Advances in HIV Prevention: Are You PrEP-ared?

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Conflicts of Interest

- I have no conflicts of interest to disclose

Learning Objectives

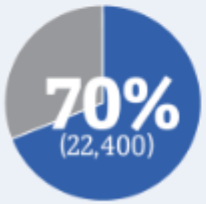
- Identify best practices for HIV pre-exposure prophylaxis
- Describe the clinical studies of the efficacy of current oral and long-acting HIV pre-exposure modalities
- Forecast the future of HIV pre-exposure prophylaxis options

Towards HIV prevention…

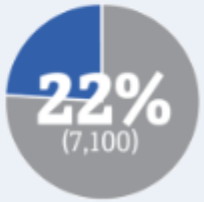
Ending the HIV Epidemic

Overall Goal: Decrease the estimated number of new HIV infections to 9,300 by 2025 and 3,000 by 2030.

There were **32,100 estimated new HIV infections** in the US in 2021. Of those:



were among gay, bisexual, and other men who reported male-to-male sexual contact*



were among people who reported heterosexual contact

were among people who inject drugs

*Includes infections attributed to male-to-male sexual contact *and* injection drug use (men who reported both risk factors).

ONLY

Of the 1.2 million people in the United States who could benefit from PrEP, only 30% were prescribed PrEP in 2021.

https://www.cdc.gov/hiv/statistics/overview/in-us/incidence.html

HIV Epidemiology

- 3 modes of transmission
  - Sexual transmission – most common
  - Perinatal infection – primary cause of pediatric infection
  - Parenteral transmission – injection drug use, blood products, etc.

Pre-Exposure Prophylaxis (PrEP) Overview

- PrEP – medication to prevent HIV acquisition for those at high/very high risk for HIV
- Goal of PrEP – To prevent the acquisition of HIV infection with its resulting morbidity, mortality, and cost to individuals and society

Who should receive PrEP?

- Anal or vaginal sex in past 6 months and any of the following:
  - HIV-positive sexual partner (or unknown or detectable viral load)
  - Bacterial STI in past 6 months
  - History of inconsistent or no condom use with sexual partner(s)
- HIV-positive injecting partner OR sharing injection equipment

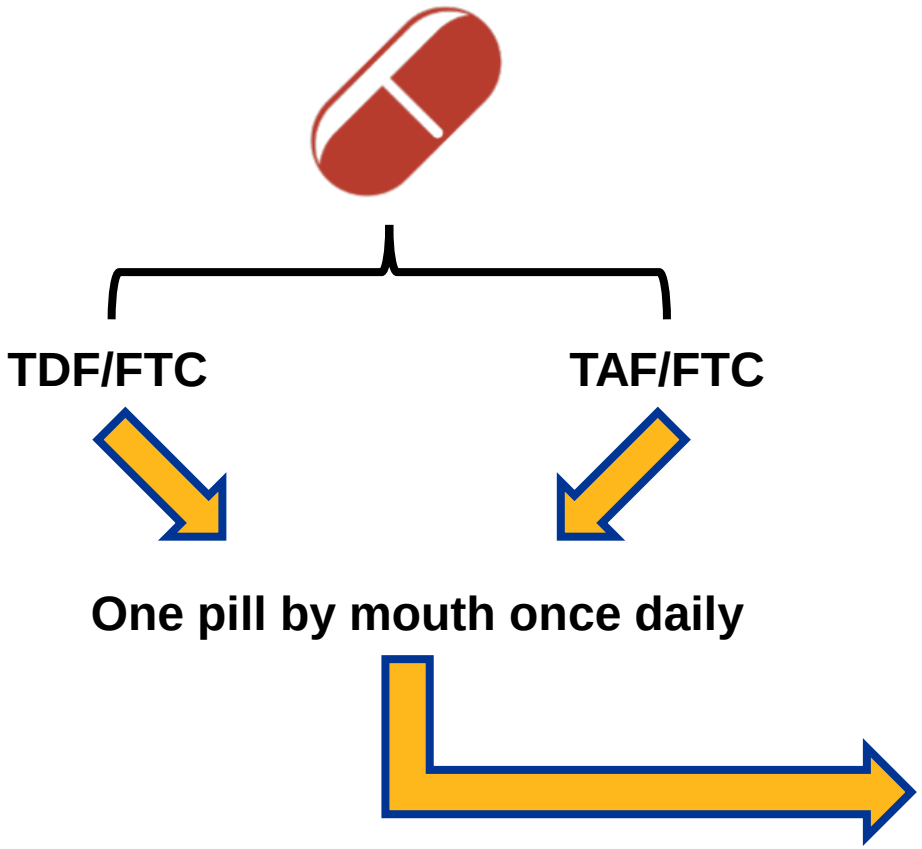
PrEP – What to Start

Regimen	Dosing	Population(s)
TDF/FTC	300/200 mg by mouth daily	All

PrEP – What to Start

Regimen	Dosing	Population(s)
TDF/FTC	300/200 mg by mouth daily	All
TAF/FTC	25/200 mg by mouth daily	MSM, transgender women

Adherence to PrEP = Effectiveness of PrEP



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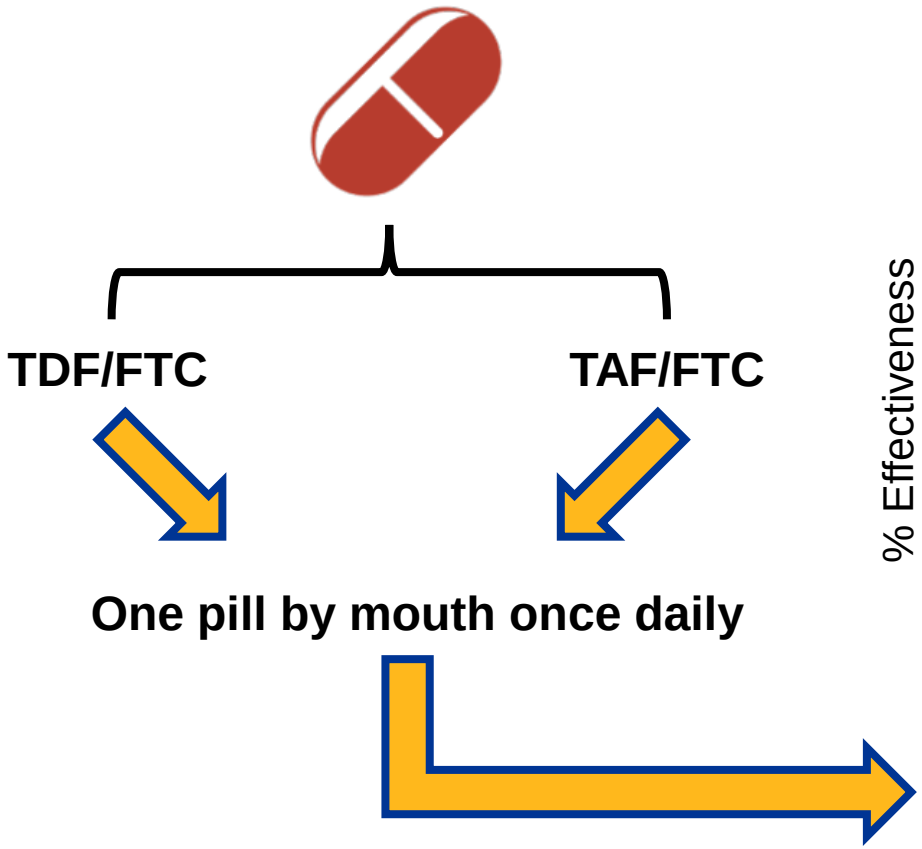

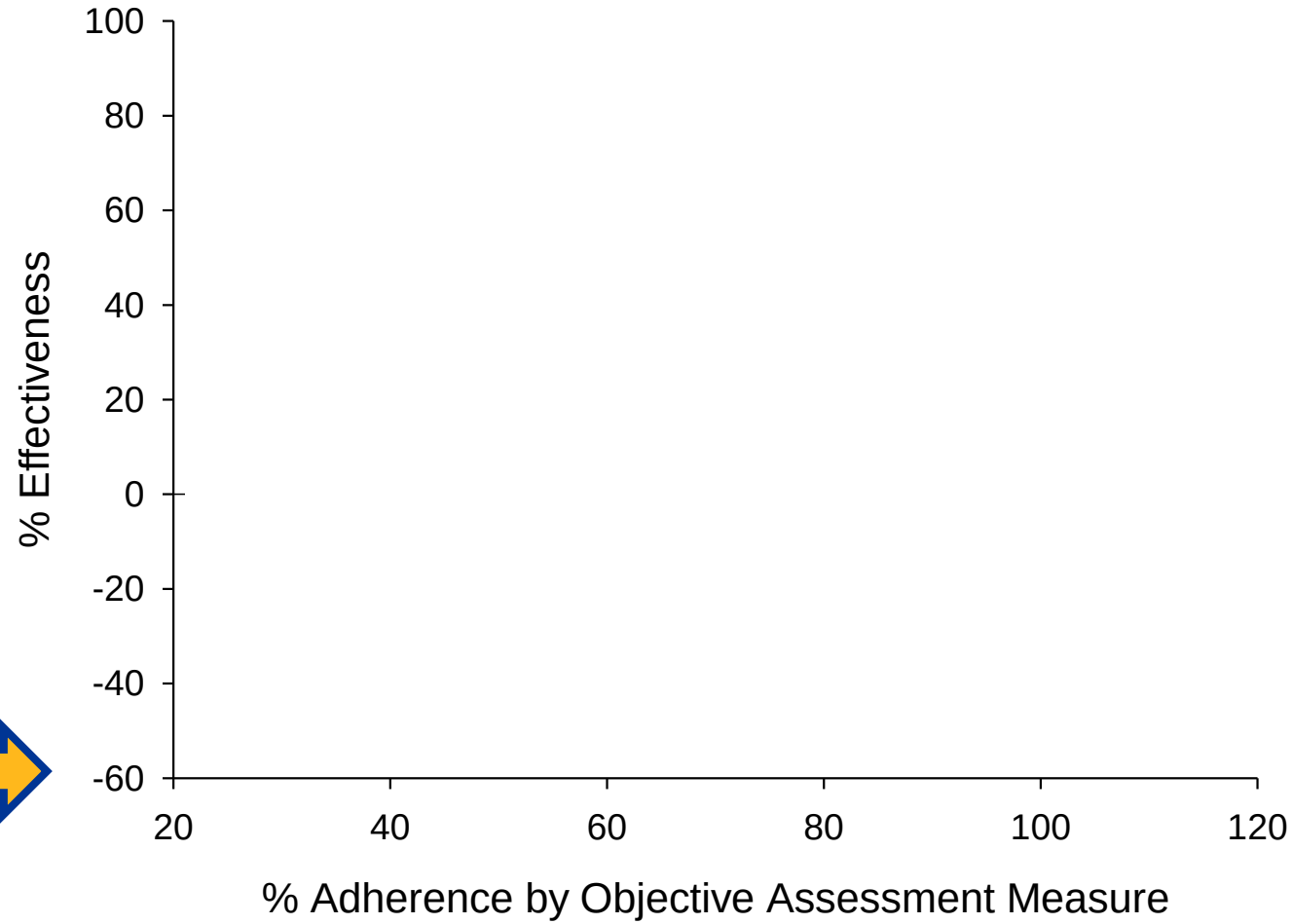

Plot adapted from Landovitz R. *PrEP for HIV Prevention: What We Know and What We Still Need to Know for Implementation*. CROI 2015.
Statistics: Pearson correlation of extracted data using PlotDigitizer v2.6.8.

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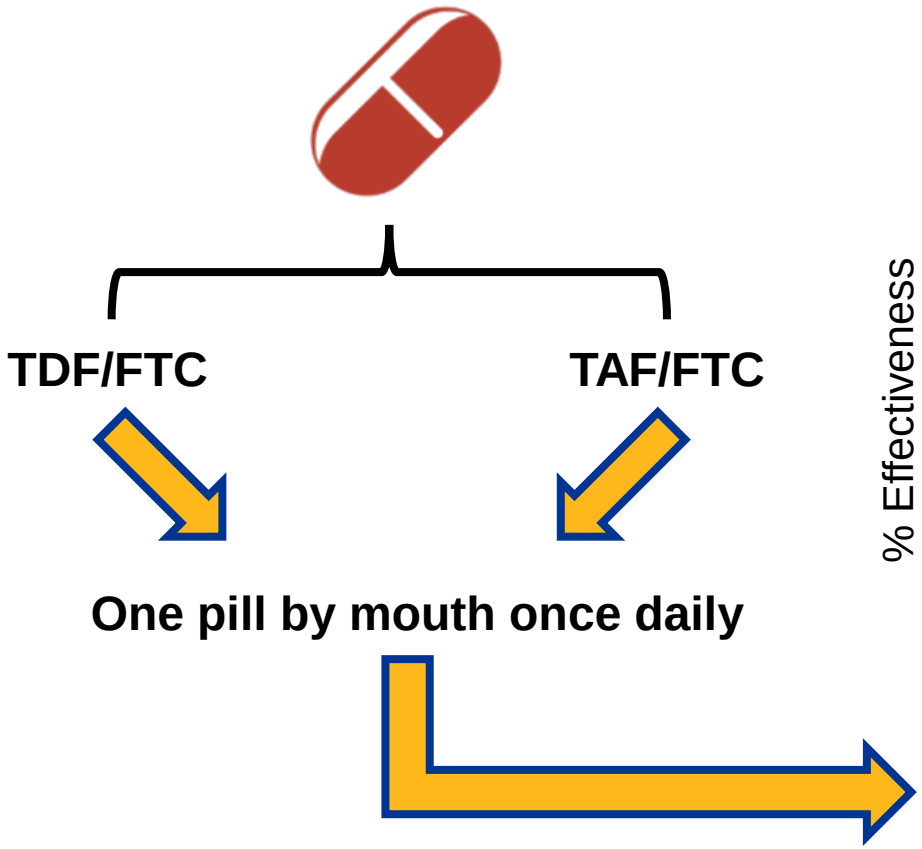

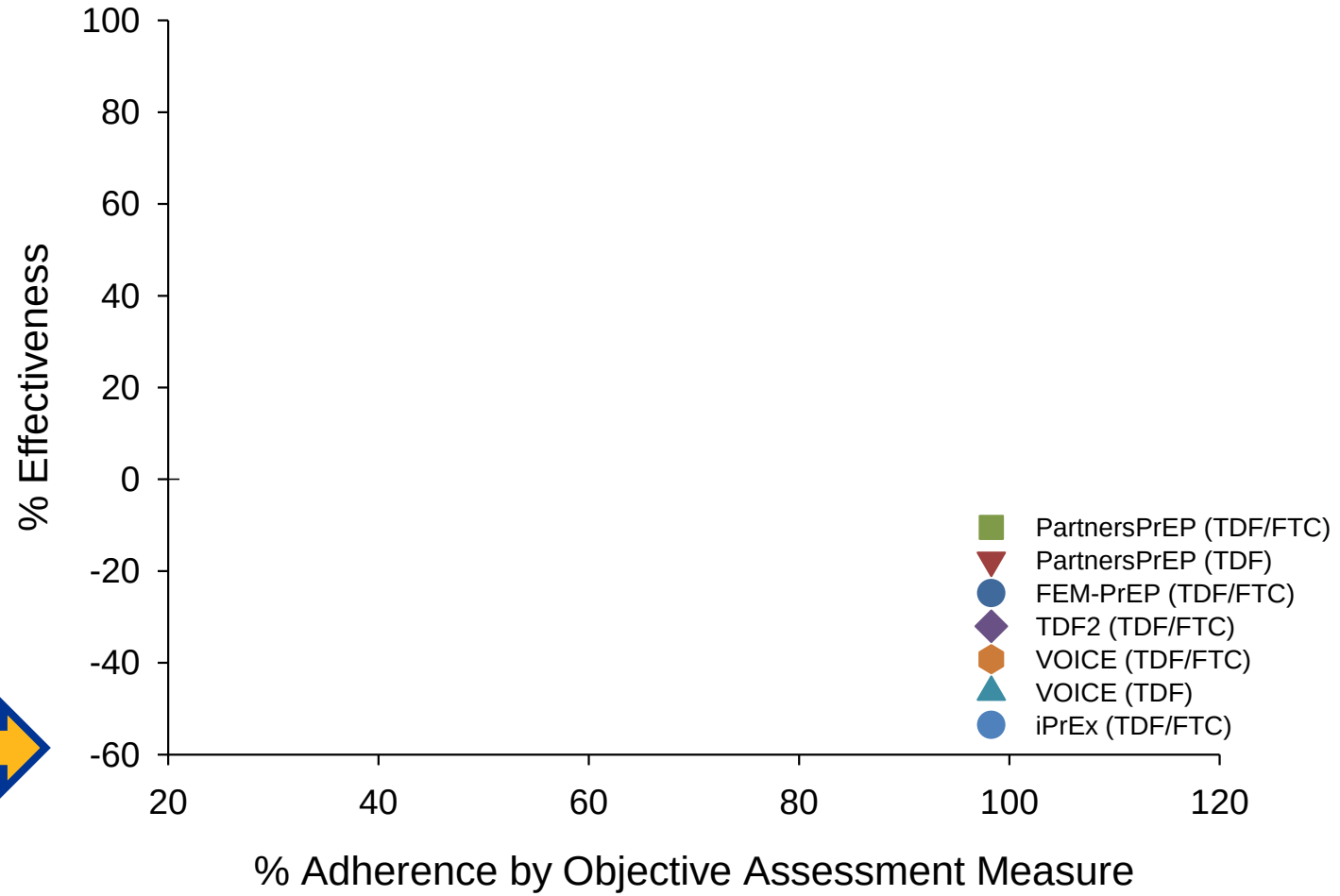

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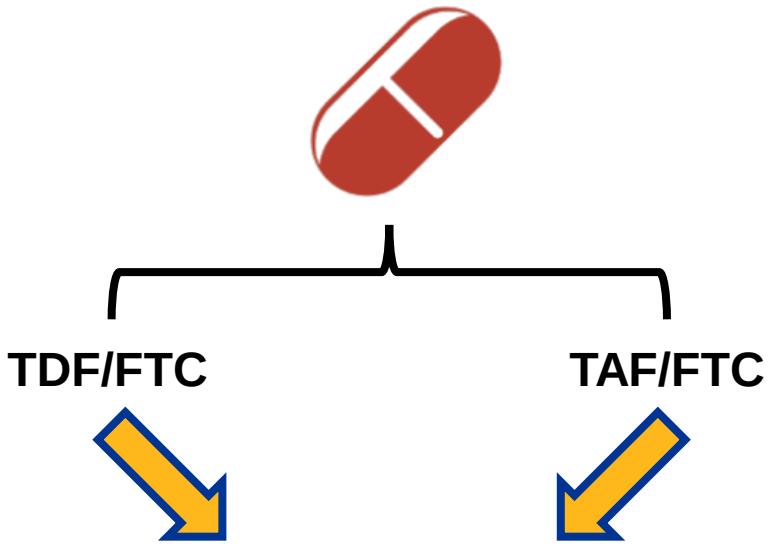

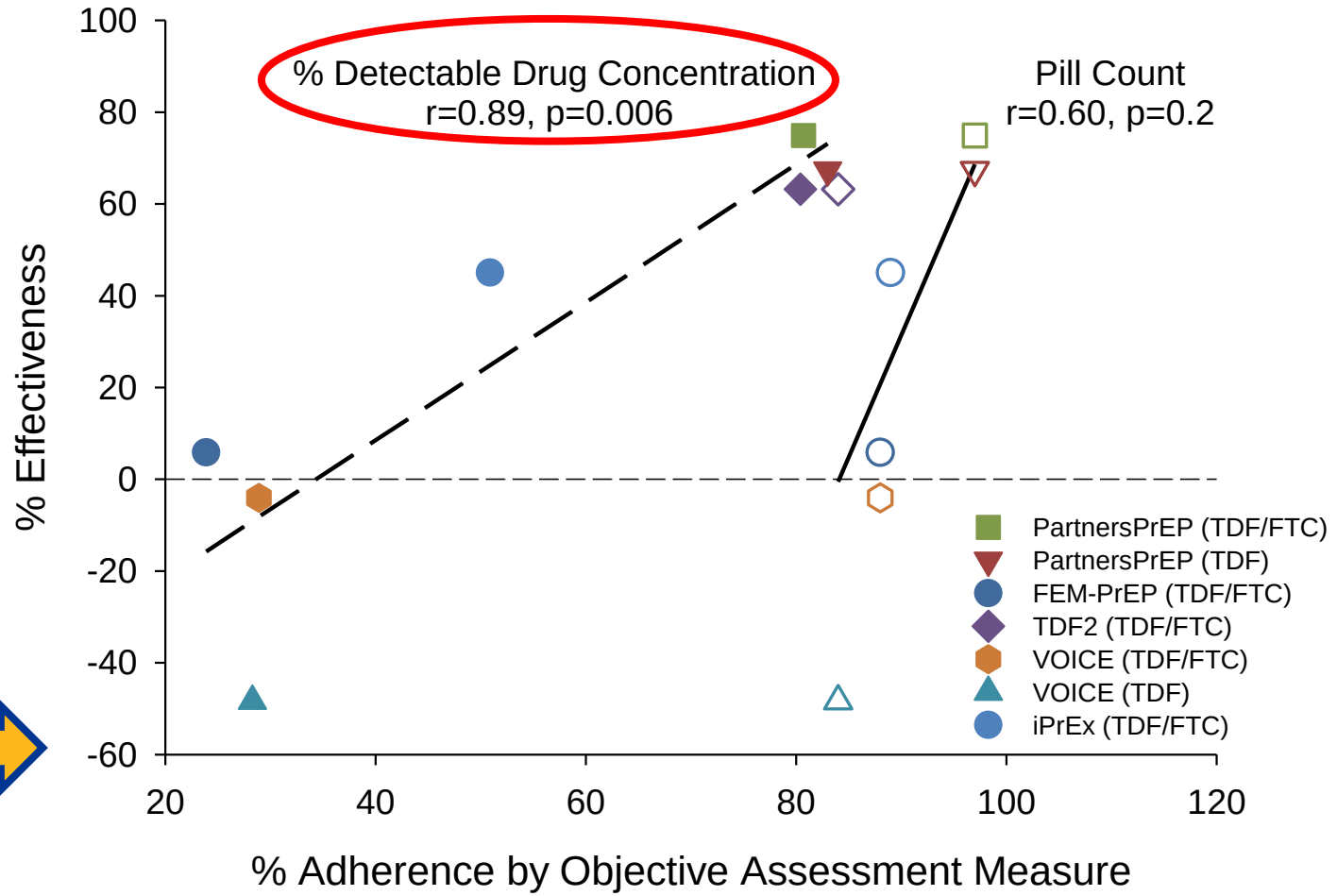

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Self-Assessment Question #1

- True or False: Intravenous drug use and sharing injection equipment is the most common form of HIV transmission

A. TRUE

B. FALSE

Long-acting formulations for PrEP

Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women

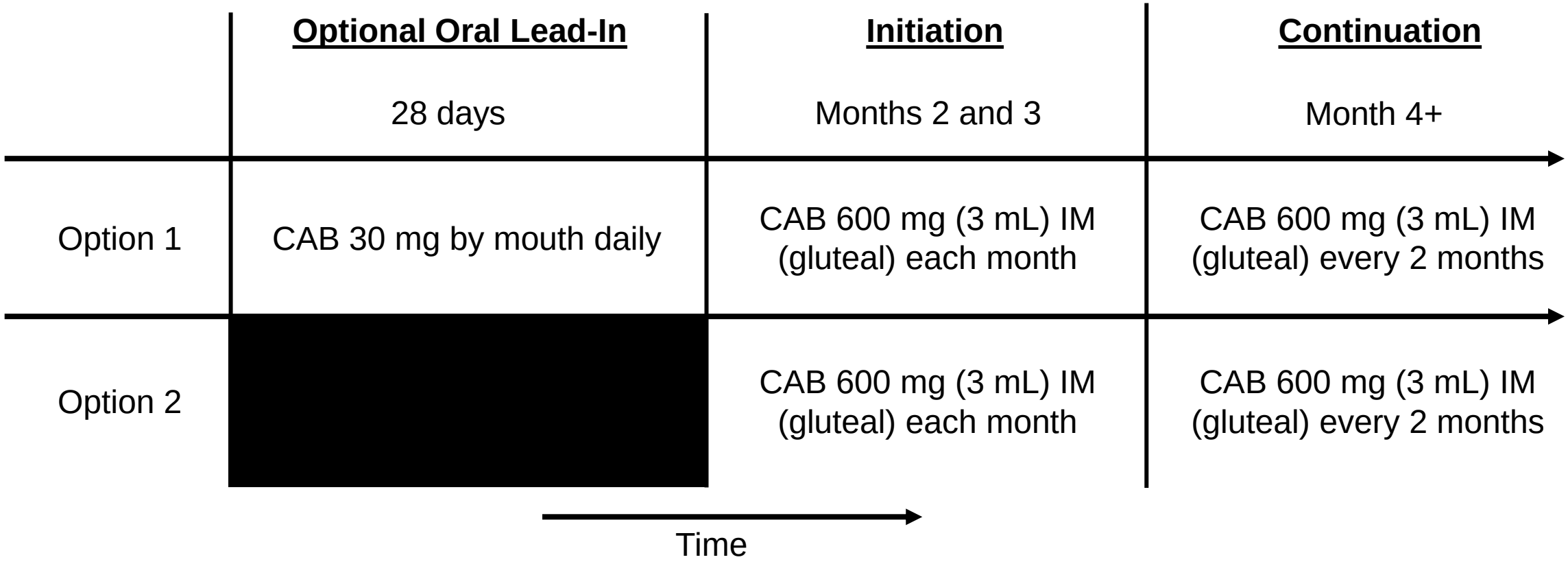
R.J. Landovitz, D. Donnell, M.E. Clement, B. Hanscom, L. Cottle, L. Coelho, R. Cabello, S. Chariyalertsak, E.F. Dunne, I. Frank, J.A. Gallardo-Cartagena, A.H. Gaur, P. Gonzales, H.V. Tran, J.C. Hinojosa, E.G. Kallas, C.F. Kelley, M.H. Losso, J.V. Madruga, K. Middelkoop, N. Phanuphak, B. Santos, O. Sued, J. Valencia Huamaní, E.T. Overton, S. Swaminathan, C. del Rio, R.M. Gulick, P. Richardson, P. Sullivan, E. Piyowar Manning, M. Marzinke, C. Hendrix, M. Li, Z. Wang, J. Marrazzo, E. Daar, A. A[illegible] M. Bryan, C. Blanchette, J. Lucas, [illegible] S.D. Fields, N.D. Sista, K. Gome[illegible] K. Shin, J.F. Rooney, K.Y. Smith, M.S. Cohen, M. McCauley, an[illegible]

Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, a phase 3, randomised clinical trial

Sinead Delany-Moretlwe, James P Hughes, Peter Bock, Samuel Gurrion Ouma, Portia Hunidzarira, Dishiki Kalonji, Noel Kayange, Joseph Makhema, Patricia Mandima, Carrie Mathew, Elizabeth Spooner, Juliet Mpendo, Pamela Mukwekwerere, Nyaradzo Mgodi, Patricia Nahirya Ntege, Gonasagrie Nair, Clemensia Nakabiito, Harriet Nuwagaba-Biribonwoha, Ravindre Panchia, Nishanta Singh, Bekezela Siziba, Jennifer Farrior, Scott Rose, Peter L Anderson, Susan H Eshleman, Mark A Marzinke, Craig W Hendrix, Stephanie Beigel-Orme, Sybil Hosek, Elizabeth Tolley, Nirupama Sista, Adeola Adeyeye, James F Rooney, Alex Rinehart, William R Spreen, Kimberly Smith, Brett Hanscom, Myron S Cohen, Mina C Hosseinipour, on behalf of the HPTN 084 study group

Cabotegravir (CAB)

CAB Dosing Scheme for Prevention



https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215499s000lbl.pdf (Page 3-5; also for missing doses)

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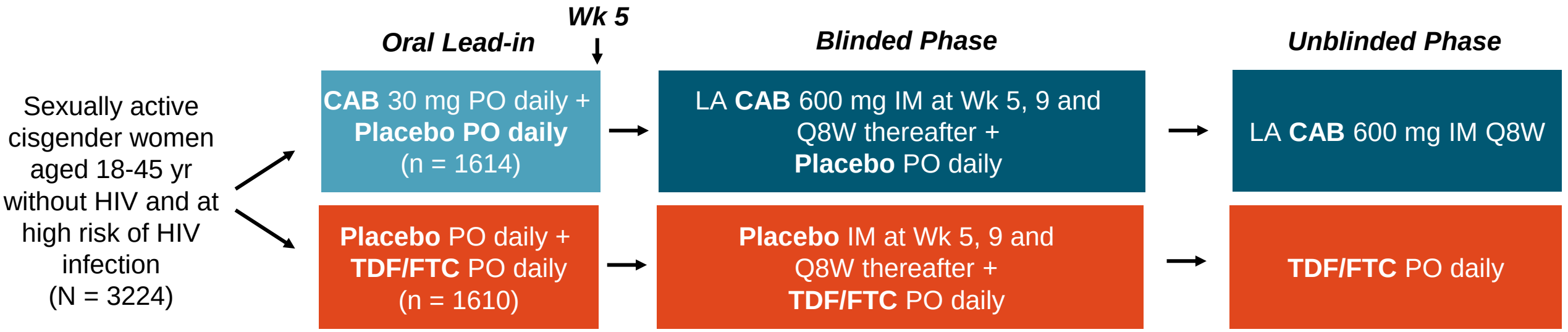
Delaney-Moretlwe et al. *The Lancet*, 399:10337:1779-1789. PMID: 35378077

HPTN 084 - Study Design



The primary efficacy endpoint was **HIV incidence**

Adapted from clinicaloptions.com
Delaney-Moretlwe et al. *The Lancet,* 399:10337:1779-1789. PMID: 35378077

HPTN 084 - Baseline characteristics

	Cabotegravir group (N=1614)	TDF-FTC group (N=1610)
Age, years	25 (22-30)	25 (22-30)
BMI ≥30 kg/m^2	28.8%	26.8%
Chlamydia trachomatis, %	20.2%	17.6%
Neisseria gonorrhoeae, %	7.0%	6.2%

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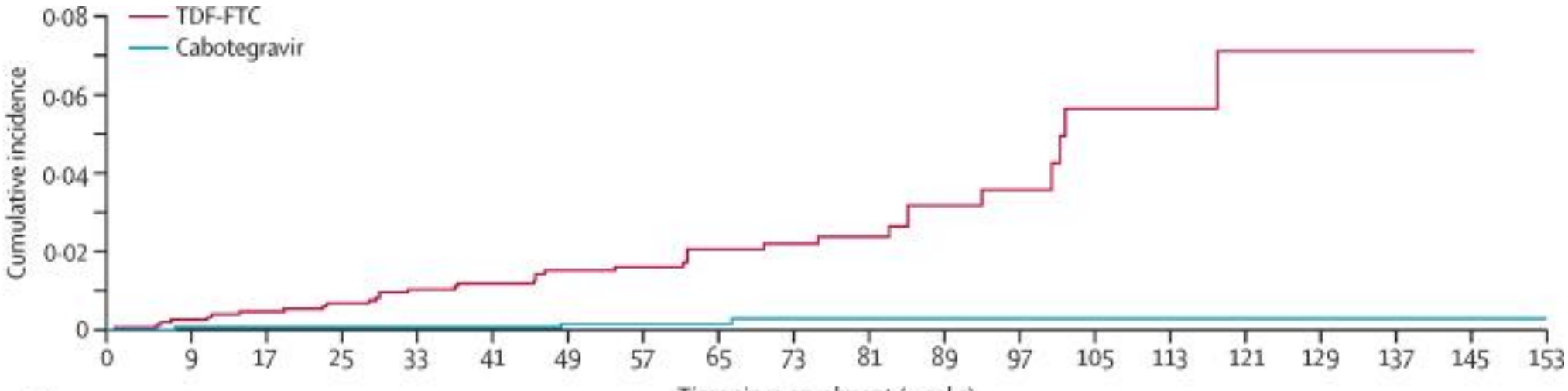
HPTN 084 - Incidence rates

	Events per total PY in CAB group	Events per total PY in TDF-FTC group	HR (95% CI)	P-value
Overall	4/1956 (0.20%)	36/1942 (1.85%)	0.12 (0.05-0.31)	**<0.0001**

Participants in the cabotegravir group had an 88% lower risk of HIV infection compared with those in the TDF-FTC group.

Delaney-Moretlwe et al. *The Lancet,* 399:10337:1779-1789. PMID: 35378077

HPTN 084 - Cumulative incidence



Number at risk																				
TDF-FTC	1610	1490	1429	1410	1353	1260	1160	984	800	656	485	306	201	115	70	63	52	22	3	0
Cabotegravir	1614	1488	1441	1429	1371	1279	1181	988	801	647	482	304	204	116	67	58	50	23	3	2
Cumulative number of events																				
TDF-FTC	0	4	7	10	15	17	21	22	26	27	28	31	32	35	35	36	36	36	36	36
Cabotegravir	0	1	1	1	2	2	3	3	3	4	4	4	4	4	4	4	4	4	4	4

Delaney-Moretlwe et al. *The Lancet,* 399:10337:1779-1789. PMID: 35378077

HPTN 084 - Adherence

Cabotegravir group

- 1678/1805 (93.0%) person-years on study were covered by injections (e.g. cabotegravir injections were received on time or with a delay of less than 2 weeks)

TDF-FTC group

- 405 randomly selected participants
- 1084/1939 (55.9%) samples yielded quantifiable TFV concentrations (≥0.31 ng/mL)
- 812/1939 (41.9%) had TFV concentrations consistent with daily use (≥40 ng/mL)
- Intraerythrocytic tenofovir diphosphate concentrations had unquantifiable concentrations observed in 456/1197 (38.1%) of dried blood spot samples
- 215/1197 (18%) concentrations consistent with at least four doses per week over the past month (≥ 700 fmol/punch)

Delaney-Moretlwe et al. *The Lancet,* 399:10337:1779-1789. PMID: 35378077

HPTN 084 - Adverse effects

- No major integrase strand transfer inhibitor resistance mutations in any of the four infections observed in the cabotegravir group
- 38.0% in cabotegravir group experienced injection site reactions
  - 12.6% in cabotegravir group experienced Grade 2 injection site reaction

HPTN 084 - Authors' conclusions

- Cabotegravir was superior to TDF-FTC in preventing HIV infection in women while being safe and well-tolerated

FDA NEWS RELEASE

FDA Approves First Injectable Treatment for HIV Pre-Exposure Prevention

Drug Given Every Two Months Rather Than Daily Pill is Important Tool in Effort to End the HIV Epidemic

For Immediate Release: December 20, 2021

Self-Assessment Question #1

- True or False: Long-acting cabotegravir for PrEP requires a 28-day oral lead-in period

A. TRUE

B. FALSE

Long-acting formulations for PrEP

Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women

L.-G. Bekker, M. Das, Q. Abdool Karim, K. Ahmed, J. Batting, W. Brumskine, K. Gill, I. Harkoo, M. Jaggernath, G. Kigozi, N. Kiwanuka, P. Kotze, L. Lebina, C.E. Louw, M. Malahleha, M. Manentsa, L.E. Mansoor, D. Moodley, V. Naicker, L. Naidoo, M. Naid
P. Selepe, N. Singh, Y. Singh, I
C.C. Carter, J.M. Ba

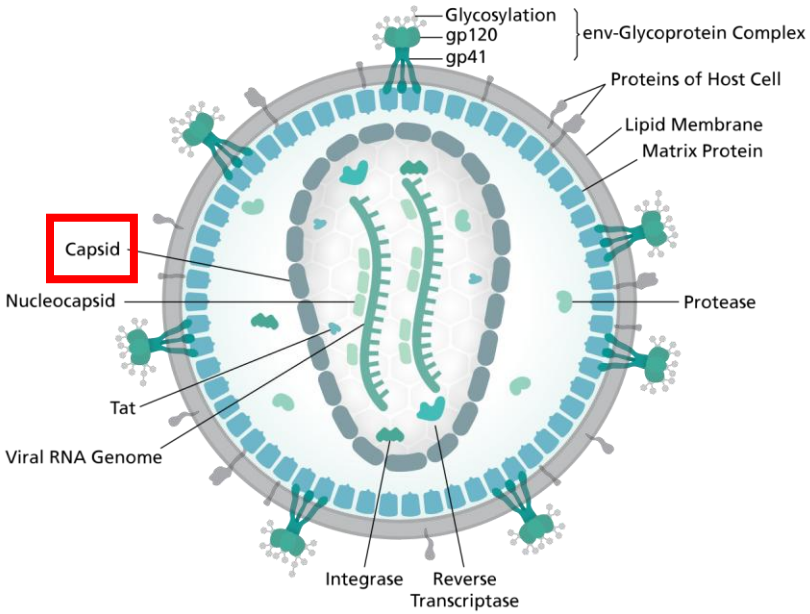
Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons

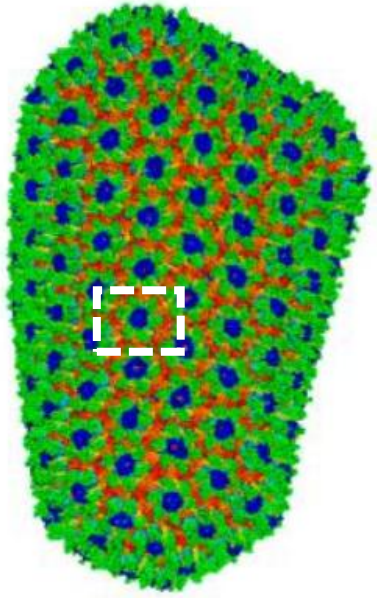
C.F. Kelley,[1,2] M. Acevedo-Quiñones,[3] A.L. Agwu,[4] A. Avihingsanon,[5] P. Benson,[6] J. Blumenthal,[7] C. Brinson,[8] C. Brites,[9] P. Cahn,[10] V.D. Cantos,[11] J. Clark,[12] M. Clement,[13] C. Creticos,[14] G. Crofoot,[15] R.S. Diaz,[16] S. Doblecki-Lewis,[17] J.A. Gallardo-Cartagena,[18] A. Gaur,[19] B. Grinsztejn,[20] S. Hassler,[21] J.C. Hinojosa,[22] T. Hodge,[23] R. Kaplan,[24] M. Lacerda,[25] A. LaMarca,[26] M.H. Losso,[27] J. Valdez Madruga,[28] K.H. Mayer,[29] A. Mills,[30] K. Mounzer,[31] N. Ndlovu,[32] R.M. Novak,[33] A. Perez Rios,[34] N. Phanuphak,[35] M. Ramgopal,[36] P.J. Ruane,[37] J. Sánchez,[18] B. Santos,[38] P. Schine,[39] T. Schreibman,[40] L.S.Y. Spencer,[41] O.T. Van Gerwen,[42] R. Vasconcelos,[43] J.G. Vasquez,[44] Z. Zwane,[45] S. Cox,[46] C. Deaton,[47] R. Ebrahimi,[46] P. Wong,[46] R. Singh,[46] L.B. Brown,[46] C.C. Carter,[46] M. Das,[46] J.M. Baeten,[46] and O. Ogbuagu,[48] for the PURPOSE 2 Study Team*

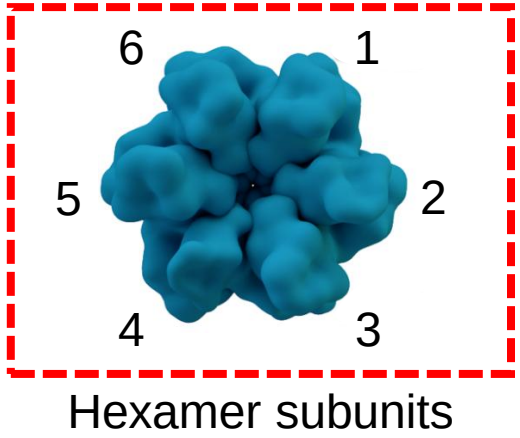
Lenacapavir (LEN)

Capsid Inhibitor Overview

- Capsid inhibitors bind to the interface between capsid protein (p24) subunit hexamers







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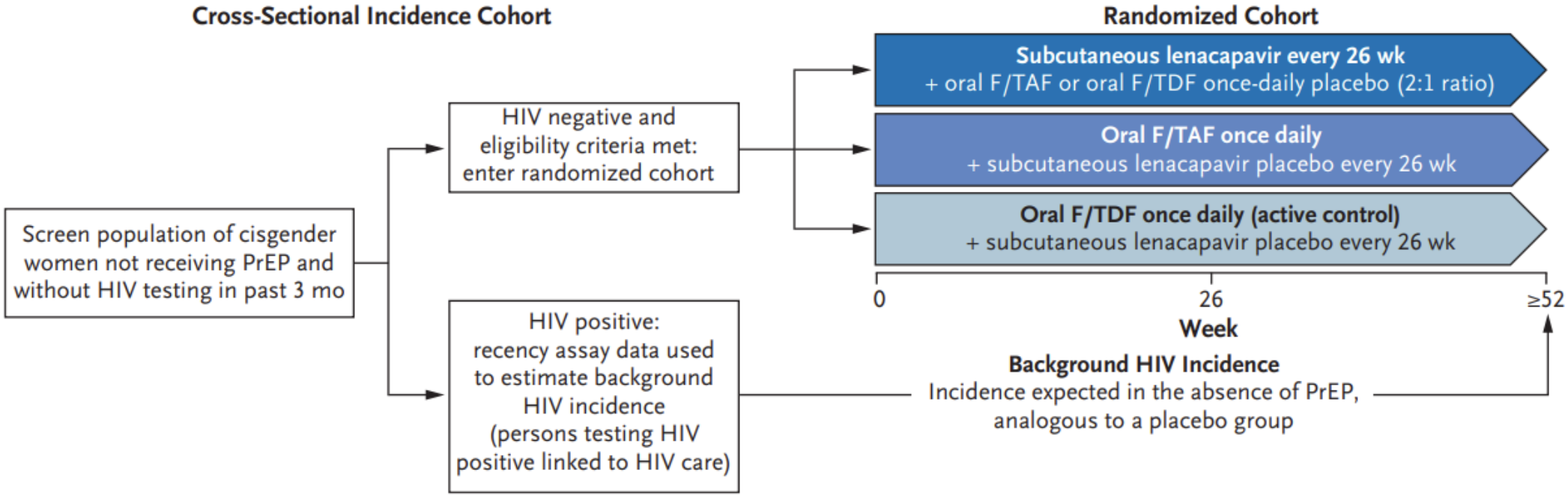
Bekker et al *N Engl J Med* 2024;391:1179-1192. PMID: 39046157

PURPOSE 1 - Study Design



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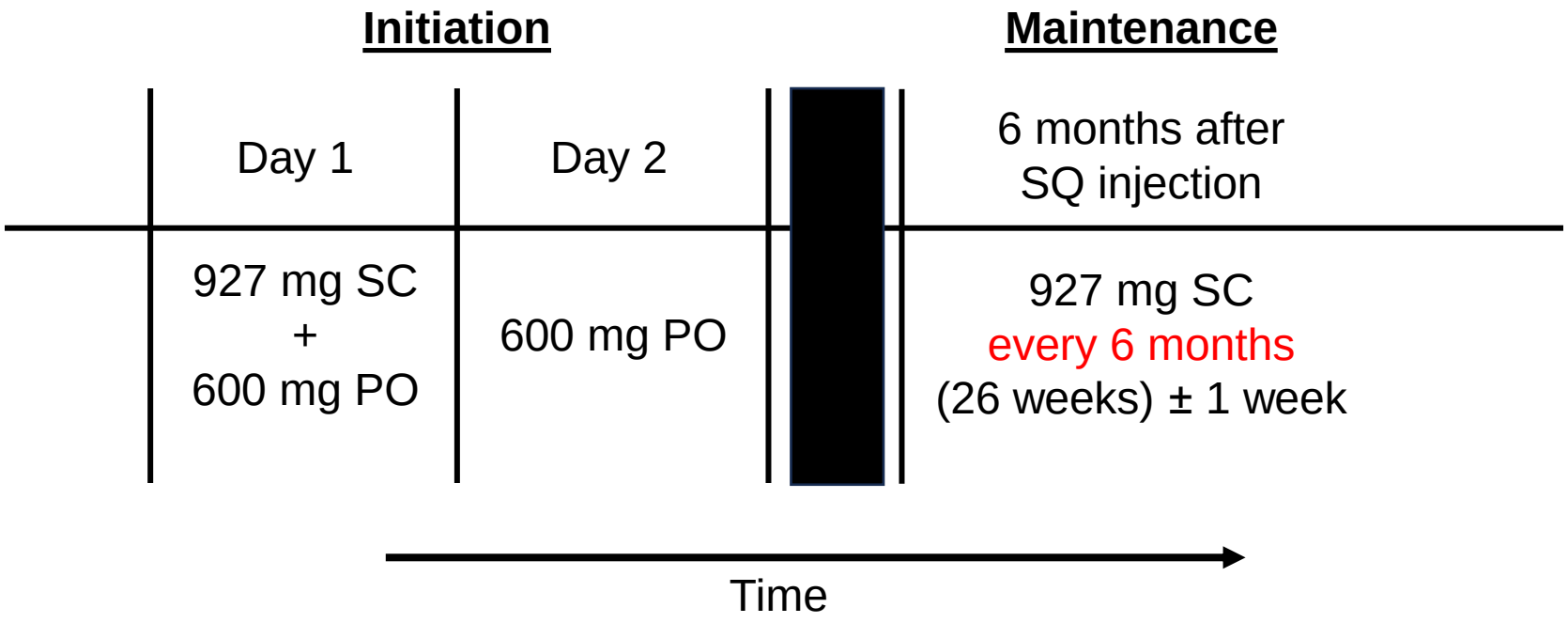
Lenacapavir Dosing Scheme



PURPOSE 1 - Baseline characteristics

	Lenacapavir (N=2138)	F/TAF group (N=2137)	F/TDF (N=1070)
Age, years	21 (16-25)	21 (16-26)	21 (16-25)
Black race (%)	99.9%	>99.9%	99.8%
Chlamydia trachomatis, %	24.3%	26.3%	24.6%
Neisseria gonorrhoeae, %	9.2%	8.3%	8.4%

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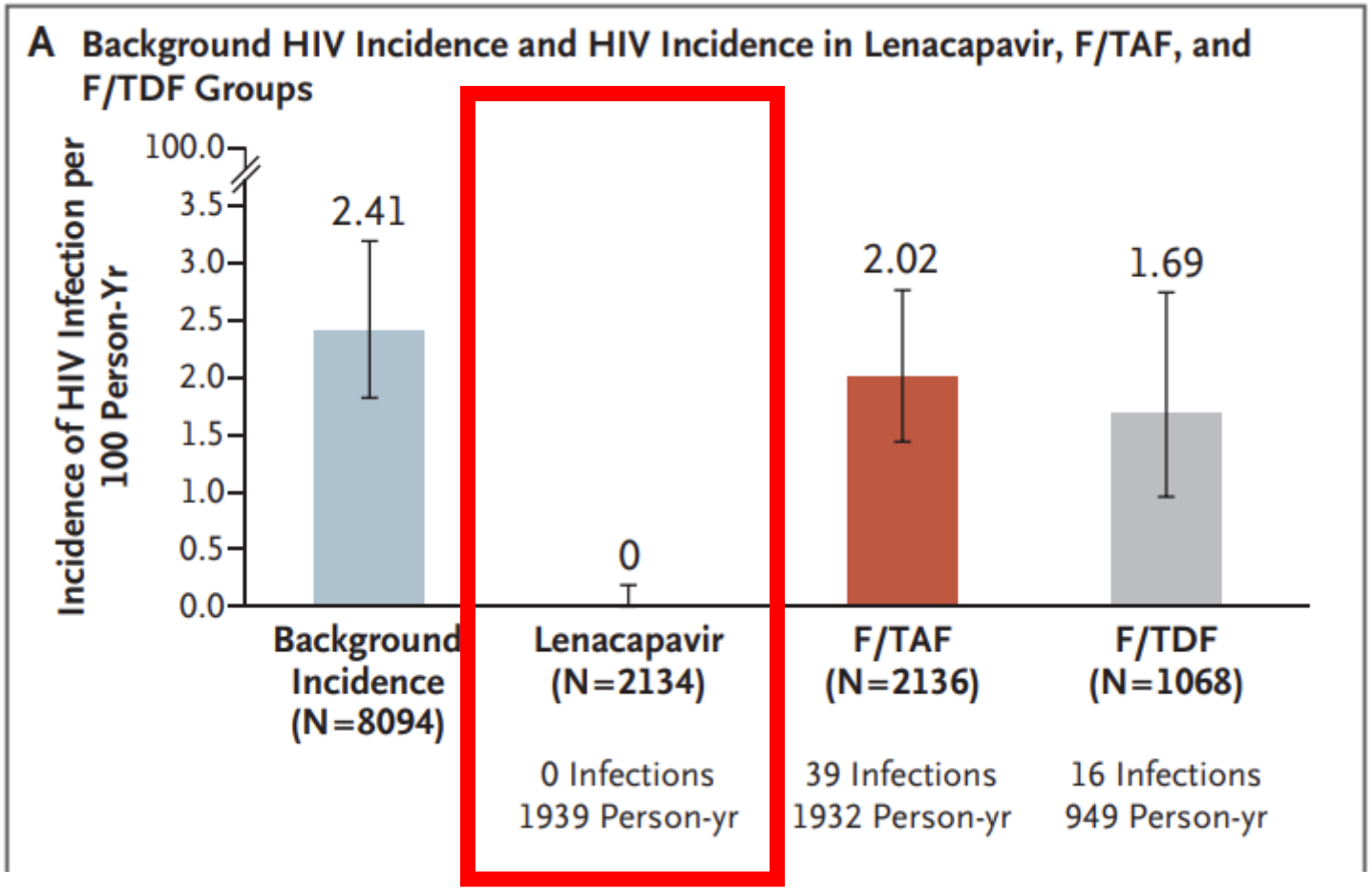
PURPOSE 1 - Incidence rates



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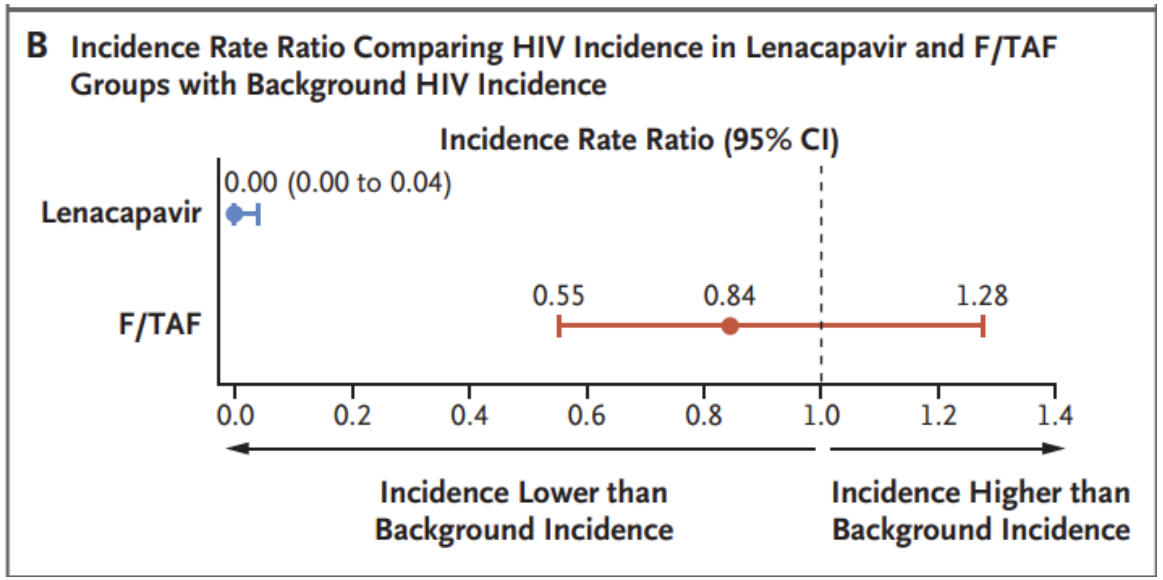
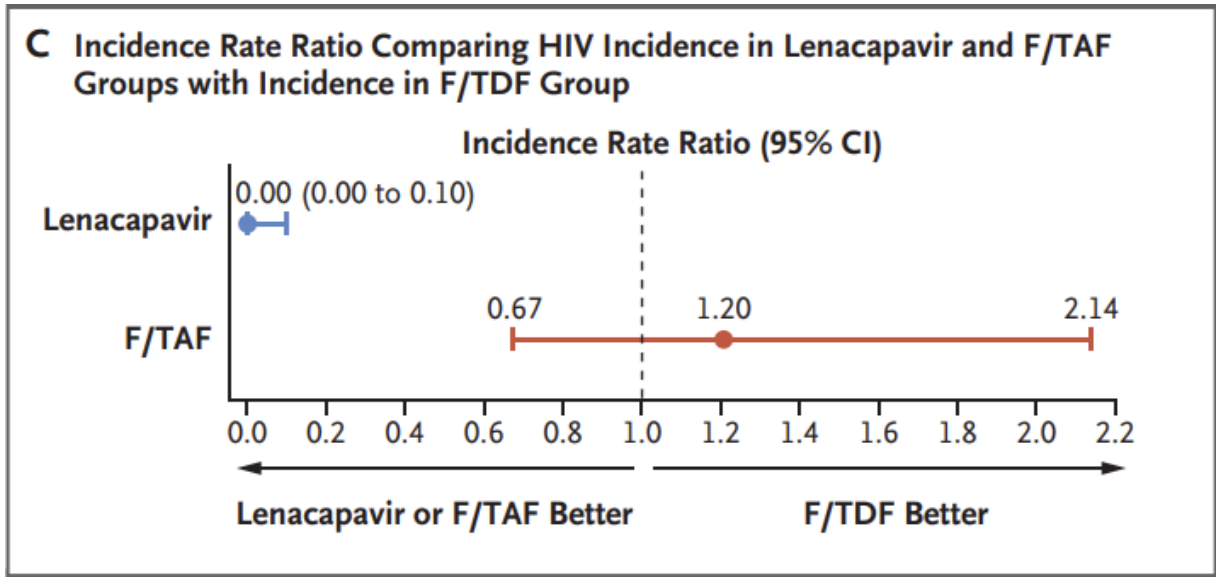
PURPOSE 1 - Incidence rate ratios





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PURPOSE 1 - Adherence

Lenacapavir group

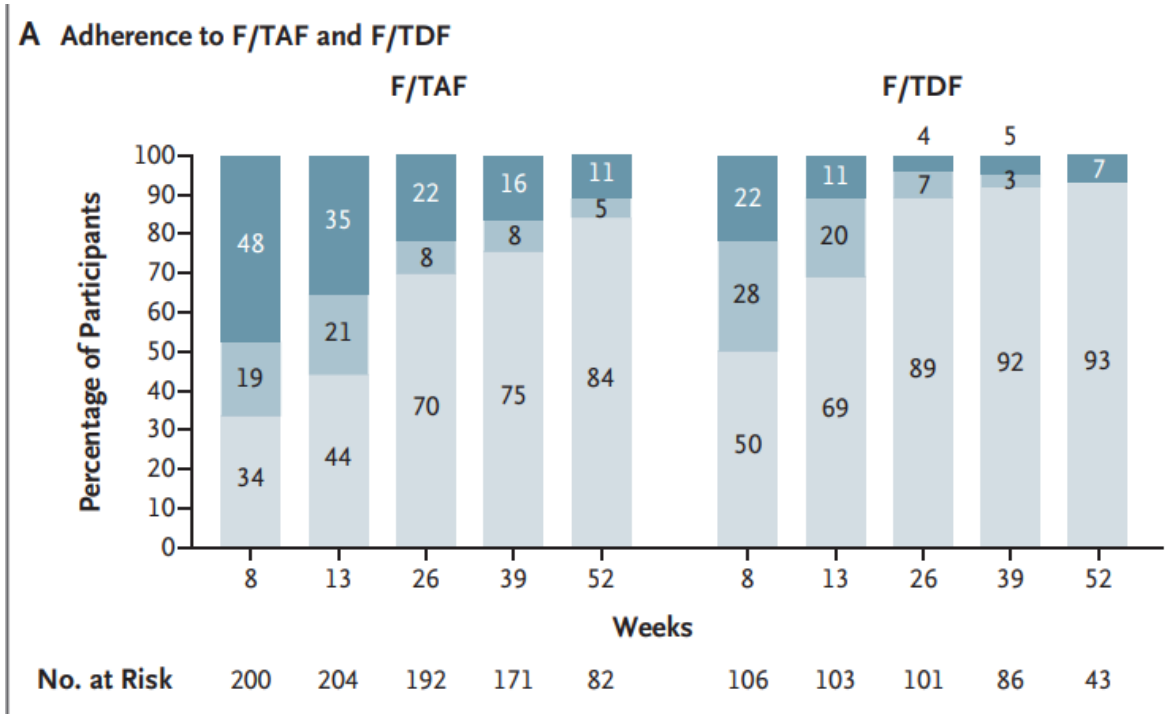
- Injections administered on time for 4545/4967 participants (**91.5%**) at week 26 and 2025/2182 participants (**92.8%**) at week 52
- Percentages similar across three groups

Table S5. Adherence Level Definitions Based on DBS Concentration

	Adherence Level (Daily Tablets/Week)		
	Low (<2)	**Medium (2-3)**	**High (≥4)**
F/TDF (fmol/Punch)	< 350	350 to < 700	≥ 700
F/TAF (fmol/Punches)	< 450	450 to < 900	≥ 900

F/TAF and F/TDF groups

- 10% randomly selected participants



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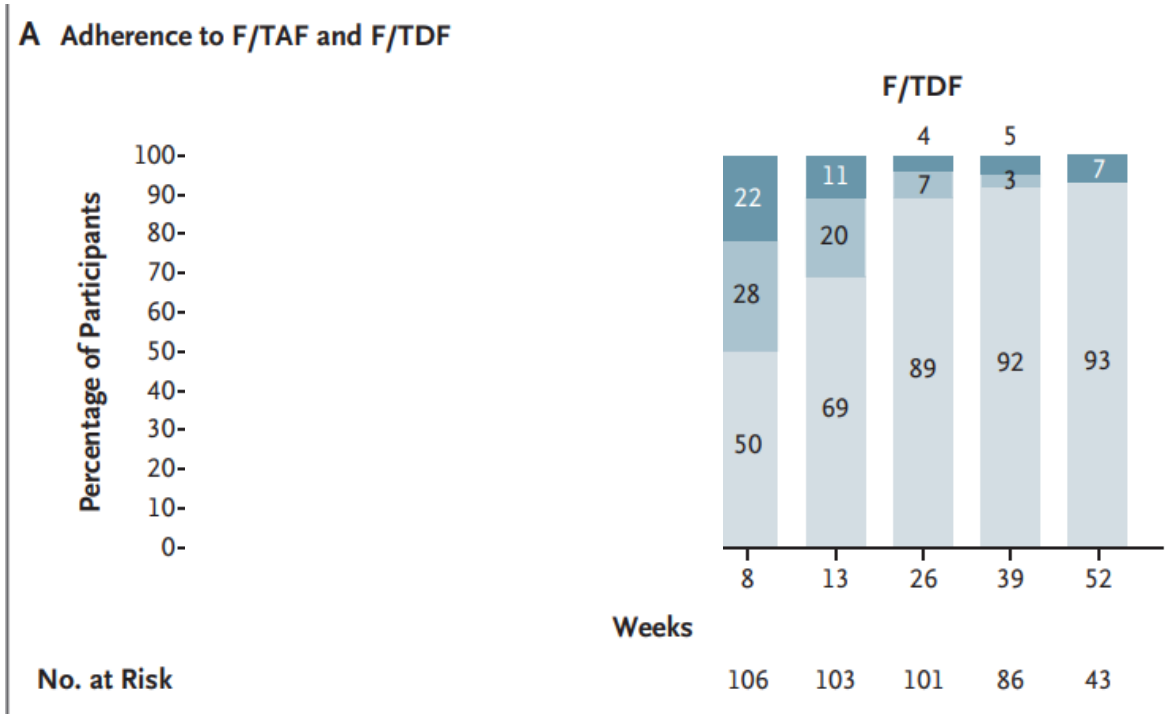

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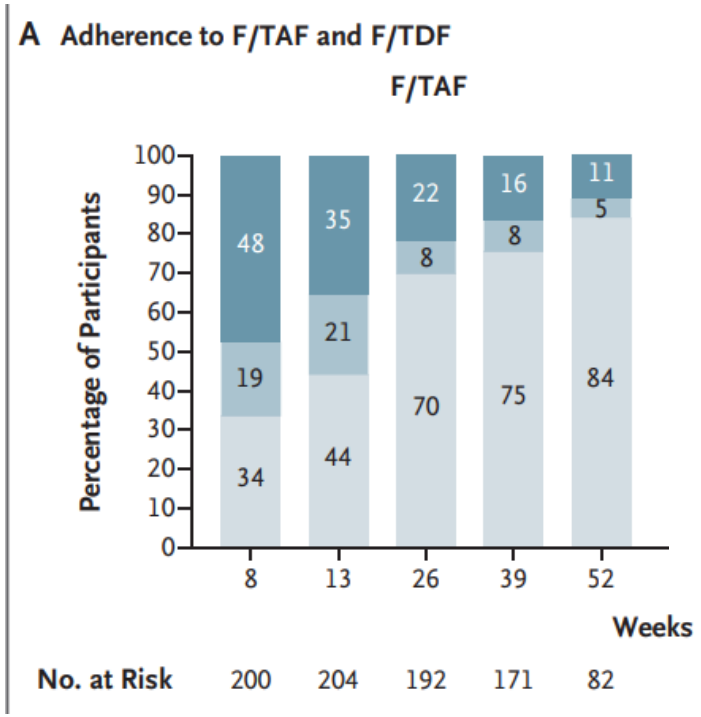

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PURPOSE 1 - Adverse effects

- 68.8% in lenacapavir group experienced injection site reactions
  - 19.0% in lenacapavir group experienced Grade 2 injection site reaction

PURPOSE 1 - Authors' conclusions

- HIV incidence was significantly lower with lenacapavir compared to background HIV incidence and HIV incidence with standard-of-care F/TDF

Self-Assessment Question #1

- Lenacapavir is a capsid inhibitor that is dosed subcutaneously at what frequency?

A. Every 2 months

B. Every 3 months

C. Every 6 months

D. Every 12 months

The Future of PrEP

Phase 1	Phase 2	Phase 3
Cabotegravir (subcutaneous; every 4 months)	PURPOSE 3	PURPOSE 1
Tenofovir-containing rectal douche	PURPOSE 4	PURPOSE 2
	PURPOSE 5	Dapivirine intravaginal ring
	VRC01	Cabotegravir IM (thigh)
	CAP256V2LS and VRC07-523LS	

The Future of PrEP

December 19, 2024

Gilead Submits New Drug Application to U.S. Food and Drug Administration for Twice-Yearly Lenacapavir for HIV Prevention

https://www.gilead.com/company/company-statements/2024/gilead-submits-new-drug-application-to-us-food-and-drug-administration-for-twice-yearly-lenacapavir-for-hiv-prevention

February 18, 2025

U.S. FDA Accepts Gilead's New Drug Applications for Twice-Yearly Lenacapavir for HIV Prevention Under Priority Review

https://www.gilead.com/news/news-details/2025/us-fda-accepts-gileads-new-drug-applications-for-twice-yearly-lenacapavir-for-hiv-prevention-under-priority-review

February 24, 2025

European Medicines Agency Validates Gilead's Marketing Authorization Application and EU-Medicines for All Application for Twice-Yearly Lenacapavir for HIV Prevention

https://www.gilead.com/news/news-details/2025/european-medicines-agency-validates-gileads-marketing-authorization-application-and-eu-medicines-for-all-application-for-twice-yearly-lenacapavir-for-hiv-prevention

Factors Influencing Adherence to Injectable PrEP

HPTN 083-02: factors influencing adherence to injectable PrEP and retention in an injectable PrEP study

Christina Psaros[1,2,§], Georgia R. Goodman[1,3], Jasper S. Lee[1], Whitney Rice[4], Colleen F. Kelley[5], Temitope Oyedele[6], Lara E. Coelho[7], Nittaya Phanuphak[8,9], Yashna Singh[10], Keren Middelkoop[10,11], Sam Griffith[12], Marybeth McCauley[12], James Rooney[13], Alex R. Rinehart[14], Jesse Clark[15], Vivian Go[16], Jeremy Sugarman[17], Sheldon D. Fields[18], Adeola Adeyeye[19], Beatriz Grinsztejn[7], Raphael J. Landovitz[20], Steven A. Safren[21] and the HPTN 083-02 Study Team

3.2.7 | Facilitators of adherence to injectable PrEP: clinic staff and environment play a key role in facilitating attendance at injection visits and supporting adherence

For some, the extent to which work schedules represented a barrier to attending injection visits depended primarily on the flexibility of their employers.

> *One time I was working… and I double-booked this on top of that. And so I had to call off there and come here and they ended up putting me on suspension for two days and so I couldn't go to work for two days.* – Adherent, MSM, Domestic

Participants also reported that both personal reminders, and clinic-based reminders directly from study staff, were key facilitators of their injection visit adherence.

> *They've been helpful, and they've been reminding me. I get text messages to remind me that my appointment is coming because, if not, I'll never make it.* – Early discontinuer, TGW, International

Psaros et al. *J Int AIDS Soc.* 2024 May;27(5):e26252. PMID: 38783534

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Pharmacists can play a large role here!

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Landmark PrEP trials

Trial	Regimen	Population	Link
IPrEx	TDF/FTC vs placebo	MSM, TGW	http://www.ncbi.nlm.nih.gov/pubmed/21091279
IPERGAY	TDF/FTC vs placebo		http://www.ncbi.nlm.nih.gov/pubmed/26624850
PROUD	TDF/FTC vs placebo		http://www.ncbi.nlm.nih.gov/pubmed/26364263
DISCOVER	TAF/FTC vs TDF/FTC		https://pubmed.ncbi.nlm.nih.gov/32711800/
HPTN 083	LA-CAB vs TDF/FTC		http://www.ncbi.nlm.nih.gov/pubmed/34379922
PURPOSE 2	LEN vs TDF/FTC vs TAF/FTC	MSM, TGM, TGW, GNB	https://clinicaltrials.gov/study/NCT04925752?cond=HIV&term=purpose%202&rank=1

Landmark PrEP trials (continued)

Trial	Regimen	Population	Link
Partners PrEP	TDF vs TDF/FTC vs placebo	Heterosexual couples	http://www.ncbi.nlm.nih.gov/pubmed/22784037
TDF2	TDF/FTC only	Heterosexual men and women	http://www.ncbi.nlm.nih.gov/pubmed/22784038

Landmark PrEP trials (continued)

Trial	Regimen	Population	Link
Bangkok Tenofovir	TDF vs placebo	People without HIV who inject drugs	http://www.ncbi.nlm.nih.gov/pubmed/23769234

Landmark PrEP trials (continued)

Trial	Regimen	Population	Link
FEM-PrEP	TDF/FTC vs placebo	Cisgender women	http://www.ncbi.nlm.nih.gov/pubmed/22784040
MTN-020-ASPIRE	Dapivirine vaginal ring vs placebo		http://www.ncbi.nlm.nih.gov/pubmed/26900902
Ring	Dapivirine vaginal ring vs placebo		http://www.ncbi.nlm.nih.gov/pubmed/27959766
HPTN 084 (LIFE Study)	LA-CAB vs TDF/FTC		http://www.ncbi.nlm.nih.gov/pubmed/35378077
PURPOSE 1	LEN vs TDF/FTC vs TAF/FTC		https://pubmed.ncbi.nlm.nih.gov/39046157/

Advances in HIV Prevention: Are You PrEP-ared?

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