Staying PrEPared

An Update on Injectable Pre-Exposure Prophylaxis

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Dr. Hurt is supported by the Health Resources and Services Administration (HRSA-17-039, U1OHA30535), the National Institute on Drug Abuse (UH3DA044823), and the National Institute of Allergy and Infectious Diseases (P30AI50410, UM1AI069423, UM1AI068619, UM1AI068614).

The views expressed are not necessarily those of HRSA or NIH.

20 August 2021

Objectives

- Name the currently available options for pre-exposure prophylaxis (PrEP) in the United States.
- Outline key clinical trial data supporting the use of long-acting injectables for HIV prevention.
- Identify candidates for PrEP who might benefit from a long-acting, injectable option.
- Describe other long-acting forms of PrEP in the development pipeline.

Two pills are approved for PrEP

Truvada[TDF]

emtricitabine / tenofovir disoproxil fumarate

Approved in 2012

Proven to protect people during:
Injection drug use
Insertive vaginal sex
Insertive anal sex (topping)
Receptive vaginal sex
Receptive anal sex (bottoming)

Descovy[TAF]

emtricitabine / tenofovir alafenamide fumarate

Approved in 2019

Proven to protect people during:
~~Injection drug use~~
~~Insertive vaginal sex~~
Insertive anal sex (topping)
~~Receptive vaginal sex~~
Receptive anal sex (bottoming)

Pregnancy Prevention	HIV Prevention
Education & behavior modification	Education & behavior modification
Condoms	Condoms
Rings	Rings
Birth control pill & injection	PrEP (oral & injectable)
"Morning-after pill"	Post-exposure prophylaxis
Spermicide	Topical microbicides
Implantable birth control	Broadly neutralizing Abs Implantables
Vasectomy Tubal Ligation	U=U / TasP Vaccination

Adapted from HPTN

HPTN 083 & 084

Oral FTC/TDF vs Injectable Cabotegravir-LA
MSM & TGW (083) and Cisgender Women (084)

	Screening day and informed consent	STEP 1	STEP 2	STEP 3
		Every day for 5 weeks	Weeks 5 and 9; Every 2 months for approximately 3 years	Every day for 1 year
Group A		CAB	Cabotegravir (CAB) injection; TDF/FTC placebo (Every day, Steps 1–2)	TDF/FTC
Group B		CAB placebo	Placebo injection; TDF/FTC (Every day, Steps 1–3)	

TDF/FTC pill

Cabotegravir (CAB) injection

Placebo for TDF/FTC pill

Placebo for cabotegravir (CAB) injection

CAB: Cabotegravir (CAB) pill

CAB (grey): Placebo for cabotegravir (CAB) pill

HPTN 083

Oral FTC/TDF vs Injectable CAB-LA for MSM & TGW

December 2016 – May 2020

4566
at-risk persons
(ITT; target N = 5000)
87.5% MSM 12.4% TGW

50%
daily
FTC/TDF
(n=2284)

50%
long-acting
injectable CAB
(n=2282)

26
median age
(IQR 22-32)

37%
from US
(n=1698)

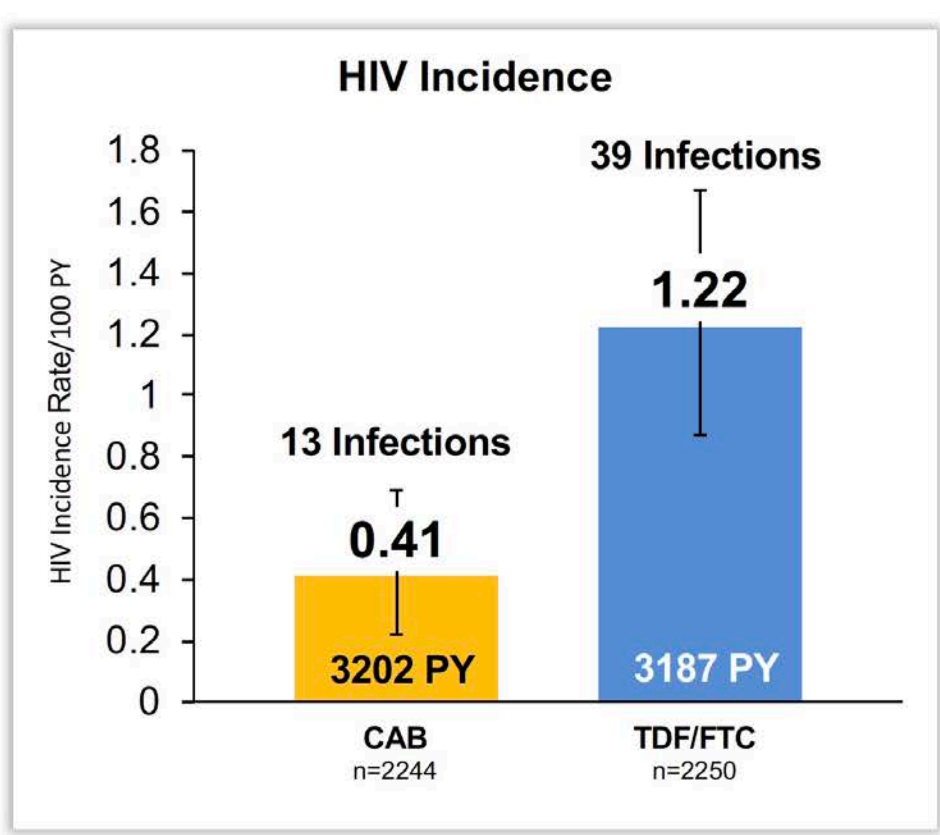
49.8%
of US participants
were Black
(n=845)

Landovitz RJ, et al. N Engl J Med. 2021 Aug 12;385(7):595-608

HPTN 083

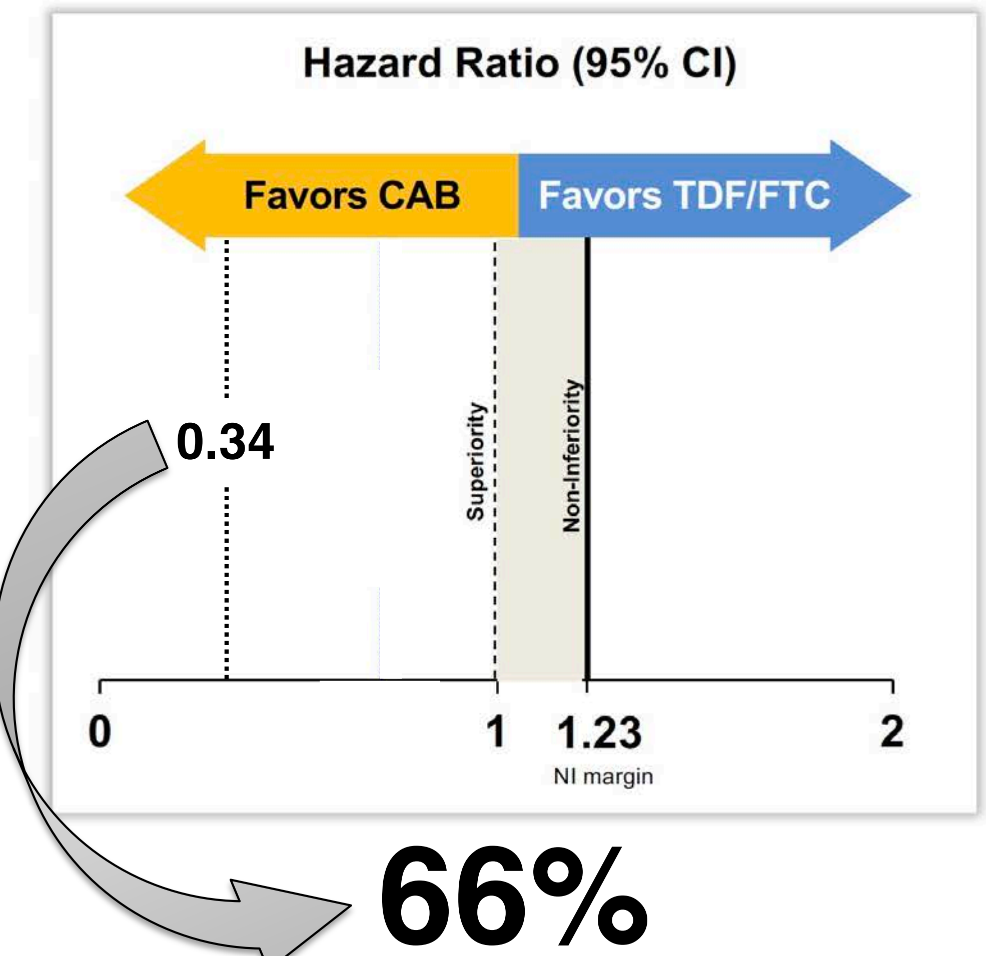
Oral FTC/TDF vs Injectable CAB-LA for MSM & TGW

IM CAB-LA was statistically superior to oral FTC/TDF for preventing HIV



CI, confidence interval

52 infections
6389 PY of follow-up



66%

reduced hazard of HIV among CAB recipients, compared with FTC/TDF
(95%CI: 18%, 62%; p=0.0005)

Landovitz RJ, et al. AIDS 2020. Abstract OAXLB01
Landovitz RJ, et al. N Engl J Med. 2021 Aug 12;385(7):595-608

HPTN 083

Oral FTC/TDF vs Injectable CAB-LA for MSM & TGW

Cabotegravir: Mild (Grade 1), Moderate (Grade 2), Severe (Grade 3)

TDF/FTC: Mild (Grade 1), Moderate (Grade 2), Severe (Grade 3)

Percentage of participants reporting an ISR (0%–100%)

	Overall	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Cabotegravir (%)	81.4	58.1	48.7	38.5	35.7	35.3	33.8	33.2	30.9	28.8	28.4	26.9	30.1	28.1	25.3	27.3	23.2	19.7	20.2	22.5
TDF/FTC (%)	31.3	15.8	9.3	7.5	7.1	6.1	3.9	5	4.5	3.8	3.8	3.9	4.3	4.7	3.3	3	1.7	3.2	1.4	0
Cabotegravir, n	2117	2117	2037	1938	1872	1761	1620	1465	1360	1200	1034	877	744	602	466	374	298	234	168	111
TDF/FTC, n	2081	2081	2014	1940	1869	1760	1607	1463	1356	1195	1037	903	761	597	481	370	287	220	146	89

50 (2.4%) of CAB participants permanently discontinued due to an adverse effect of an injection

Severity of an injection site reaction was strongly associated with odds of permanently discontinuing

Supplementary Figure 5 from Landovitz RJ, et al. N Engl J Med. 2021 Aug 12;385(7):595-608

HPTN 083

Oral FTC/TDF vs Injectable CAB-LA for MSM & TGW

IQR
Duration: 3 (2, 6)

All ISRs
N=10,666

Time from injection to onset (median and IQR)
Time from injection to resolution (median and IQR)

IQR
Duration: 3 (1, 5)

Pain
n=6,486 (60.8%)

IQR
Duration: 3 (2, 6)

Tenderness
n=2,530 (23.7%)

IQR
Duration: 5 (3, 9)

Other
n=1650 (15.5%)

0 1 2 3 4 5 6 7 8 9 10 11 12

Time in days

Supplementary Figure 6 from Landovitz RJ, et al. N Engl J Med. 2021 Aug 12;385(7):595-608

HPTN 083

Oral FTC/TDF vs Injectable CAB-LA for MSM & TGW

Estimated mean weight change (kg/y)
CAB: +1.23 (95%CI 1.05, 1.42) kg/y
TDF/FTC: 0.37 (95%CI 0.18, 0.55) kg/y

Week 0-40
CAB: +1.26 (95%CI 0.98, 1.54) kg/y
TDF/FTC: -0.50 (95%CI -0.78, -0.22) kg/y

Week 40-105
CAB: +1.11 (95%CI 0.82, 1.41) kg/y
TDF/FTC: +1.19 (95%CI 0.90, 1.49) kg/y

Median weight change from enrollment (kg)
5.0
2.5
0.0
-2.5

W0 W2 W4 W5 W9 W17 W25 W33 W41 W49 W57 W65 W73 W81 W89 W97 W105
Visit week

Study arm
CAB
TDF/FTC

Supplementary Figure 12 from Landovitz RJ, et al. N Engl J Med. 2021 Aug 12;385(7):595-608

HPTN 084

Oral FTC/TDF vs Injectable CAB-LA for Cisgender Women

November 2017 – November 2020

3224
at-risk persons
(ITT; target N = 3200)
20 sites in Sub-Saharan Africa

50%
daily
FTC/TDF
(n=1610)

50%
long-acting
injecteable CAB
(n=1614)

25
median age
(IQR 22-30)

57%
aged 18-25
(n=1837*)

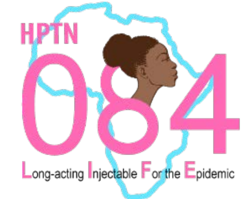
55%
had BMI ≥ 25
(n=1773*)

Delany-Moretlwe S, et al. R4P 2020. Abstract LB1479

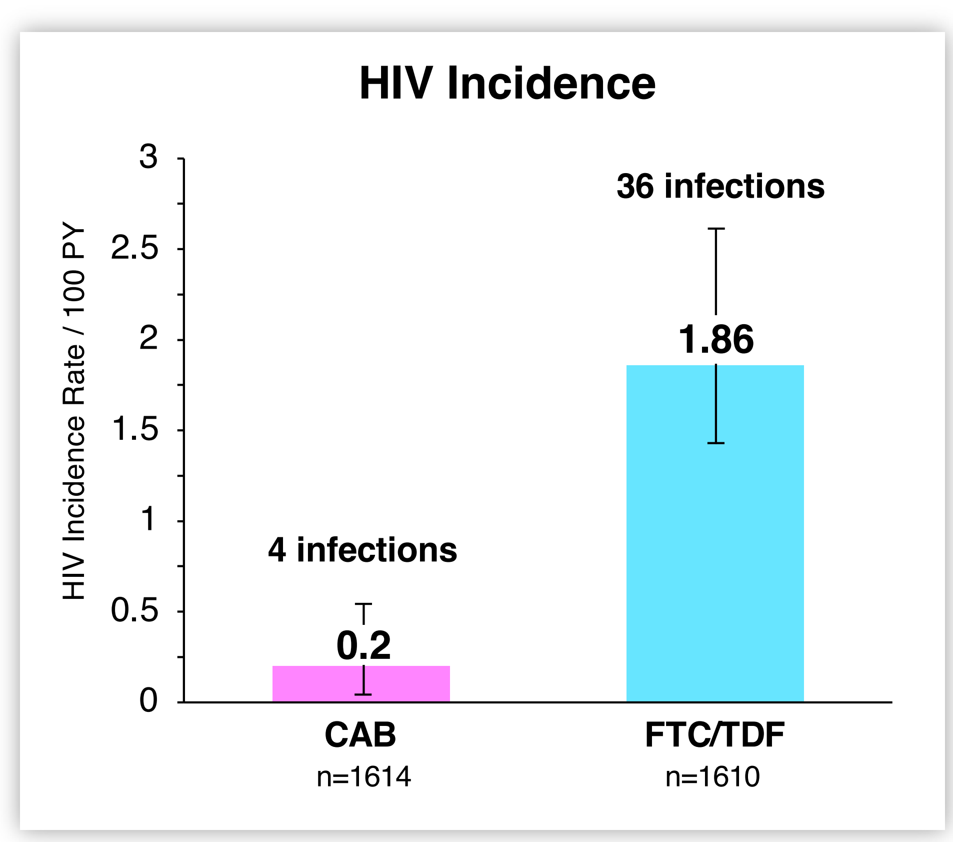
* calculated value

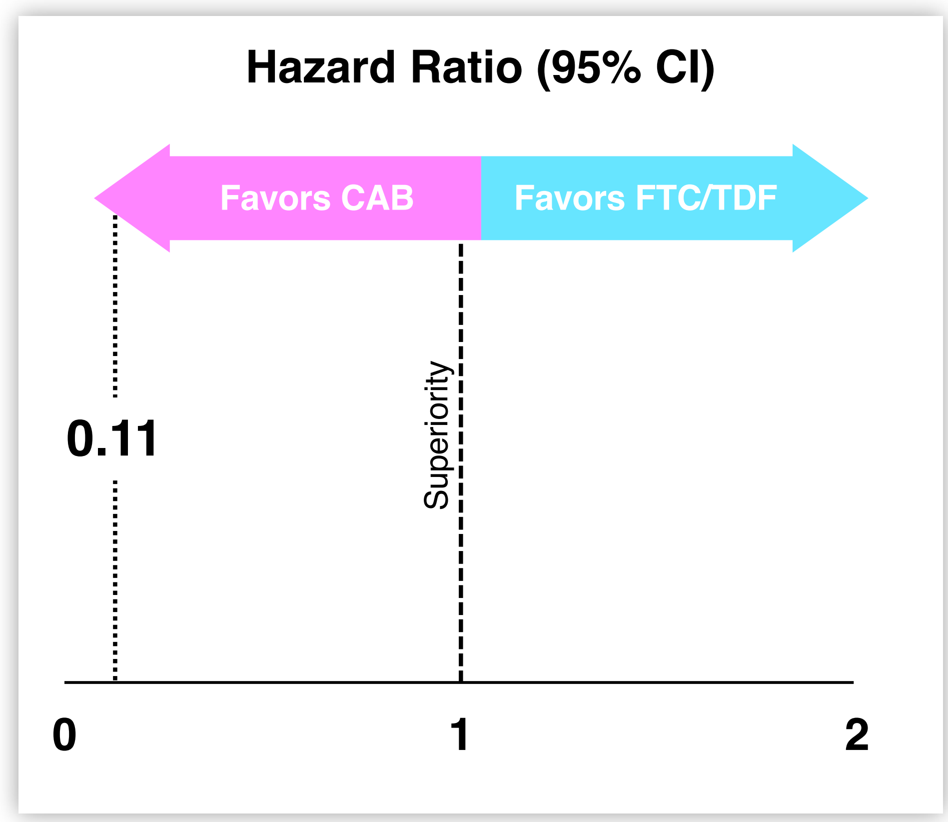
HPTN 084

Oral FTC/TDF vs Injectable CAB-LA for Cisgender Women



IM CAB-LA was statistically superior to oral FTC/TDF for preventing HIV





40 infections
3892 PY of follow-up

89%

reduced hazard of HIV among CAB recipients, compared with FTC/TDF
(95%CI: 69%, 99%; p=0.000027)

Figures (re)constructed from data presented in Delany-Moretlwe S, et al. R4P 2020. Abstract LB1479

HPTN 084

Oral FTC/TDF vs Injectable CAB-LA for Cisgender Women

Estimated mean weight change

CAB
(2.4 kg/yr)

FTC/TDF
(2.2 kg/yr)

Weight Gain(kg)

6
5
4
3
2
1
0

0 1 2 3

Time since enrollment (years)

Delany-Moretlwe S, et al. R4P 2020. Abstract LB1479

HPTN 084

Oral FTC/TDF vs Injectable CAB-LA for Cisgender Women

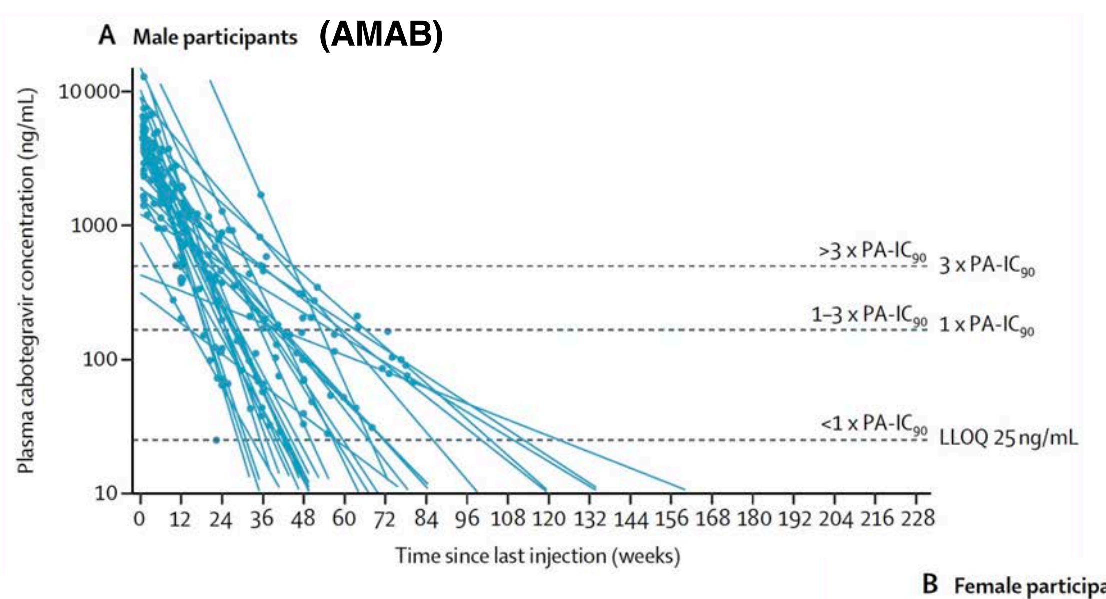
	Total (n=50)	CAB (n=29)	FTC/TDF (n=21)
Ongoing (as of Jan 2021)	23	15	8
Known outcomes (n=27)			
Live births	20	10	10
Pregnancy loss			
≥ 37 weeks	0	0	0
20-36 weeks	3	1	2
<20 weeks*	4	3	1
Ectopic	0	0	0
Congenital anomalies (n=27)			
No	23	11	12
Unknown	4	3	1

Delany-Moretlwe S, et al. R4P 2020. Abstract LB1479

* includes elective terminations

Unanswered questions

What about covering the "tail"?



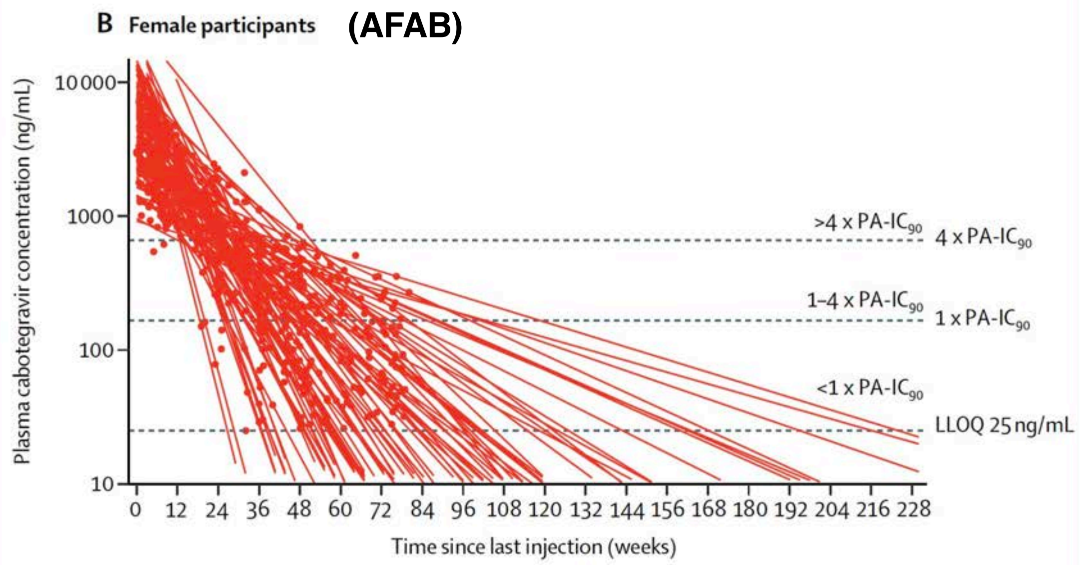
CAB dropped below LLOQ after a median of

10 months

among participants assigned male at birth

15.5 months

among participants assigned female at birth



HPTN 077

Landovitz RJ, et al. *Lancet HIV*. 2020;7(7):e472-e481.

Unanswered questions

Is an oral "lead-in" really necessary?

	TOTAL (n=4566)	TDF-FTC (n=2284)	CAB (n=2282)	p-value
Participants with grade 3+ AEs, n (%)	1490 (32.7%)	766/2282 (33.6%)	724/2280 (31.8%)	
CPK increased	633 (13.9%)	309 (13.5%)	324 (14.2%)	0.51
Creatinine clearance decreased	348 (7.6%)	190 (8.3%)	158 (6.9%)	0.08
Lipase increased	152 (3.3%)	76 (3.3%)	76 (3.3%)	0.99
Creatinine increased	152 (3.3%)	75 (3.3%)	77 (3.4%)	0.87
AST/SGOT increased	122 (2.7%)	69 (3.0%)	53 (2.3%)	0.14

Participants with EAEs and SAEs, n (%)	240 (5.3%)	122 (5.4%)	118 (5.2%)
Participant deaths, n (%)	11 (0.24%)	7 (0.3%)	4 (0.2%)

Landovitz RJ, et al. AIDS 2020. Abstract OAXLB01

Unanswered questions

Is Ag/Ab testing sufficient for persons on CAB-LA?

Four infections occurred among participants despite adherence to CAB-LA

D1 NA

D2 NA

D3 • K103N : K103N, **R263K**

D4 G140A, **Q148R**

0 10 20 30 40 50 60 70 80 90 100 110 120 130 140

Weeks since Enrollment

First HIV-positive visit; First site-positive visit; First HIV-positive and site-positive visit

CAB-LA injection; TDF–FTC dispensed; • First genotyping test; : Second genotyping test

≥8×PA-IC90; 4×PA-IC90 to <8×PA-IC90; 1×PA-IC90 to <4×PA-IC90; >LLOQ to <1×PA-IC90; BLQ

Landovitz RJ, et al. N Engl J Med. 2021 Aug 12;385(7):595-608

Unanswered questions

Is Ag/Ab testing sufficient for persons on CAB-LA?

In each case, HIV RNA was detectable SIGNIFICANTLY EARLIER than Ag or Ab

16 weeks
D1
NA
14 weeks
D2
NA
17 weeks
D3
K103N
K103N, **R263K**
6.5 weeks
D4
G140A, **Q148R**
0 10 20 30 40 50 60 70 80 90 100 110 120 130 140
Weeks since Enrollment

First HIV-positive visit | First site-positive visit | First HIV-positive and site-positive visit
CAB-LA injection | TDF–FTC dispensed | First genotyping test | Second genotyping test
≥8×PA-IC90 | 4×PA-IC90 to <8×PA-IC90 | 1×PA-IC90 to <4×PA-IC90 | >LLOQ to <1×PA-IC90 | BLQ

Landovitz RJ, et al. N Engl J Med. 2021 Aug 12;385(7):595-608

Unanswered questions

Is Ag/Ab testing sufficient for persons on CAB-LA?

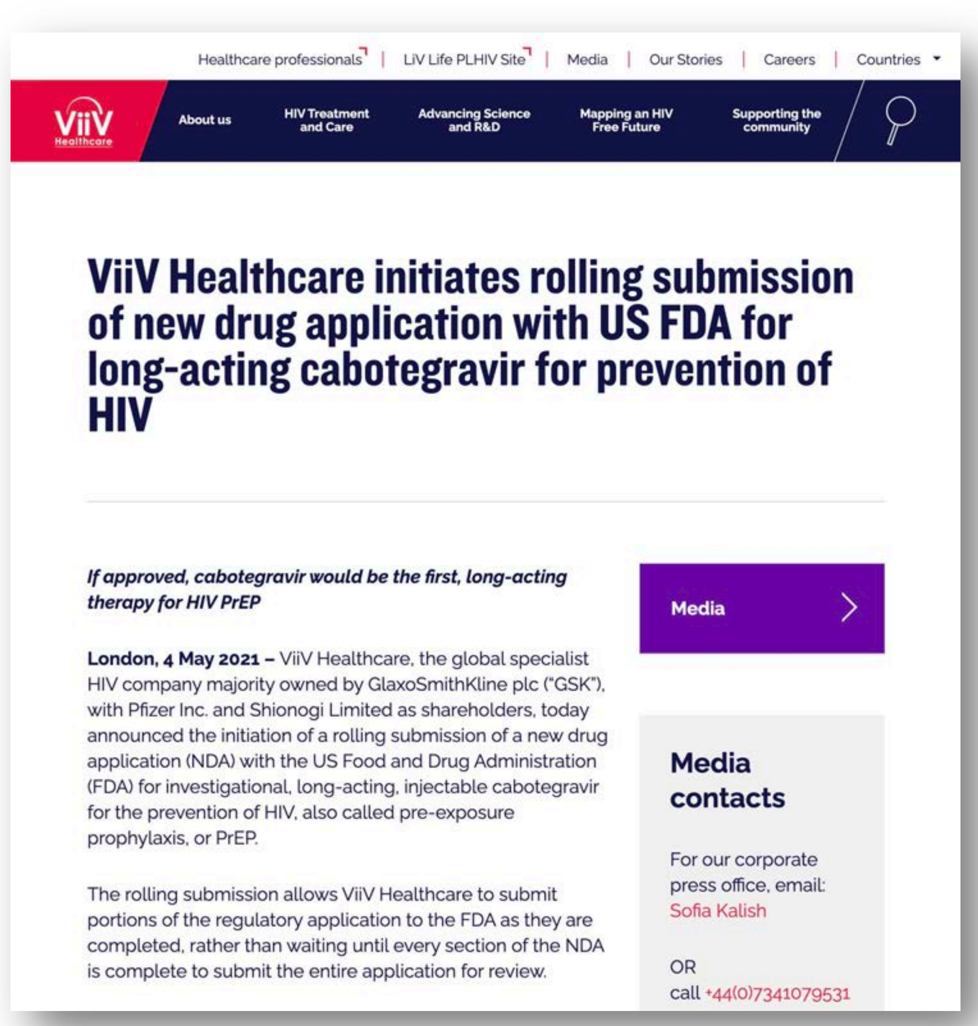
Two of four "breakthrough" infections acquired integrase resistance

Neither of these two had integrase resistance at time first HIV RNA was detected
(first detection of resistance was at "first site-positive" time point)

Landovitz RJ, et al. N Engl J Med. 2021 Aug 12;385(7):595-608

What's the timeline for CAB?

- FDA submission opened May 2021
- Final elements submitted to FDA in summer 2021
- Typical timeline is 6 months from final submission to decision
  (so Jan/Feb 2022 at latest)



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ViiV Healthcare

About us | HIV Treatment and Care | Advancing Science and R&D | Mapping an HIV Free Future | Supporting the community

ViiV Healthcare initiates rolling submission of new drug application with US FDA for long-acting cabotegravir for prevention of HIV

If approved, cabotegravir would be the first, long-acting therapy for HIV PrEP

London, 4 May 2021 – ViiV Healthcare, the global specialist HIV company majority owned by GlaxoSmithKline plc ("GSK"), with Pfizer Inc. and Shionogi Limited as shareholders, today announced the initiation of a rolling submission of a new drug application (NDA) with the US Food and Drug Administration (FDA) for investigational, long-acting, injectable cabotegravir for the prevention of HIV, also called pre-exposure prophylaxis, or PrEP.

The rolling submission allows ViiV Healthcare to submit portions of the regulatory application to the FDA as they are completed, rather than waiting until every section of the NDA is complete to submit the entire application for review.

Media

Media contacts

For our corporate press office, email: Sofia Kalish

OR
call +44(0)7341079531

What are the likely recommendations for CAB?

Draft for Public Comment

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES-2021 UPDATE

A Clinical Practice Guideline

Cabotegravir may be "especially appropriate" for HIV-uninfected persons at risk of HIV acquisition* who:

have significant renal disease

have had difficulty with adherent use of oral PrEP

prefer bimonthly (every 8 week) injections over daily oral dosing

DRAFT May 2021

*no distinction made in draft for sexual vs parenteral exposures (i.e., PWID)

What are the likely recommendations for CAB?

Draft for Public Comment

US Public Health Service

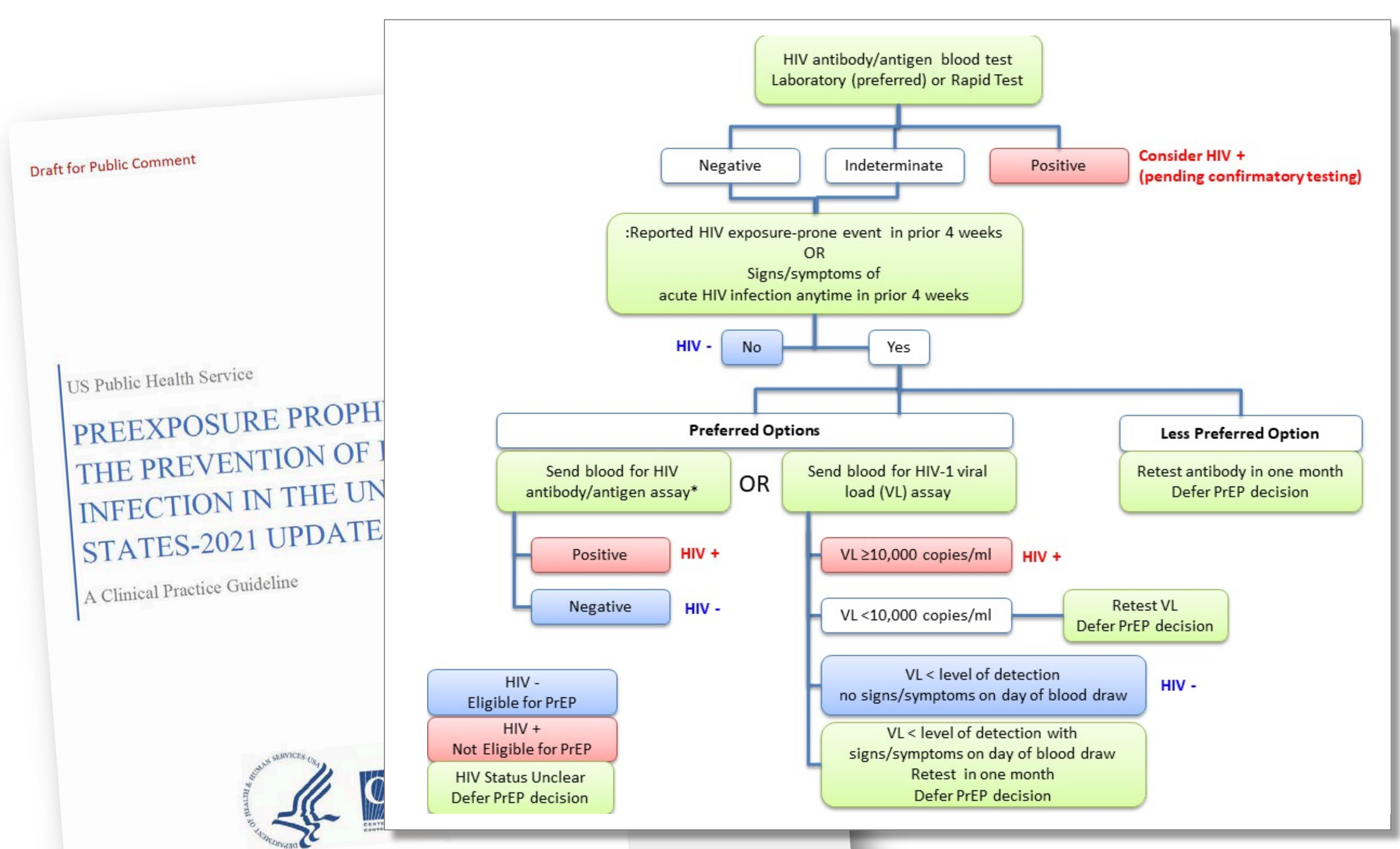
PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES-2021 UPDATE

A Clinical Practice Guideline

"Because of the long duration of drug exposure following injection, exclusion of acute HIV infection is necessary with the most sensitive test available, an **HIV-1 viral load assay**…. within 1 week prior to the initiation visit."

DRAFT May 2021

What are the likely recommendations for CAB?



DRAFT May 2021

What are the likely recommendations for CAB?

Draft for Public Comment

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES-2021 UPDATE

A Clinical Practice Guideline

"[T]he following tests **are NOT indicated** before starting CAB injection or for monitoring patients during its use:
creatinine,
eCrCl,
hepatitis B serology,
lipid panels,
liver function tests."

DRAFT May 2021

What are the likely recommendations for CAB?

Draft for Public Comment

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES-2021 UPDATE

A Clinical Practice Guideline

Follow-up visit one month following the first injection is recommended.

After initial follow-up at one month, injections are every 8 weeks thereafter.

There is no option for self-administration.

DRAFT May 2021

What are the likely recommendations for CAB?

Draft for Public Comment

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES-2021 UPDATE

A Clinical Practice Guideline

DRAFT May 2021

The tail should be addressed, up-front.

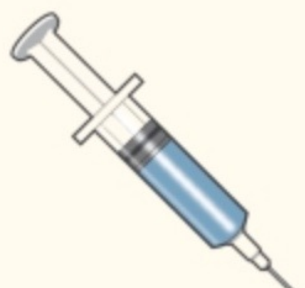
Persons initiating CAB must be informed of risks of HIV acquisition and ARV resistance during the tail.

Effective HIV prevention option(s) should be offered for persons stopping CAB, within 8 weeks of last injection – with follow-up for another 12 months.

What's in the pipeline?

Long-acting options are the goal…

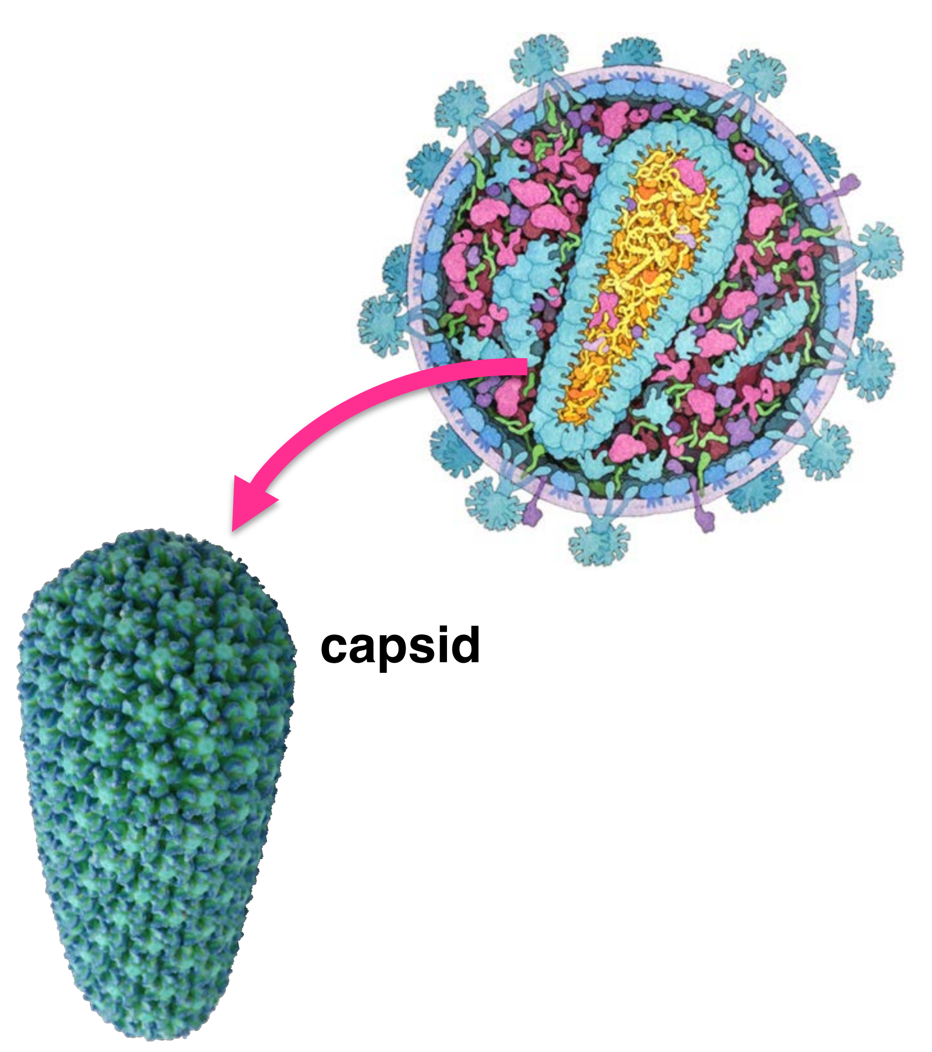
NIAID is funding research on 4 types of long-acting HIV prevention.

INTRAVAGINAL RING (IVR)	IMPLANT	INJECTABLE	ANTIBODY
			
Polymer ring inserted into the vagina releases antiretroviral drug over time.	Device implanted in the body releases antiretroviral drug over time.	Long-acting antiretroviral drug is injected into the body.	Antibody is infused or injected into the body.

https://www.hiv.gov/hiv-basics/hiv-prevention/potential-future-options/long-acting-prep

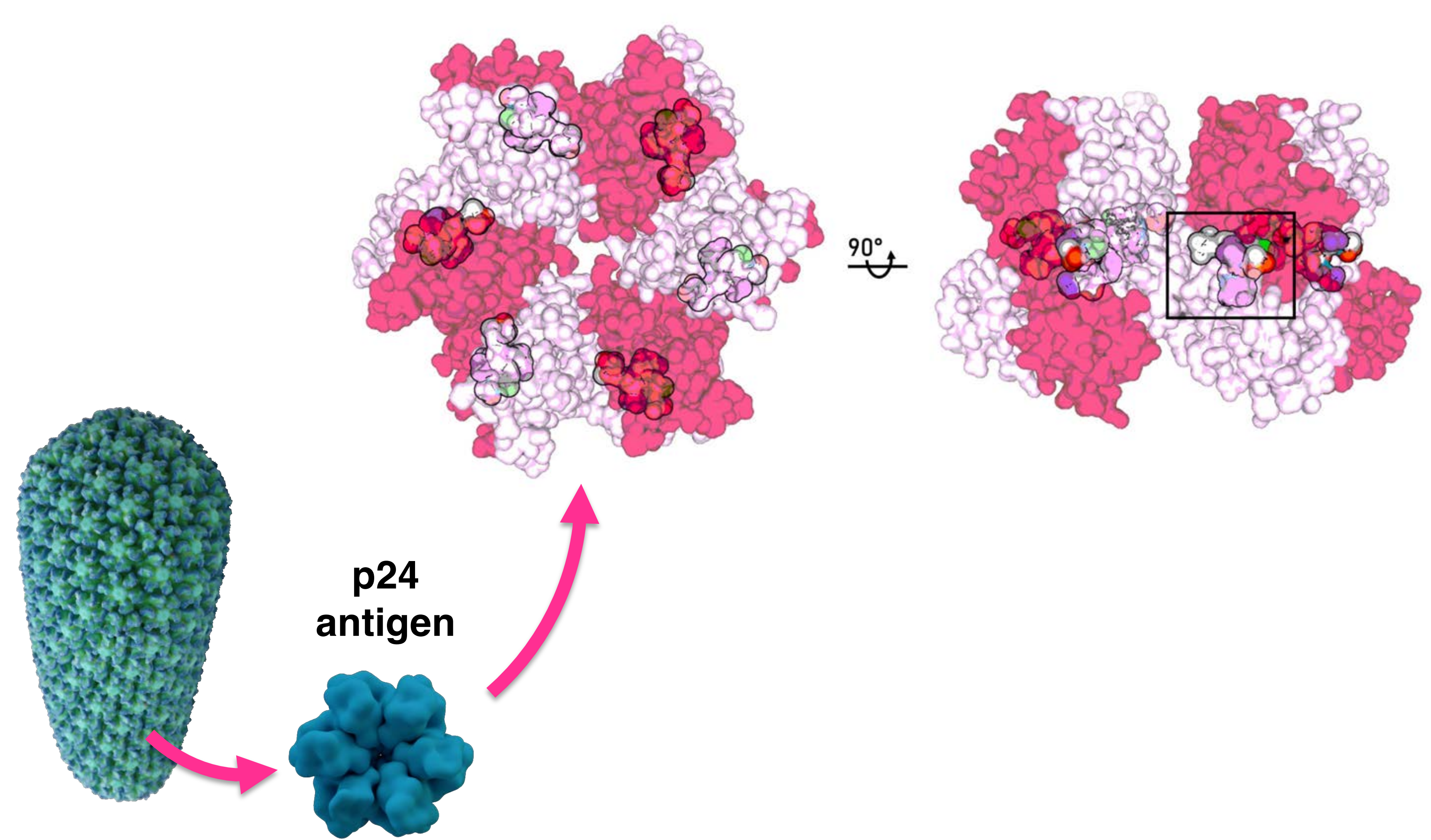
Lenacapavir

First-in-class **capsid** inhibitor, formerly known as GS-6207



Lenacapavir

First-in-class **capsid** inhibitor, formerly known as GS-6207

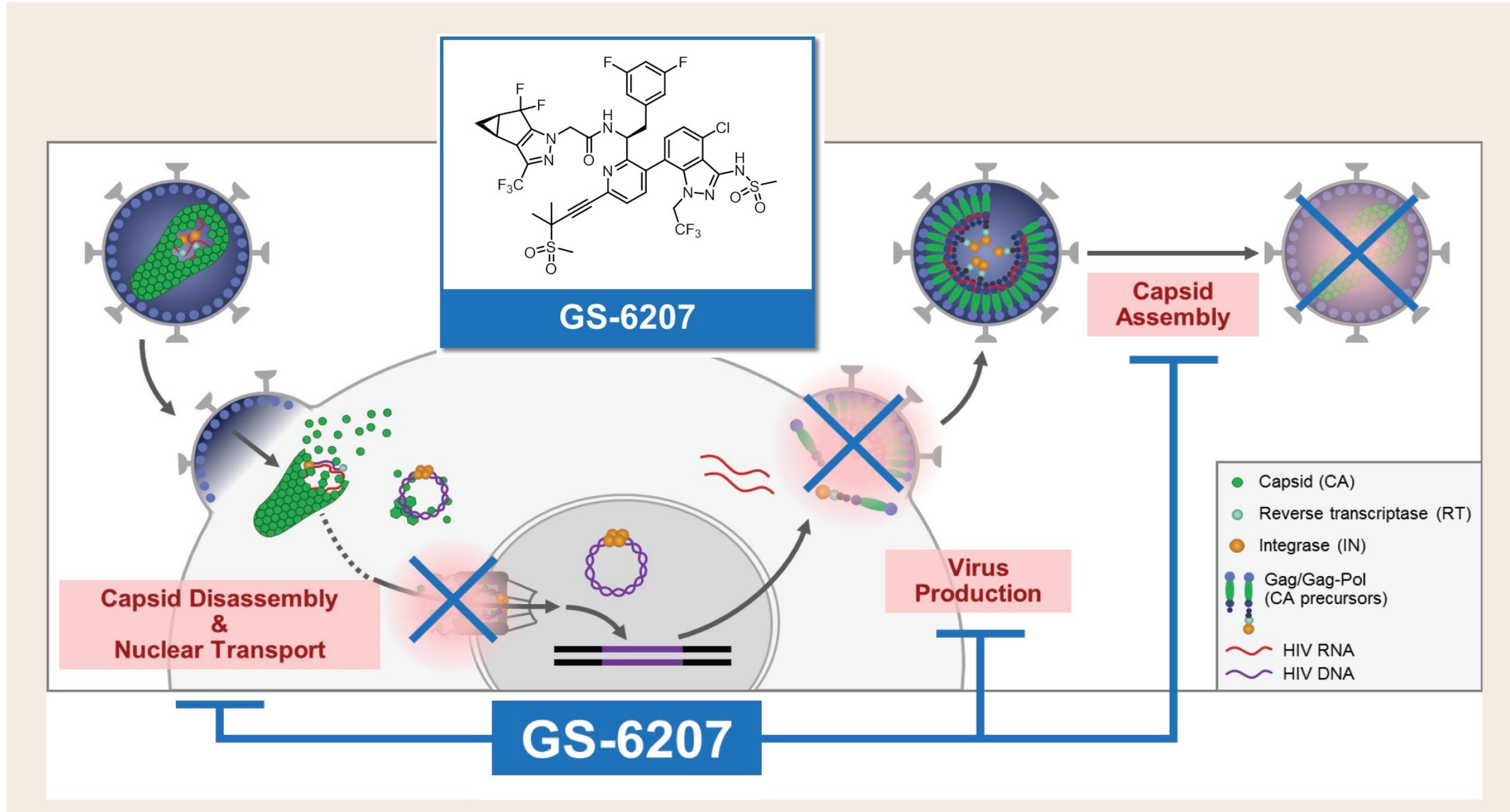


https://drughunter.com/2020smotygs/

Link JO, et al. Nature. 2020 Aug;584(7822):614-618 ← mechanism

Lenacapavir

First-in-class **capsid** inhibitor, formerly known as GS-6207



Yang SR, et al. AIDS 2019. Poster TUPEA075. Accessed at: https://programme.ias2019.org/PAGMaterial/eposters/683.pdf

Lenacapavir

First-in-class **capsid** inhibitor, formerly known as GS-6207

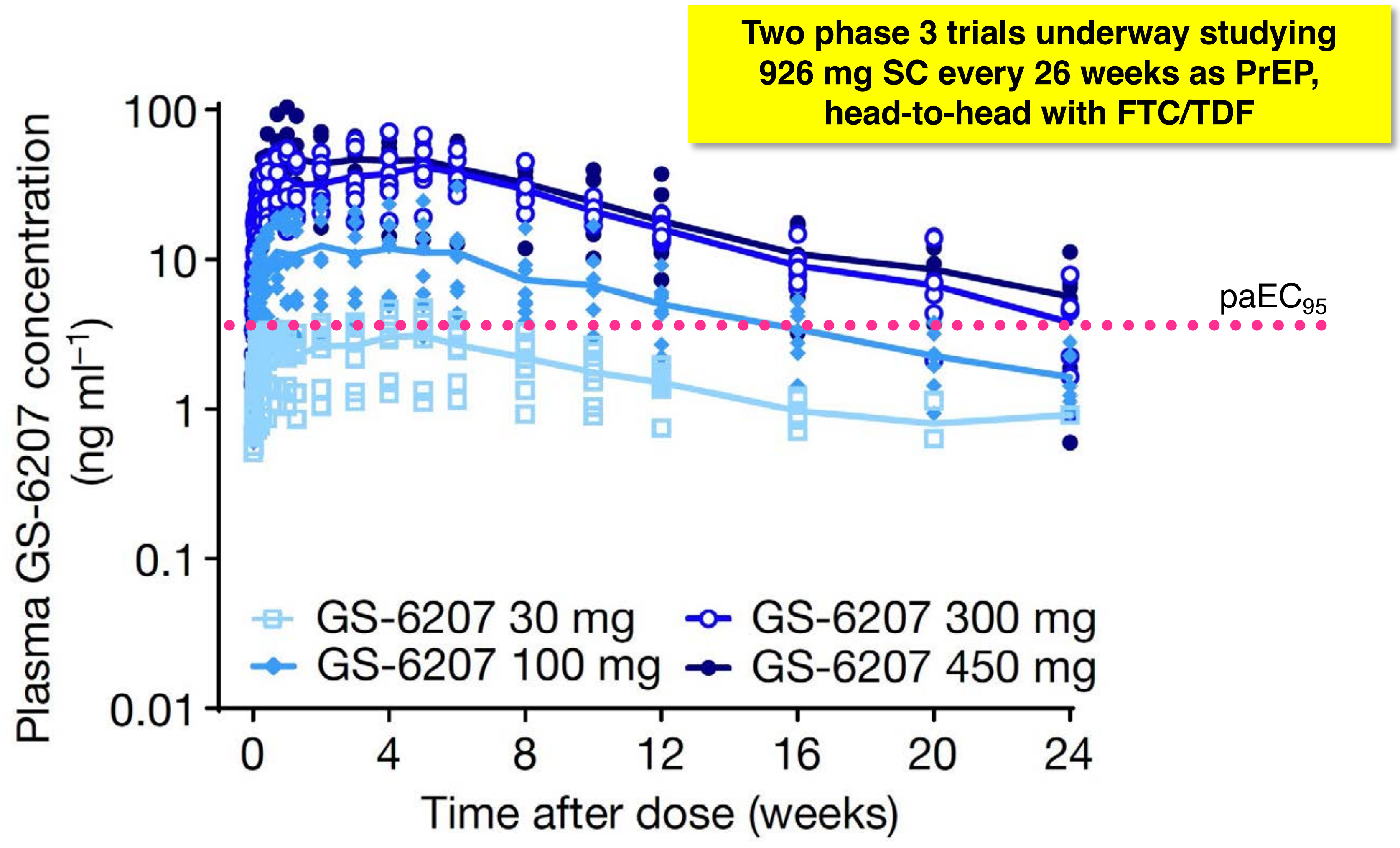


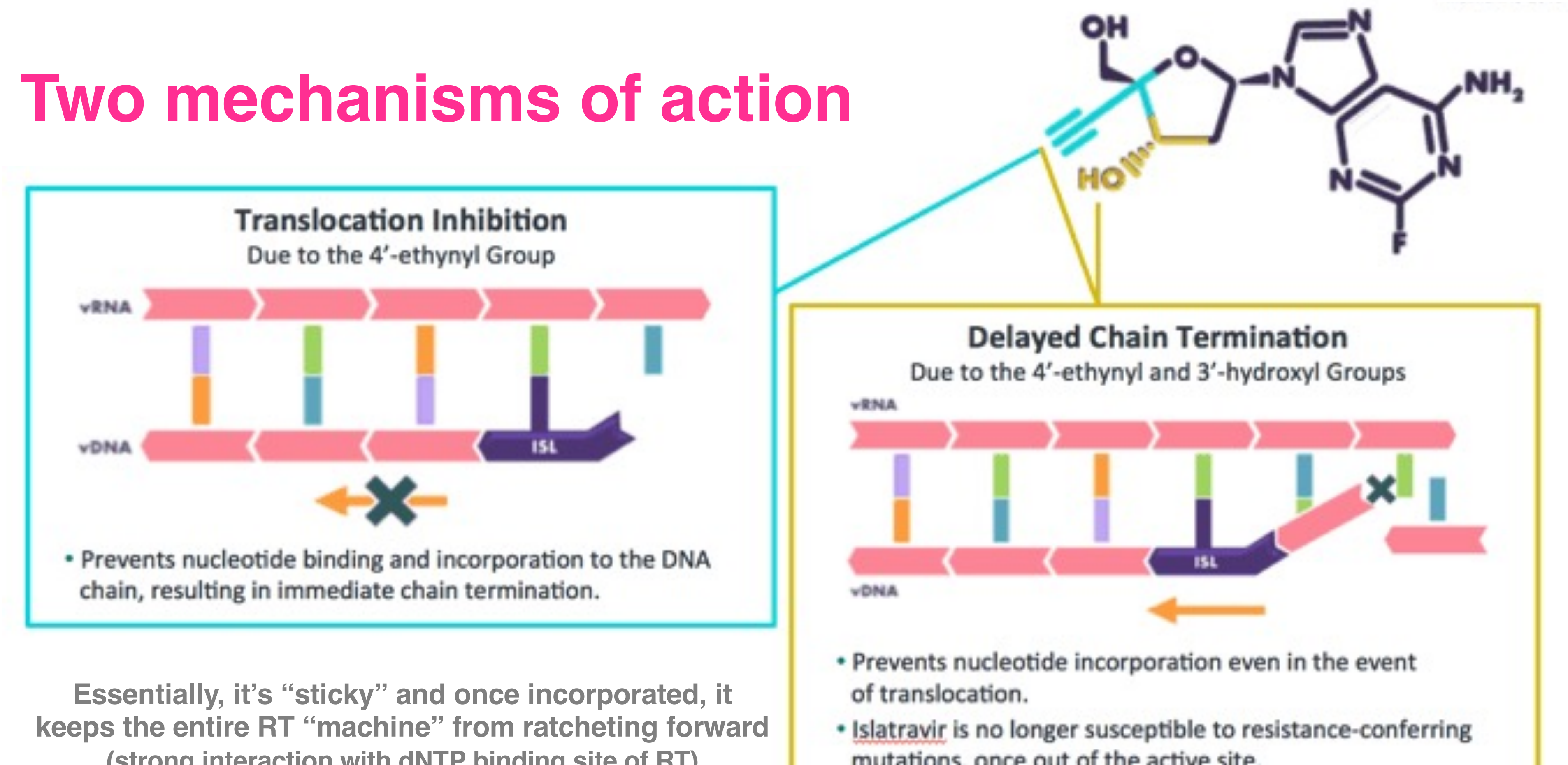
Figure 4a from: Link JO, et al.
Nature. 2020 Aug;584(7822):614-618

PURPOSE 1 → https://clinicaltrials.gov/ct2/show/NCT04994509
PURPOSE 2 → https://clinicaltrials.gov/ct2/show/NCT04925752

Islatravir

First-in-class nucleoside reverse transcriptase **translocation** inhibitor NRTTI
Formerly known as MK-8591 or EFdA

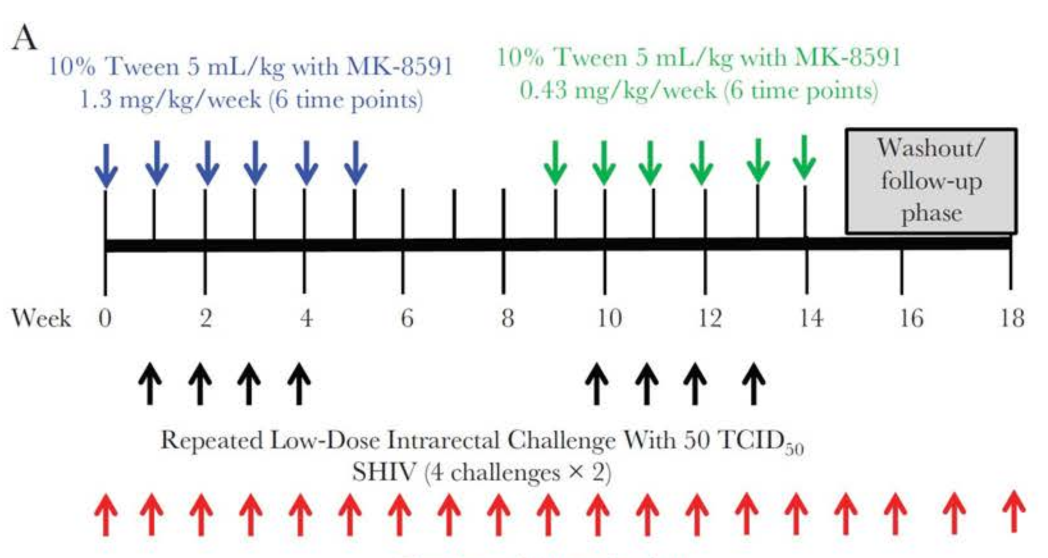
Two mechanisms of action

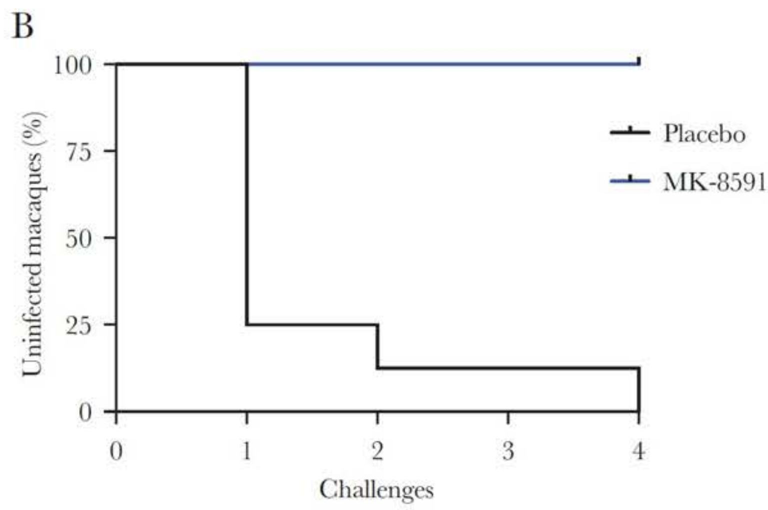


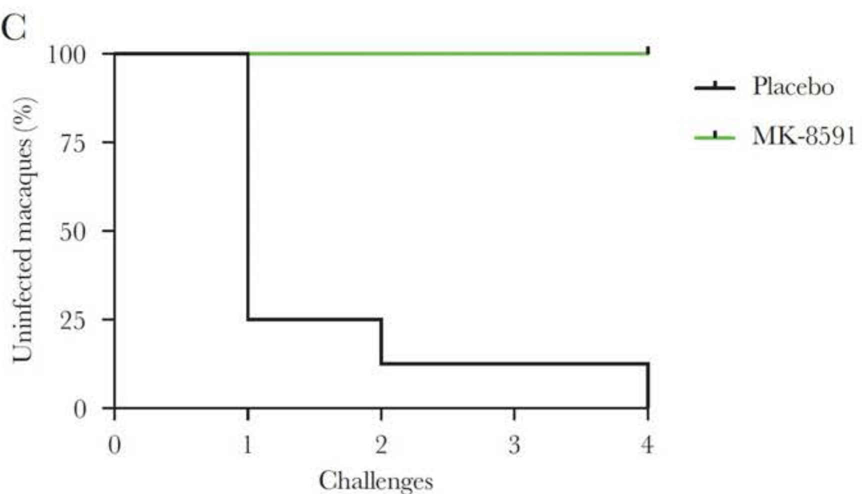
Essentially, it's "sticky" and once incorporated, it keeps the entire RT "machine" from ratcheting forward (strong interaction with dNTP binding site of RT)

https://www.natap.org/2019/EACS/EACS_81.htm
Markowitz M, Sarafianos SG. Curr Opin HIV AIDS. 2018;13(4):294-299 ← for more on the mechanism of action

Islatravir PO once weekly protects macaques

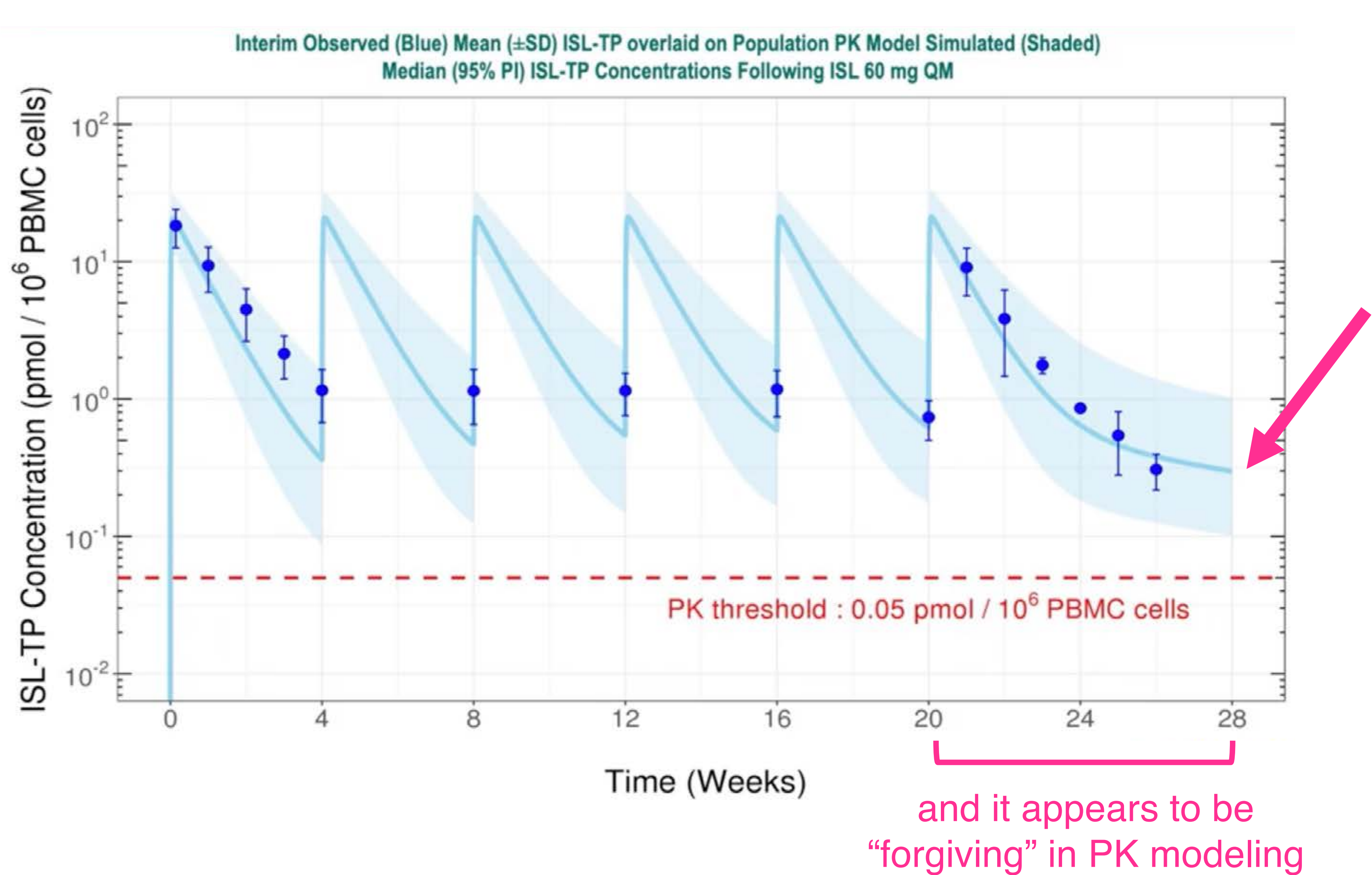






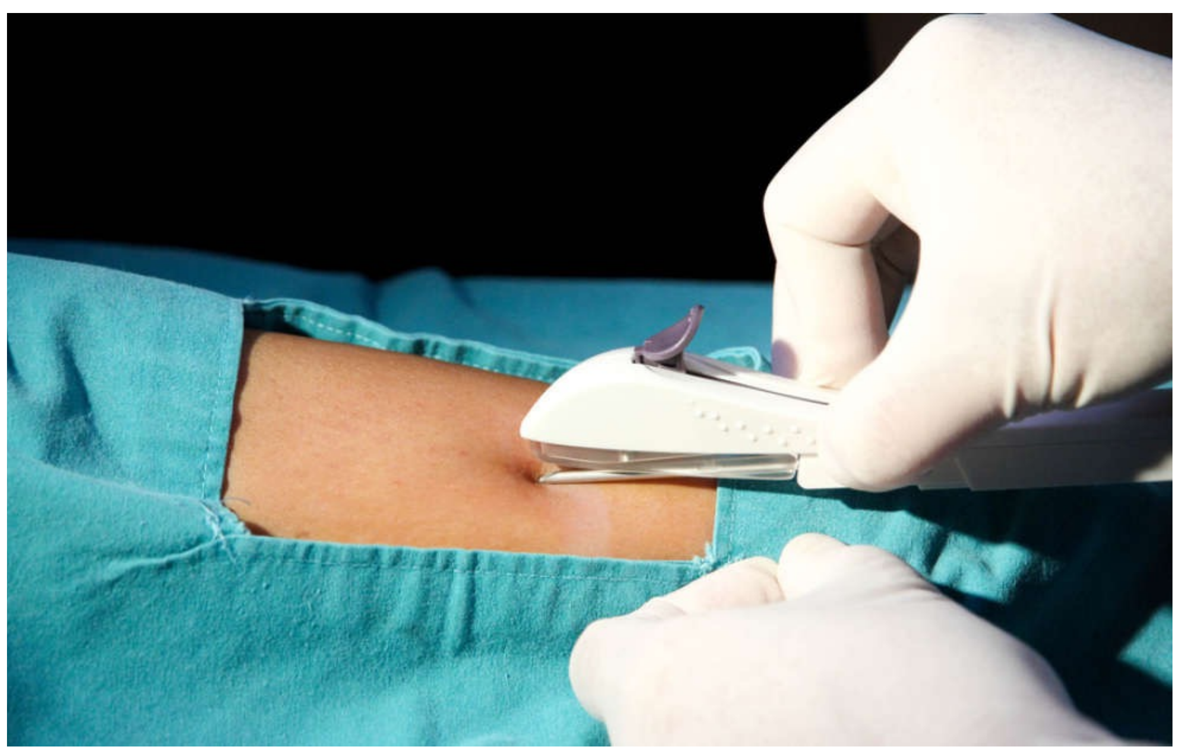
Markowitz M, et al. J Infect Dis. 2020;221(9):1398-1406

Islatravir PO once monthly maintains levels



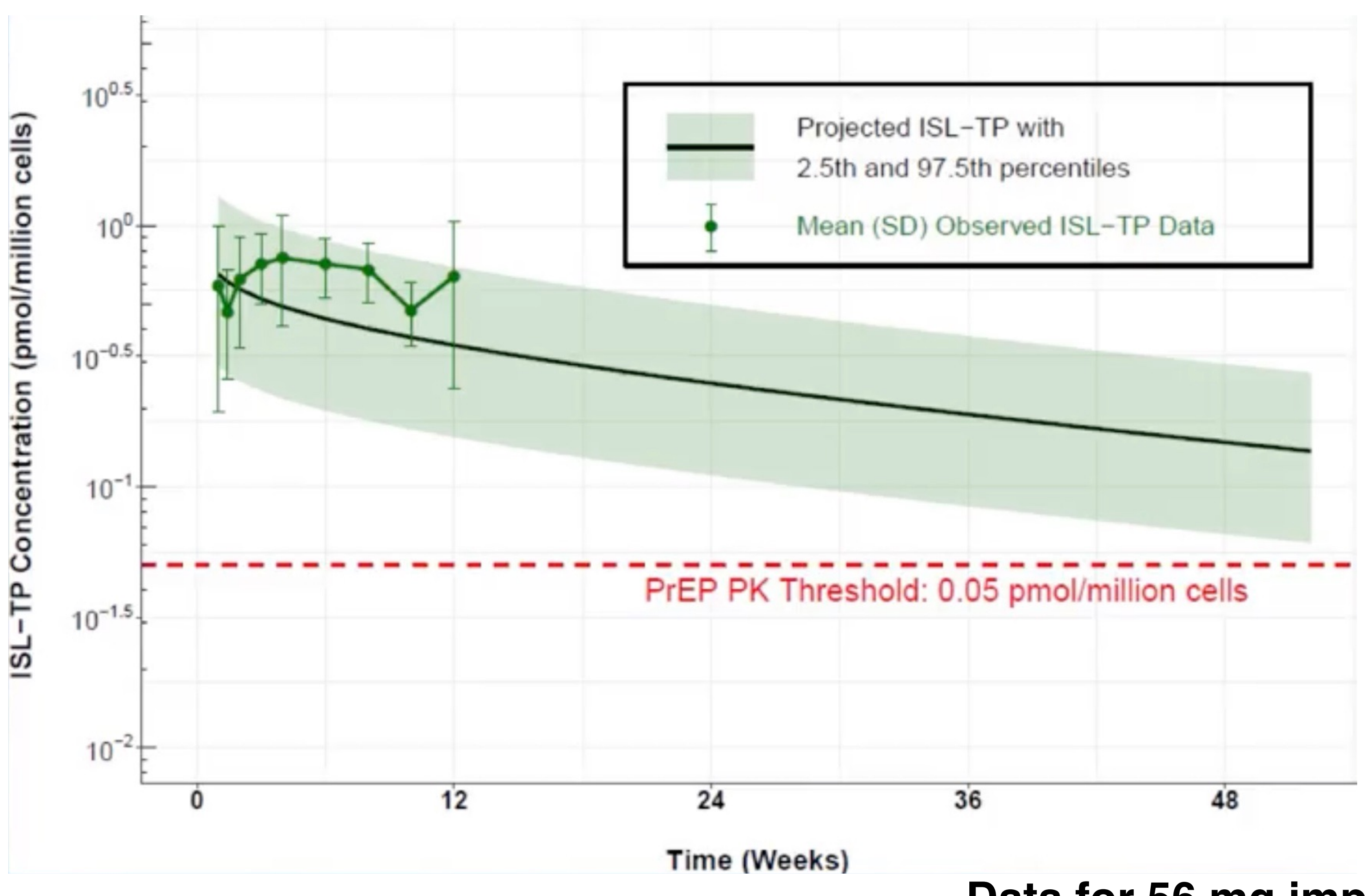
https://www.croiconference.org/abstract/islatravir-pk-threshold-dose-selection-for-monthly-oral-hiv-1-prep/
Figure from: Hillier S, et al. HIV R4P 2021. Abstract OA04.05LB. Accessed at https://programme.hivr4p.org/Abstract/Abstract/1363

Islatravir prototype similar to Nexplanon



https://www.sfaf.org/collections/beta/islatravir-a-potential-prep-hiv-drug-now-being-tested/

Islatravir-eluting implants may last up to a year

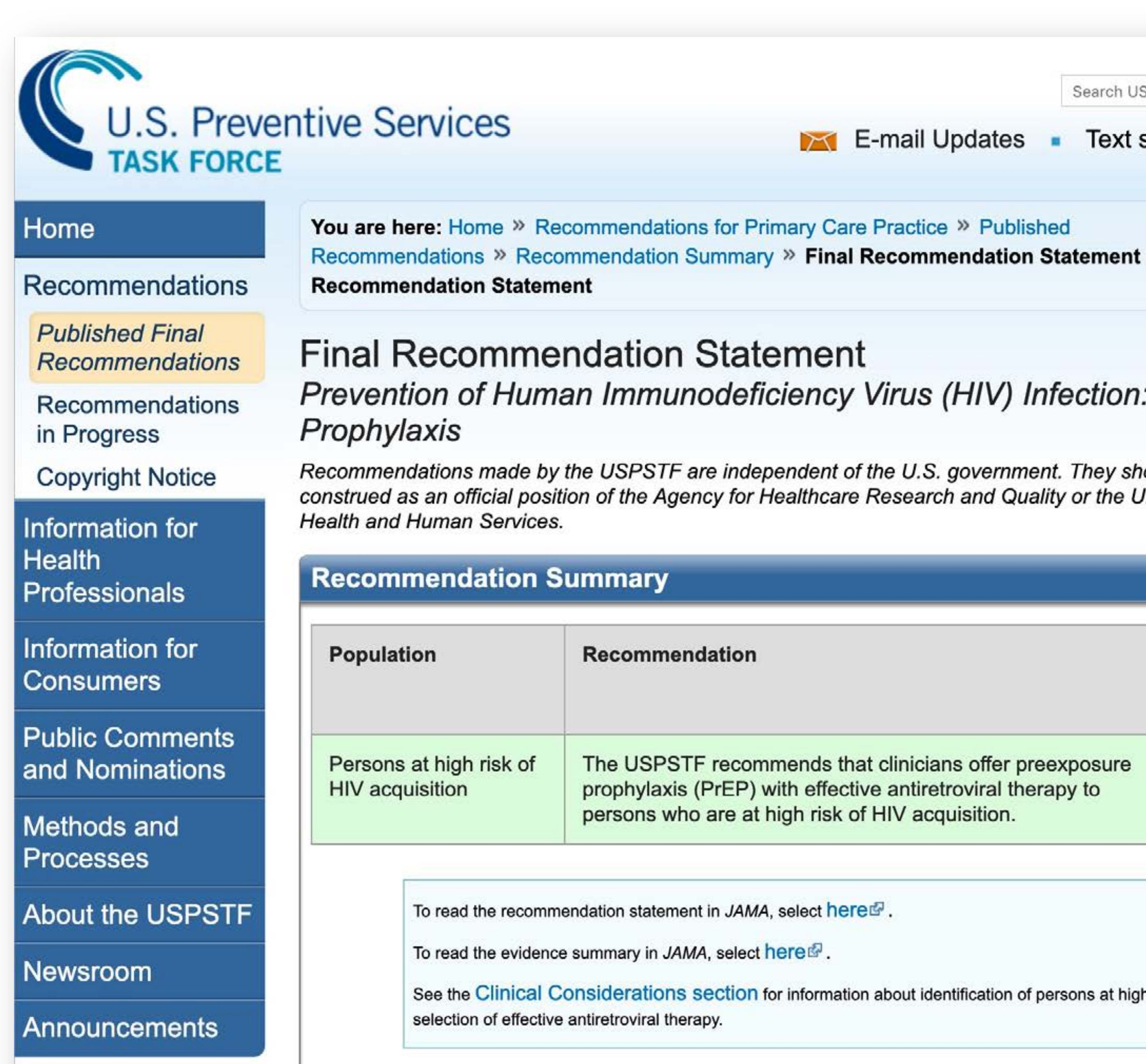


Data for 56 mg implant

https://www.croiconference.org/abstract/next-generation-islatravir-implants-projected-to-provide-yearly-hiv-prophylaxis/

One final note…

USPSTF recommends PrEP, June 2019



What impact did this have on access?

August 2015 | Fact Sheet

Preventive Services Covered by Pr
the Affordable Care Act

A key provision of the Affordable Care Act (ACA) is the requirement that private insurance plans cover recommended preventive services without any patient cost-sharing.[1] Research has shown that evidence-based preventive services can save lives and improve health by identifying illnesses earlier, managing them more effectively, and treating them before they develop into more complicated, debilitating conditions, and that some services are also cost-effective.[2] However, costs do prevent some individuals from obtaining preventive services (**Figure 1**). The coverage requirement aims to remove cost barriers.

Figure 1
Cost barriers t
men
Share of w
Women All
Insured
Uninsured
Less than 200% FPL
200% FPL or greater
Men All
Insured
Uninsured
Less than 200% FPL
200% FPL or greater
NOTE: Among women and m
statistically significant differe
SOURCE: Kaiser Family Found

ACA Requirements for Coverage of Pre

Under Section 2713 of the ACA, private health plans must p and may not impose cost-sharing (such as copayments, de these services.[3] These requirements apply to all private pla and self-insured plans in which employers contract admin exception of those plans that maintain "grandfathered" sta "grandfathered," plans must have been in existence prior t changes to their coverage (for example, increasing patient contributions). In 2014, 26% of workers covered in employ plans,[4] and it is expected that over time almost all plans will lose their grandfathered status.

"A key provision of the Affordable Care Act (ACA) is … private insurance plans cover recommended preventive services without any patient cost-sharing. … **Insurers now must cover evidence-based services for adults that have a rating of "A" or "B"** in the current recommendations of the [USPSTF]"

The Biden admin removed ambiguity in July ’21

https://www.nastad.org/resource/nastad-prep-coverage-brief-prep-services-covered-no-cost-sharing

NASTAD PrEP Coverage Brief: PrEP Services Covered with No Cost-Sharing

July 2021

Pre-exposure prophylaxis (PrEP) – a once daily antiretroviral medication taken to prevent HIV – is an incredibly effective HIV prevention tool. In light of its effectiveness and safety, in June, 2019, the US Preventive Services Task Force (USPSTF) gave PrEP an “A” grade recommendation, noting that “the USPSTF concludes with high certainty that the net benefit of the use of PrEP to reduce the risk of acquisition of HIV infection in persons at high risk of HIV infection is substantial.” This fact sheet will walk through the coverage and cost-sharing requirements for public and private payers that come with this USPSTF Grade A recommendation.

What Does a USPSTF Grade A Recommendation Mean for Coverage and Cost Sharing?

The Affordable Care Act (ACA) requires commercial health plans and Medicaid expansion programs to cover select preventive services – including any service with a Grade A or B from the USPSTF – without cost-sharing, which means that these services must be covered before any deductible and without coinsurance or a copayment.[1] Now that PrEP has a Grade A recommendation from USPSTF, most commercial health plans and Medicaid expansion programs must cover PrEP without cost sharing as of January 1, 2021.

Preventive Services

The list of preventive services that must be covered without cost-sharing is based on the recommendations of several expert bodies, including the USPSTF, which is an independent, volunteer panel of national experts in prevention and evidence-based medicine. The USPSTF works to improve the health of all Americans by making evidence-based recommendations about clinical preventive services such as screenings, counseling services, and preventive medications. In addition to PrEP, there are other sexual health services that have a USPSTF A or B grade, including screening for HIV, chlamydia, gonorrhea, HBV, HCV, and Syphilis. A list of preventive services is available at healthcare.gov/preventive-care-benefits

What Plans Must Cover PrEP without Cost Sharing?

All non-grandfathered commercial health plans are required to cover PrEP services without cost sharing. This includes individual marketplace plans, and small and large group employer-sponsored plans. In addition, state Medicaid expansion coverage programs, including Basic Health Plans, must also cover PrEP without cost sharing.

[1] A summary of Section 2713 in the context of HIV, hepatitis, and STI prevention is available at cdc.gov/nchhstp/highqualitycare/preventiveservices

By 17 September 2021, non-grandfathered health plans will be required to cover PrEP services without cost-sharing (before deductible and without coinsurance or copayment).

- Marketplace plans
- Employer-sponsored plans
- Medicaid
- Medicare provider & lab services

PrEP is defined as the service, not the drug

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What's covered?

- HIV testing every 3 months
- Baseline hepatitis B screening
- Baseline and periodic hepatitis C screening
- Creatinine assessments
- Pregnancy testing
- STI screening from exposed anatomical sites
- Adherence counseling
- Medications approved for PrEP

One extra step is needed: modifier 33

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Just to be on the safe side, <u>append modifier 33</u> to these encounters!

"When the primary purpose of the service is the delivery of an evidence-based service in accordance with a [USPSTF] A or B rating in effect and other preventive services identified in preventive services mandates … the service may be identified by adding 33 to the procedure."

Questions?

Please email me!

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