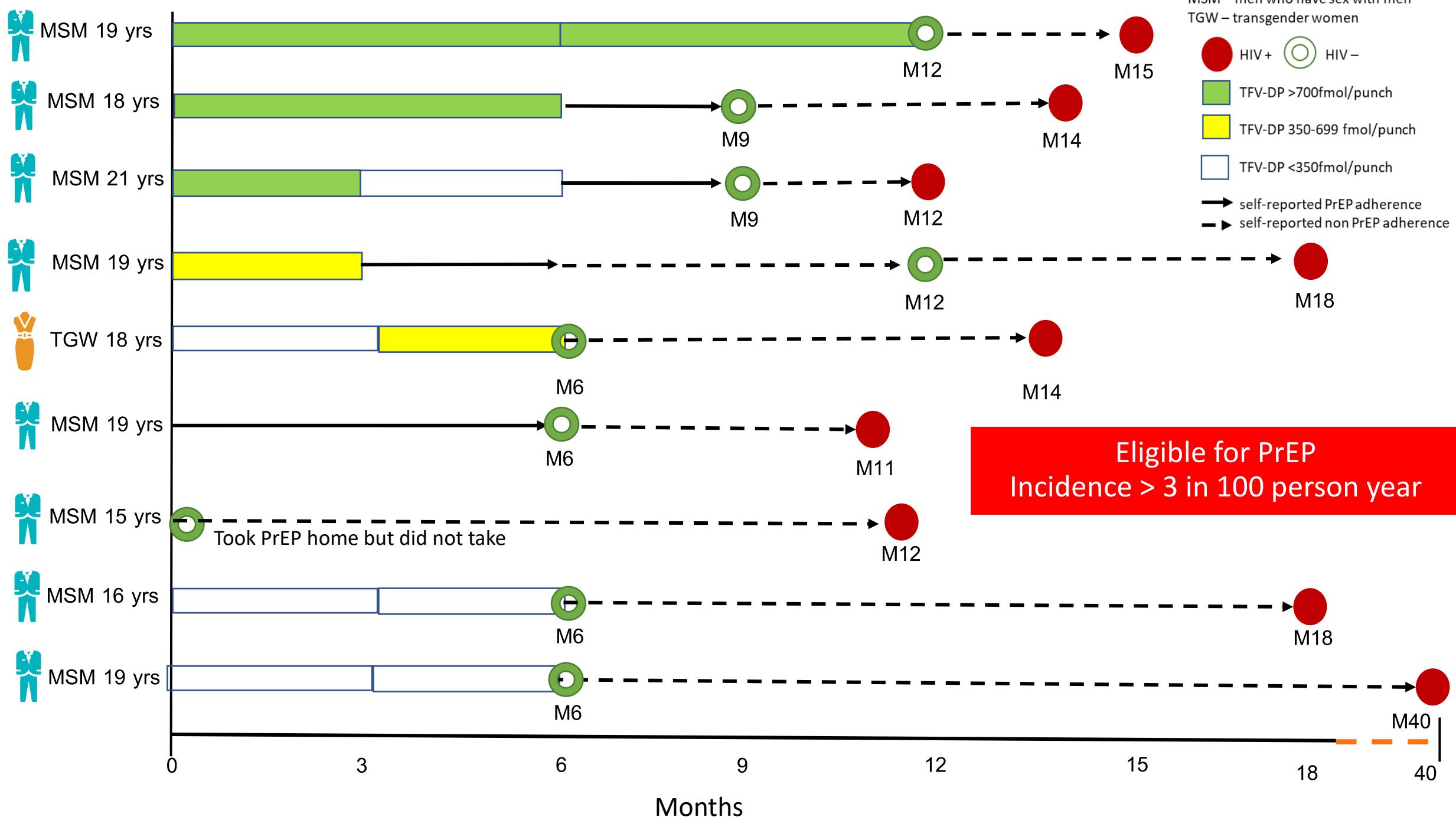
AFTER SEX



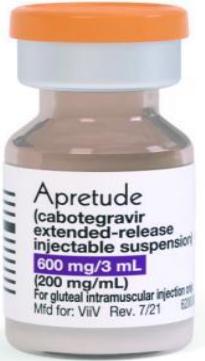
02.00 12.00 23.00 + 01.00



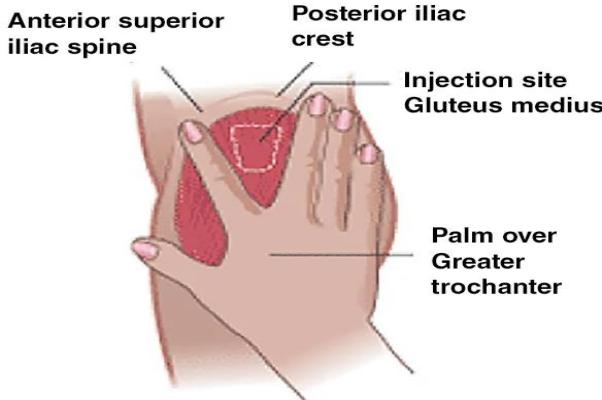
ระยะเวลาที่กินยาเพร็พ จนระดับยาเพียงพอ
= 2 เม็ด อย่างน้อย 2 ชั่วโมง หรือ 1 เม็ด * 7 วัน
การหยุดกินยาเพร็พ = 2 วันหลังจากมีเพศสัมพันธ์ครั้งสุดท้าย



Cabotegravir



Ventrogluteal Site



Lenacapavir



Sunlenca®
(lenacapavir) injection
463.5 mg/1.5 mL (309 mg/mL)
For Subcutaneous Injection
2 x 1.5 mL lenacapavir single-dose vials

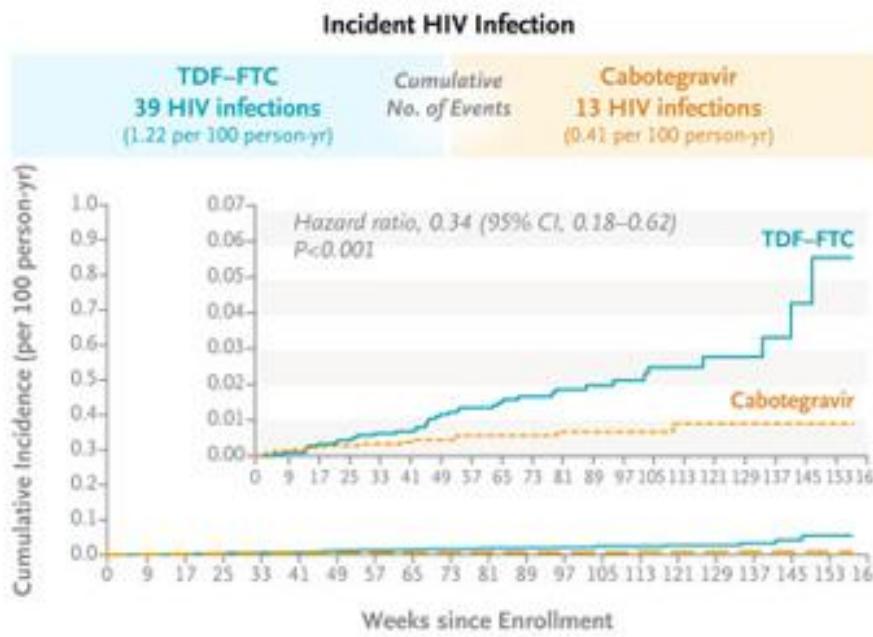
SUNLENCA 4-Tablets™ blister pack contains 4 tablets
(Lenacapavir 300mg/tab)



Long acting injectable: Cabotegravir

HPTN 083

TDF/FTC = 1.2 per 100 person-year
Cabotegravir= 0.4 per 100 person-year
600 mg, given IM q 8 weeks



Landovitz RJ. N Engl J Med 2021; 385:595-608

HPTN 084

TDF/FTC = 1.8 per 100 person-year
Cabotegravir= 0.2 per 100 person-year

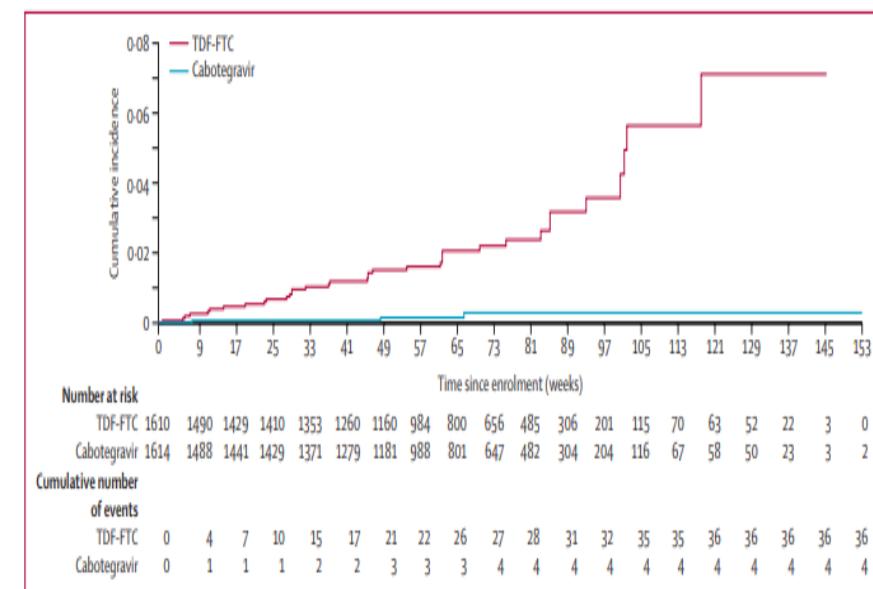


Figure 3: Cumulative HIV incidence by study group

Kaplan-Meier estimates of HIV infection are shown. Four HIV infections were observed in the cabotegravir group (HIV incidence 0.20 per 100 person-years [95% CI 0.06–0.52]) and 36 in the TDF-FTC group (1.85 per 100 person-years [1.3–2.5]). Participants in the cabotegravir group had an 88% lower risk of HIV infection than those in the TDF-FTC group (hazard ratio 0.12 [0.05–0.31]; $p<0.0001$). TDF-FTC=tenofovir disoproxil fumarate plus emtricitabine.



July 2022

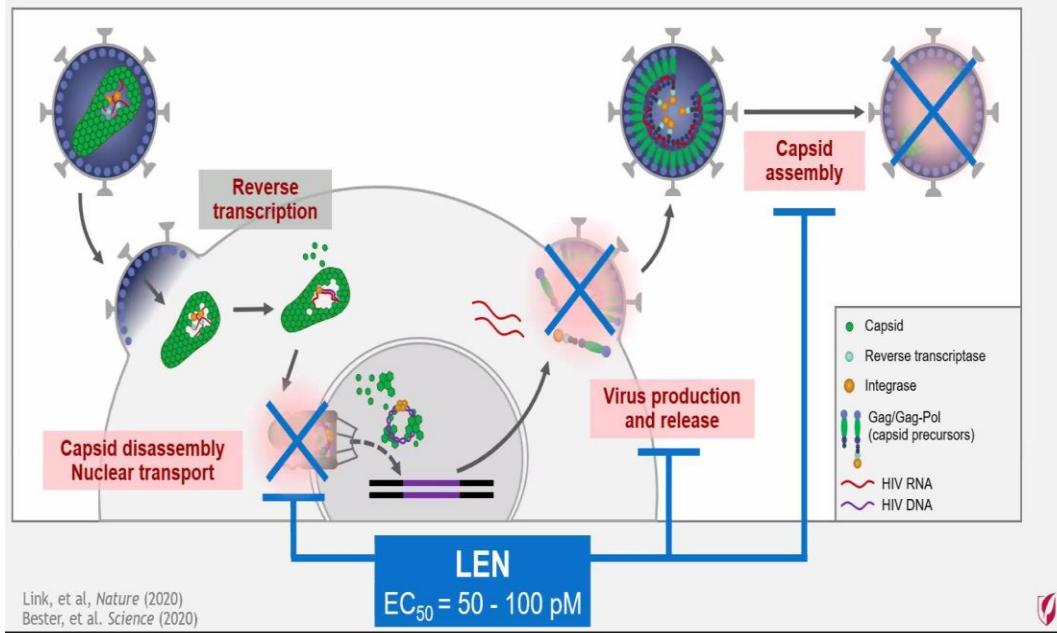


Delany-Moretlwe S et al. Lancet 2022; 399: 1779–89

Lenacapavir for HIV prevention (Phase III clinical trial)

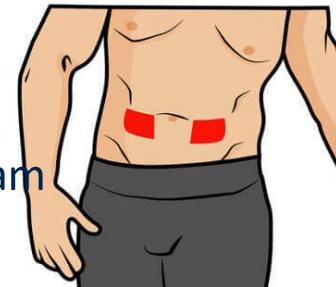
Lenacapavir: a novel HIV capsid inhibitor

LEN blocks several steps of HIV replication with high potency

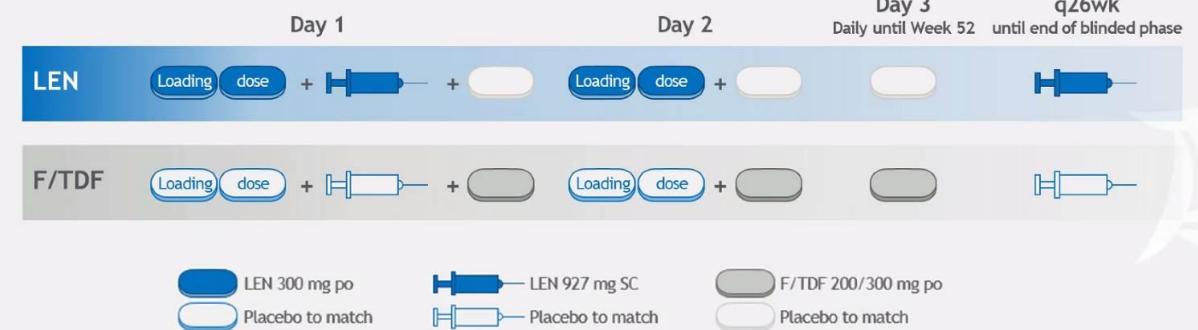


PURPOSE1: 5,000 women in South Africa /Uganda

PURPOSE2: 3,000 MSM/ Trans in LATAM/Thai/Vietnam



Randomized phase Study drug administration



ClinicalTrials.gov Identifier: NCT04925752

DPP: Dual Prevention Pill

oral PrEP + oral contraception

- Viatris developing **co-formulated tablet with 28-day regimen** (TDF/FTC, oral PrEP + LNG/EE, combined oral contraception (COC))
- **Different color pills** for 21 vs. 7 days (dark pink and light peach, respectively)
- **Packaging will be wallet pack** with tear-off weekly sheets with instructions on them
- Pill color, packaging, brand names **validated with women**
- **Branding/secondary packaging** will have women's lifestyle feel
- Longer term, Population Council/Medicines360 to **develop F/TAF-based DPP**

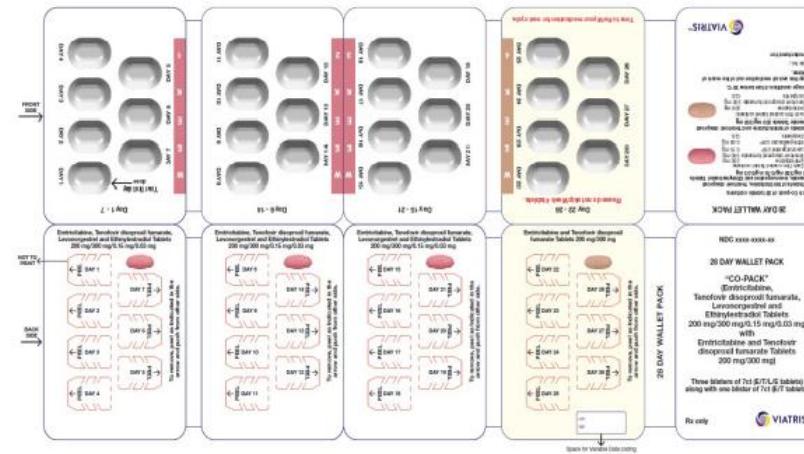
Viatris plans to file for regulatory approval with US Food & Drug Administration in early 2024

MPT = multipurpose prevention technology

Figure 1: Proposed DPP tablet colors



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



Jessica Rodrigues, AVAC July 2022

Rectal microbicide

A randomized trial of safety, acceptability and adherence of three rectal microbicide placebo formulations among young sexual and gender minorities who engage in receptive anal intercourse (MTN-035)

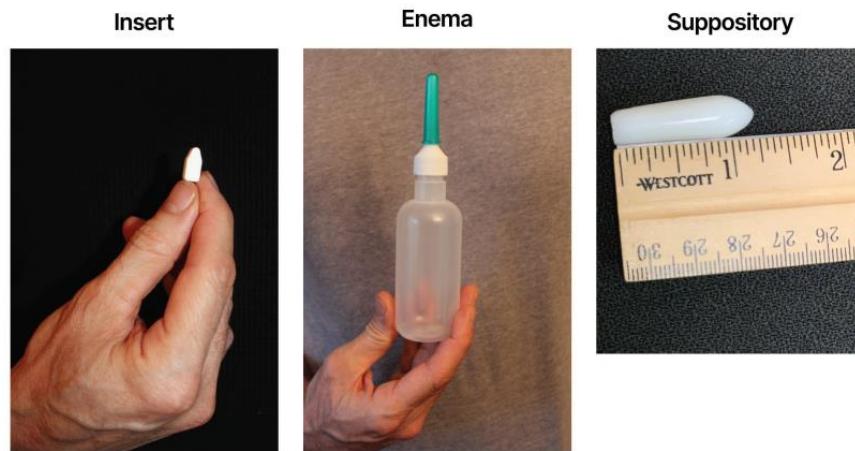


Fig 2. MTN-035 placebo study products.
<https://doi.org/10.1371/journal.pone.0284339.g002>

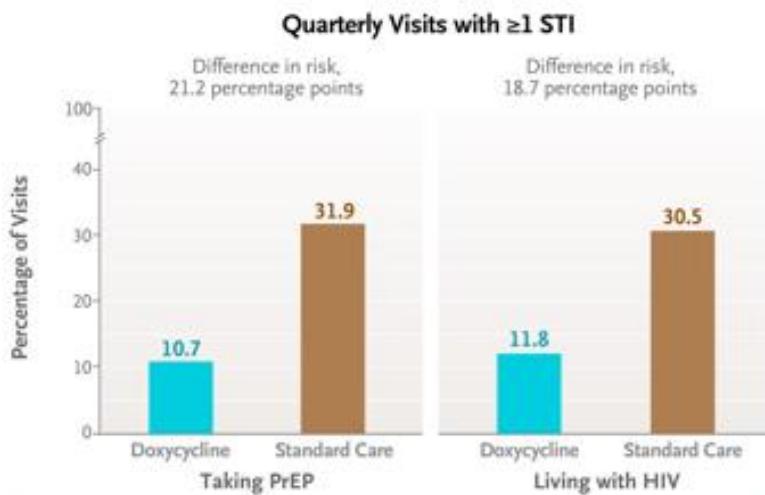
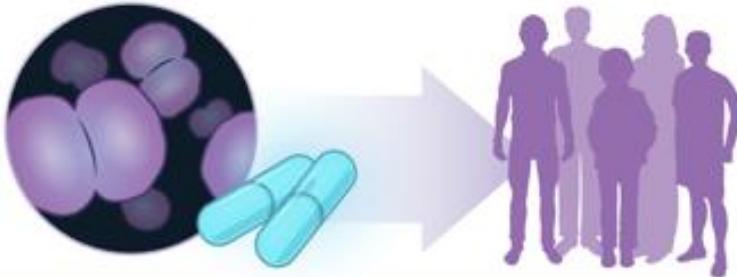
MTN017: reduced glycerin formulation of tenofovir gel
MTN-026 MTN-033: Gel based on dapivirine
MTN 039: tenofovir and elvitegravir rectal insert

Table 4. Acceptability and adherence by study product.

	Acceptability		Adherence			
	Rectal Insert	Suppository	Rectal Enema	Rectal Insert	Suppository	Rectal Enema
Percentage with High Acceptability/Adherence and 95% Confidence Interval	72% (65%, 78%)	66% (59%, 73%)	73% (66%, 79%)	75% (69%, 81%)	74% (68%, 80%)	83% (77%, 88%)
Participants with high acceptability/adherence by site						
Birmingham, USA	21/29 (72%)	19/29 (66%)	23/29 (79%)	26/29 (90%)	22/29 (76%)	24/29 (83%)
Blantyre, Malawi	24/29 (83%)	21/29 (72%)	26/29 (90%)	23/29 (79%)	16/29 (55%)	20/29 (69%)
Chiang Mai, Thailand	25/30 (83%)	21/30 (70%)	13/30 (43%)	25/30 (83%)	30/30 (100%)	29/30 (97%)
Johannesburg, South Africa	22/27 (81%)	21/27 (78%)	20/28 (71%)	10/27 (37%)	14/27 (52%)	18/28 (64%)
Lima, Peru	18/26 (69%)	18/26 (69%)	23/25 (92%)	22/26 (85%)	19/26 (73%)	22/25 (88%)
Pittsburgh, USA	17/30 (57%)	16/30 (53%)	23/30 (77%)	20/30 (67%)	23/30 (77%)	26/30 (87%)
San Francisco, USA	16/30 (53%)	16/30 (53%)	15/30 (50%)	24/30 (80%)	24/30 (80%)	26/30 (87%)

Prevention of bacterial STIs: doxycycline PEP

Doxycycline 200 mg within 72 hr after condomless sex



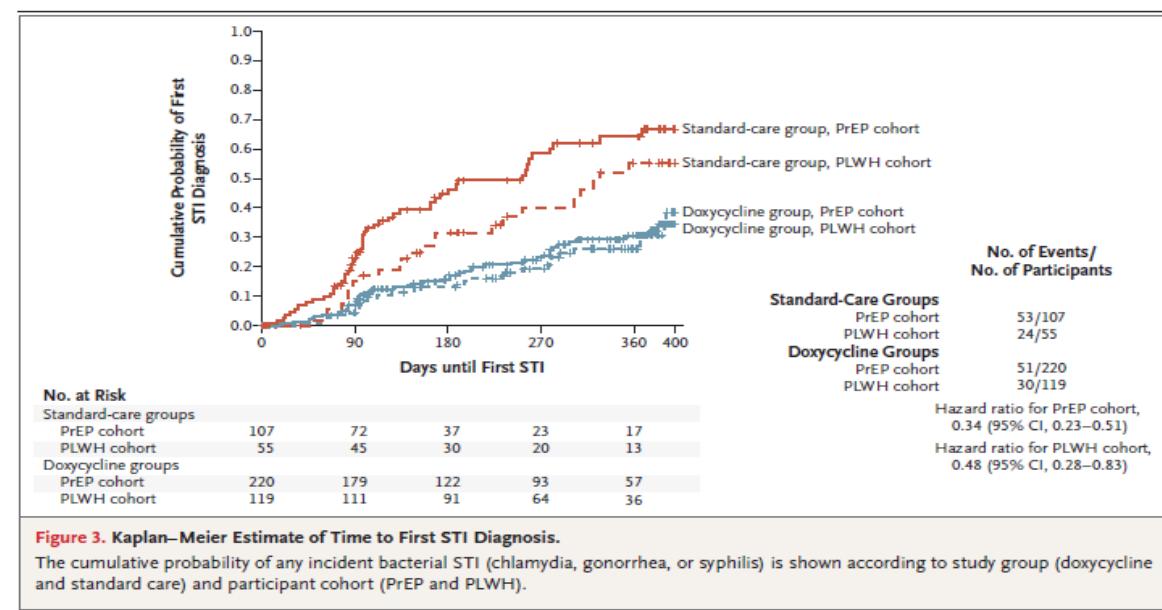
STIs	Doxy		Doxy	
Gonorrhea	9.1%	20.2%	8.9%	20.3%
C.trachomatis	1.4%	12.1%	3.9%	14.8%
Syphilis	0.4%	2.7%	0.7%	2.3%

Population

- PrEP user (n 432, median age 36 yr)
- PLHIV (N=209, median age 42 yr)

Sexual pattern: median 9 partners in 3 month

History of STIs in past 12 months: GC (68%), CT (58%), Sy (20%)



Communication of HIV prevention

Put people first approach, empowerment

Communications have shifted from risk to empowerment framing

There has been a **significant shift in communications** for OCP/PrEP from risk-based motivations, towards more positive motivations such as empowerment, relationship building and choice.



Slide from Jessica Rodrigues, AVAC. July 2022

Take home message: HIV/STDs prevention

- Say zero transmission: Treatment as Prevention
- Offer more HIV testing in different settings, include HIV-self test
- Provide “pre-exposure prophylaxis” for HIV/STIs
 - Condom
 - Antiretroviral drugs: once daily, event-driven, long acting injectable
 - Antibiotics: DoxyPEP ?
 - Microbicide: dapivirine ring, rectal microbicide
- Service delivery: on-line, on-site comprehensive care /collaborative care