2020 Ryan White HIV/AIDS Program CLINICAL CONFERENCE

The Data-Free Zone: Tough Cases in HIV Prevention

Raphael J. Landovitz, MD, MSc
Professor of Medicine
University of California Los Angeles
Los Angeles, California

Financial Relationships With Commercial Entities

Dr Landovitz has served as a consultant to Gilead Sciences, Inc, Merck & Co, Inc, and Roche. (Updated 08/05/20)

Slide 2 of 48

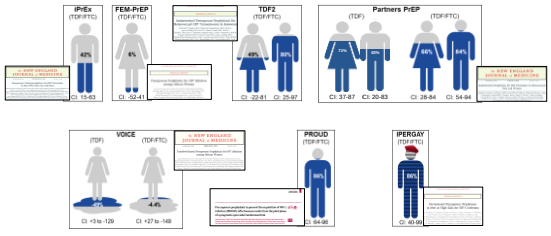
Learning Objectives

After attending this presentation, learners will be able to describe:

- Options for preexposure prophylaxis (PrEP) in patients with decreased kidney function and low bone mineral density
- The state of the science on sexually transmitted infection (STI) prevention strategies
- Recent data on the safety and efficacy on injectable PrEP options

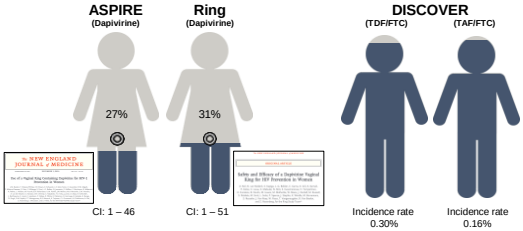
Slide 3 of 48

Effectiveness of TDF/FTC in Placebo-Controlled Clinical Trials



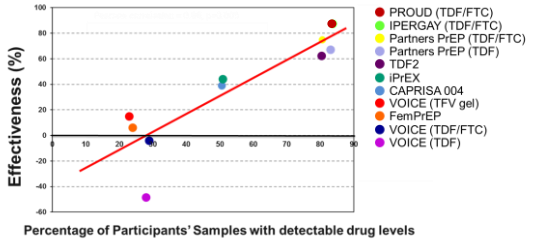
Landovitz RJ et al. AIDS 2020, #OAXLB0101

"PrEP 2.0": Trials of Novel PrEP Agents



Landovitz RJ et al. AIDS 2020, #OAXLB0101

Effectiveness of Daily TDF/FTC in Clinical Trials



Slide 6 of 48

SS Abdool Karim, personal communication

PrEP is straightforward when…

- Cr Cl ≥ 60
- No history of osteopenia/osteoporosis/non-traumatic fractures
- HBsAg negative
- Patients come in every 3 months for safety labs, STI testing, and adherence checks prior to refills
- Limited medical co-morbidities

Slide 7 of 48

Case 1:
Beans, beans and nothing but beans

- A 50-year-old man with type 2 DM, CKD 3, and hypertension recently started a new relationship with an HIV-infected man and is seeking advice on how best to avoid HIV infection
- His partner admits to struggling with taking ART regularly, but says he is "mostly adherent" and does not like to use condoms
- One month after initiating PrEP, Cr Cl dropped to 55 mL/min
- UA is normal and safety labs are rechecked and show Cr Cl is further decreased to 50 mL/min

Slide 8 of 48

ARS Question #1

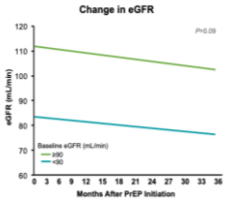
Your best advice regarding his PrEP is:

1. Continue daily oral TDF/FTC, recheck in 1 month
2. Switch to event-based ("2-1-1") dosing of TDF/FTC
3. Dose reduce TDF/FTC to 3 x week
4. Switch to TAF/FTC daily
5. Something else

Slide 9 of 48

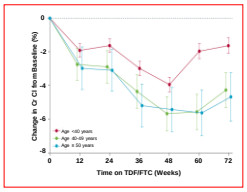
Impact of Long-Term PrEP Use and Renal Function

- Longitudinal clinical cohort study (2014-2017)
  - PrEP users (n=172 over 689 visits)
  - Baseline creatinine <1 year before PrEP initiation and ≥1 follow-up creatinine
- Mean Cr Cl change: -6 mL/min at month 24
  - No cases of elevated creatinine with Cr Cl <60 mL/min
  - No discontinuations of PrEP due to decline in eGRF
- Cr Cl <70 mL/min after baseline Cr Cl ≥70 mL/min (n=8)
  - Recovered (n=3); remained >60 mL/min (n=5)
  - Significantly associated with age ≥ 50 years and baseline Cr Cl <90 mL/min (both P<0.0001)



Harvey M et al., AIDS Res Hum Retroviruses, 2018

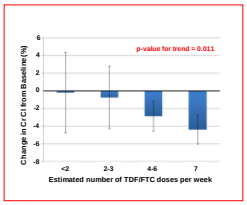
↑ Age, ↓ Baseline Cr Cl , and Adherence Associated with Declining Renal Function



- iPrEx-Ole (n=1224) found a greater decline in renal function with older age
  - 40–50 years: –4.2% [–2.8,–5.5]
  - 50+ years: –4.2% [–2.8,–5.5]
- The likelihood of Cr Cl falling below 60 mL/min were higher in participants with a baseline Cr Cl of 90 mL/min or less.

Gandhi M et al., Lancet, 2016

↑ Age, ↓ Baseline Cr Cl , and Adherence Associated with Declining Renal Function



- The EPIC Hair study enrolled and collected hair samples for 280 PrEP Demo participants
- Drug level concentrations in hair were highly correlated with DBS concentrations
- Decline in renal function associated with higher drug level concentrations.

Gandhi M et al., AIDS, 2017

CCTG 595: PrEP Associated with Fanconi Syndrome

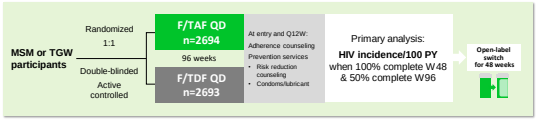
- 49-year-old white man, Hx kidney stones, HBV/HCV negative, no ongoing medical problems or medication use
- Mild renal impairment detected at baseline (Cr Cl: 79.9 mL/min).
- Initiated daily oral TDF/FTC-based PrEP
- 12 weeks after PrEP initiation
  - 25% decrease in Cr Cl,
  - Hypophosphatemia with renal phosphate wasting

Test	Screen	Week 4	Week 12		Week 16	Week 18	Week 21	Week 24
Estimated creatinine clearance*, mL/min	79.9	68.7	58.9		69.1	66.6	71.0	74.0
Serum creatinine, mg/dL	1.15	1.33	1.58		1.28	1.32	1.27	1.20
Serum phosphorus, mg/dL (normal 2.7–4.5)	—	—	1.8	Stop TDF-FTC	2.7	3.2	2.6	2.8
Fractional excretion of Phosphate, % (normal 10–20)	—	—	26.6		12.2	—	—	—

Abbreviations: FTC, emtricitabine; TDF, tenofovir disoproxil fumarate.
*Estimated creatinine clearance by Cockcroft-Gault formula.

Khan S et al., OFID, 2017

DISCOVER: A Randomized, Noninferiority Trial of F/TAF for PrEP



Eligibility required high sexual risk of HIV
- 2+ episodes condomless anal sex in past 12W or rectal gonorrhea/ chlamydia, syphilis in past 24W
- HIV & HBV negative, eGFR ≥60 mL/min
- Prior use of PrEP allowed

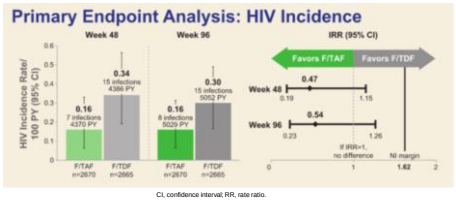
Study conducted in NA, EU in cities/sites with high HIV incidence
- 94 sites in 11 countries
- Participants: US, 60%; EU, 34%; Canada, 7%

Primary efficacy endpoint: HIV incidence
- Evaluated by rate ratio with noninferiority (NI) margin <1.62
- Expected incidence of 1.44/100 PY based on pooled studies: iPrEx, PROUD, IPERGAY

F/TAF dose: 200/25 mg; F/TDF dose: 200/300 mg. eGFR, estimated glomerular filtration rate.

Slide courtesy of Gilead Sciences

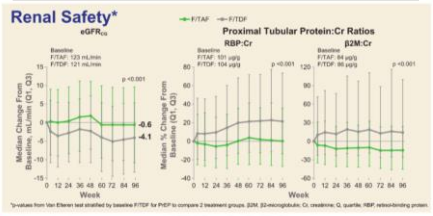
DISCOVER: HIV Incidence



CI, confidence interval; RR, rate ratio.

Ruane PJ. EACS 2019, Abstract PS3/1

DISCOVER: Renal Safety



- Renal discontinuations: F/TAF, n=2; F/TDF, n=6
- Fanconi syndrome: F/TAF, n=0; F/TDF, n=1

Slide 16 of 48

Rhame PJ. EACS 2019. Abstract PS3/1

IPERGAY: eGFR changes not different TDF/FTC v. PBO

	Blind phase			All participants on TDF/FTC (N=389)
	TDF/FTC (n=201)	Placebo (n=199)	*P* value	
Median of follow-up - months (IQR)	9.4 (5.1-20.6)	9.4 (5.1-20.6)		19.2 (18-26.9)
Mean slope of eGFR decline per year[a] (mL/min/1.73m²)	- 1.53	- 0.88	0.27	- 1.20
At least one eGFR <70mL/min/1,73m² - n	20	9	0.04[b]	45
At least one eGFR <60mL/min/1,73m² - n	4	3	0.74[b]	14
Treatment discontinuation for kidney adverse event - n (%)	0	0		3[c] (1%)

- The slope of eGFR decline was not statistically different between TDF/FTC and placebo group.

Slide 17 of 48

Liegeon B et al., CROI, 2019

Case 2: Broken Dreams

- A 35-year-old man reports having receptive anal sex with 2-3 different partners each month, and he is eager to start PrEP
- He was diagnosed with early osteoporosis in 2015 and has a history of non-traumatic fractures.

Slide 18 of 48

ARS Question #2

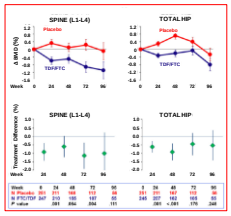
Your best advice is:

1. Proceed with daily oral TDF/FTC alone
2. Initiate PrEP with TAF/FTC
3. Proceed with daily oral TDF/FTC but recommend Vitamin D and Calcium supplementation
4. Something else

Slide 19 of 48

iPrEx: Bone Mineral Density Loss and Recovery

1.



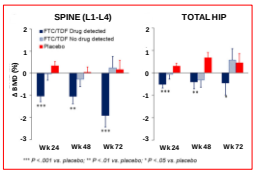
- iPrEx DXA substudy (n=498) found spine BMD decreases in the TDF/FTC group compared to the PBO group.
- Hip BMD initially decreased TDF/FTC group, but rebounded before decreasing again at Week 96

1. Mulligan K et al., CID, 2015
2. Glidden D V et al., JAIDS, 2017

Slide 20 of 48

iPrEx: Bone Mineral Density Loss and Recovery

1.



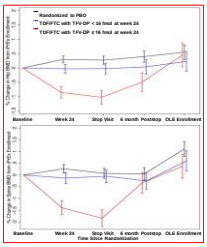
- iPrEx DXA substudy (n=498) found spine BMD decreases in the TDF/FTC group compared to the PBO group
- Hip BMD initially decreased TDF/FTC group, but rebounded before decreasing again at Week 96
- Decreases in BMD were statistically significant in those with detectable drug levels when compared to the PBO group

1. Mulligan K et al., CID, 2015
2. Glidden D V et al., JAIDS, 2017

Slide 21 of 48

iPrEx: Bone Mineral Density Loss and Recovery

2.

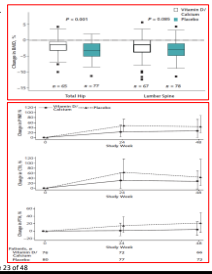


- iPrEx DXA substudy (n=498) found spine BMD decreases in the TDF/FTC group compared to the PBO group
- Hip BMD initially decreased TDF/FTC group, but rebounded before decreasing again at Week 96
- Decreases in BMD were statistically significant in those with detectable drug levels when compared to the PBO group
- Recovery of BMD realized between 48 and 79 weeks after discontinuing TDF/FTC.
  - Similar results were noted in young African women in the VOICE substudy (MTN-003B)

1. Mulligan K et al., CID, 2015
2. Glidden D V et al., JAIDS, 2017

BMD Loss Attenuated by Vitamin D and Calcium

1.

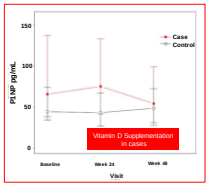


- 167 HIV-infected patients initiating ART were randomized to receive vitamin D3 plus calcium (n=81) or PBO (n=86).
  - Percentage of BMD change from baseline to week 48:
    - Hip: -1.5 (IQR -3.2, -0.4) VS -3.2 (IQR -5.1 to -1)
    - Spine: -1.4 (IQR -3.8; 0) VS -2.9 (IQR -4.8 to -1.1)
  - Percentage of changes in BTM and PTH levels at weeks 24 and 48.
    - Increases were attenuated in the vitamin D3 plus calcium group compared with the placebo group at 24 weeks

1. Overton TE et al., Ann. Intern. Med., 2015
2. Nanayakkara D et al., AIDS Res Hum Retroviruses, 2019

BMD Loss Attenuated by Vitamin D and Calcium

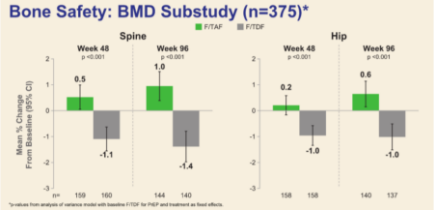
2.



- 167 HIV-infected patients initiating ART were randomized to receive vitamin D3 plus calcium (n=81) or PBO (n=86).
  - Percentage of BMD change from baseline to week 48:
    - Hip: -1.5 (IQR -3.2, -0.4) VS -3.2 (IQR -5.1 to -1)
    - Spine: -1.4 (IQR -3.8; 0) VS -2.9 (IQR -4.8 to -1.1)
  - Percentage of changes in BTM and PTH levels at weeks 24 and 48.
    - Increases were attenuated in the vitamin D3 plus calcium group compared with the placebo group at 24 weeks
- A subset of 48 HIV-uninfected men enrolled in CCTG 595 were selected to receive VitD 4000 IU/day
  - Matched 1:1 with controls based on age, race, and BMI
  - Vitamin D3 supplementation with 4000 IU/day resulted in a significant reduction in the BTM P1NP compared to controls

1. Overton TE et al., Ann. Intern. Med., 2015
2. Nanayakkara D et al., AIDS Res Hum Retroviruses, 2019

DISCOVER: Bone Safety



Slide 25 of 48

Rhame PJ. EACS 2019. Abstract PS3/1

Case 3:
A kiss is a terrible thing to waste

- 28-year-old man is referred for PrEP
- He was diagnosed with obesity, hypertension and sleep apnea and underwent gastric bypass surgery 6 months ago
- Since the surgery, he insists on "eating clean" and takes several vitamin supplements daily, including Vitamin A, B3, B6, E, gingko biloba, and milk thistle

Slide 26 of 48

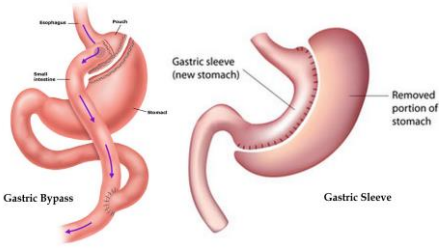
ARS Question #3

How do you instruct him to optimally implement PrEP?

1. Daily oral TDF/FTC
2. Double dose daily oral TDF/FTC
3. On-demand "2-1-1" TDF/FTC
4. Daily oral TAF/FTC
5. Something else

Slide 27 of 48

Gastric Bypass and Gastric Sleeve



Slide 28 of 48

TDF PK After Sleeve-Gastrectomy in 4 HIV-infected individuals

Time	Patient	T_{max} (h)	C_{max} (ng/mL)	C_{min} (ng/mL)	AUC (h·ng/mL)	Terminal half-life (h)	Clearance (L/h)
Pre-operative	Mean ± SD	1.25	263 ± 79	47 ± 15	2346 ± 643	13 ± 3	112 ± 37
	Patient #1	1	272	50	2364	17	104
	Patient #2	1	311	57	2528	12	97
	Patient #3	2	320	56	3017	14	81
	Patient #4	1	148	24	1476	10	166
1 month after SG	Mean ± SD	1.5	162 ± 44	34 ± 13	1529 ± 415	19 ± 3	171 ± 54
	Patient #1	2	158	48	1807	22	136
	Patient #2	1	225	41	1906	15	129
	Patient #3	2	142	22	1405	19	174
	Patient #4	1	124	23	997	19	246
3 months after SG	Mean ± SD	1.5	252 ± 93	40 ± 10	2174 ± 547	14 ± 3	119 ± 34
	Patient #1	1	150	30	1479	16	166
	Patient #2	1	340	49	2766	13	89
	Patient #3	1	322	32	2055	15	119
	Patient #4	3	197	48	2394	10	102
6 months after SG	Mean ± SD	1.25	259 ± 148	32 ± 6	1597 ± 355	15 ± 4	161 ± 45
	Patient #1	1	479	31	1870	16	131
	Patient #2	2	183	35	1776	12	138
	Patient #3	1	210	38	1661	21	148
	Patient #4	1	162	24	1079	12	227
12 months after SG	Mean ± SD	1	325 ± 43	47 ± 17	2344 ± 941	16 ± 2	114 ± 46
	Patient #1	1	294	35	1678	17	146
	Patient #2	1	355	59	3009	14	81

- Decrease in absorption of tenofovir at 1 month as assessed by AUC_{0-24h} and C_{max}
- Decrease in absorption of tenofovir at 6 months as assessed by AUC_{0-24h}
  - C_{max} comparable to pre-operative levels
- At 12-months, AUC_{0-24h} and C_{max} return to post-operative levels
- No available data on absorption of tenofovir in HIV-unfected individual after Sleeve-Gastrectomy.

Slide 29 of 48

Muzzard L et al., Obesity Research & Clinical Practice, 2017

TDF Double-Dose in Treatment-Experienced HIV-Infected Patients (n=10)

- TDF 600 mg QD added to background ART
- Patients were seen at baseline, W2, and W4 for clinical exam, plasma HIV-1 RNA load,, liver and kidney function tests, tenofovir plasma and urine concentrations, and AE assessments
- One patient (male, 50 years old) experienced Fanconi syndrome
  - W2 deceline in Cr Cl from 96 mL/min to 43 mL/min
  - Proteinuria 12g/24h
  - Hypophosphatemia, glycosuria

Slide 30 of 48

Dominguez S et al., J. Med. Virol., 2007

Case 4: It's a dangerous world out there

- A 55-year-old man comes regularly for PrEP follow-up and all indications suggest he is adherent to PrEP
- 4-5 male sexual partners per month; condom use inconsistent
- He has a history of recurrent rectal chlamydia, with interim documentation of clearance with appropriate treatment (you confirm dates and treatment provided)

Slide 31 of 48

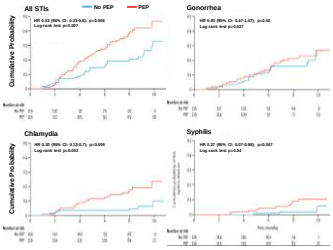
ARS Question #4

You tell him:

1. If he has one more STI you will stop his PrEP
2. This is an "Occupational Hazard" of Condomless Sex
3. "Grow Up America, Use a Condom"*
4. Daily doxycycline with his daily TDF/FTC
5. Doxycycline 200 mg post-coitally up to 3 doses per week
6. Have his partners gargle with listerine before oral sex or oral-anal contact

Slide 32 of 48

IPERGAY OLE: PEP with Doxycycline and STIs



- 232 ANRS IPERGAY OLE participants were randomly assigned to a doxycycline PEP group (n=116) no-PEP group (n=116)
- 73 participants presented with a new STI infections during follow-up, 28 (22% [15–32]) in the PEP group 45 (42% [33–53])
- Doxycycline PEP reduced the occurrence of a first episode of bacterial STI in high-risk men who have sex with men, but NOT gonorrhea
- Larger prospective studies needed
- Bacterial resistance
- Lowered gut bacterial diversity/Gut Microbiota Modification

Molina J et al., Lancet, 2017

Slide 33 of 48

Antiseptic Mouthwash Against Pharyngeal *N gonorrhoeae*

In Vitro

Mean CFU/mL *Neisseria gonorrhoeae* (10^8 CFU/mL) to various concentrations of Listerine Total Care, Cool Mint and saline after 1 min of exposure

	CFU/mL		
Dilution	Listerine Total Care	Listerine Cool Mint	Saline
Neat	–	–	$>10^8$
1/2	$<10^2$	$<10^2$	–
1/4	$<10^2$	2×10^2	–
1/8	$>10^5$	$>10^5$	–
1/16	$>10^5$	$>10^5$	–
1/32	$>10^5$	$>10^5$	–

Results are mean of three replicates. Results are expressed as '$<10^{2}$' rather than zero because only a 100th of the post exposure sample was taken for culture.
CFU/mL, colony forming units per mL

- Listerine Total Care and Cool Mint were found to significantly inhibit the growth of the tested strain of N. gonorrhoeae at dilutions of 1:2 and 1:4.
- The PBS control displayed no inhibitory effect against N. gonorrhoeae.

Slide 34 of 48

Chow E PF et al., Sex Transm Infect, 2016

Antiseptic Mouthwash Against Pharyngeal *N gonorrhoeae*

In Vitro

Mean CFU/mL *Neisseria gonorrhoeae* (10^8 CFU/mL) to various concentrations of Listerine Total Care, Cool Mint and saline after 1 min of exposure

	CFU/mL		
Dilution	Listerine Total Care	Listerine Cool Mint	Saline
Neat	–	–	$>10^8$
1/2	$<10^2$	$<10^2$	–
1/4	$<10^2$	2×10^2	–
1/8	$>10^5$	$>10^5$	–
1/16	$>10^5$	$>10^5$	–
1/32	$>10^5$	$>10^5$	–

Results are mean of three replicates. Results are expressed as '$<10^{2}$' rather than zero because only a 100th of the post exposure sample was taken for culture.
CFU/mL, colony forming units per mL

Randomized Control Trial

	Listerine group (n=33)	Saline group (n=25)	p Value*
Gonorrhoea positivity by culture after rinsing and gargling			
Pharyngeal surface (posterior oropharynx and/or tonsillar fossae)			0.013
Positive	17 (52%)	21 (84%)	
Negative	16 (48%)	4 (16%)	
Tonsillar fossae†			0.016
Positive	13 (57%)	18 (90%)	
Negative	10 (43%)	2 (10%)	
Posterior oropharynx†			0.277
Positive	13 (57%)	14 (70%)	
Negative	10 (43%)	6 (30%)	

- Men in the saline group had a higher gonorrhoea culture positivity at the tonsillar fossae
- Men in the Listerine group had a lower odds of testing positive for gonorrhoea at the tonsillar fossae

Slide 35 of 48

Chow E PF et al., Sex Transm Infect, 2016

Case 5: Shot through the heart (And you're to blame)

- 19-year-old man with a history of bulemia returned for PrEP follow-up
  - He thinks maybe he takes TDF/FTC doses twice during the week, and regularly on weekends
- 7 male sexual partners in the past month; engages in oral and insertive anal sex; does not use condoms
- HIV (4th gen) and STI testing three months ago negative
- He says he heard there is a "shot" that he can take every two months rather than taking a pill - - can he get "that"?
  - He is very concerned about weight gain

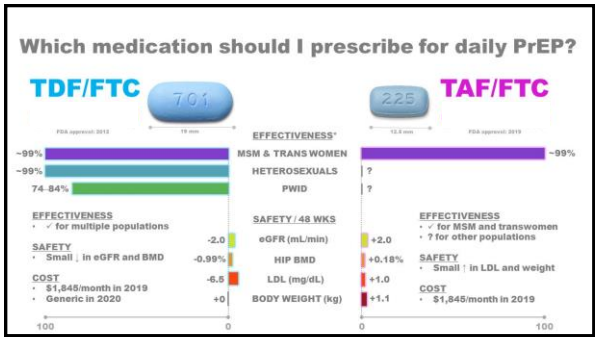
Slide 36 of 48

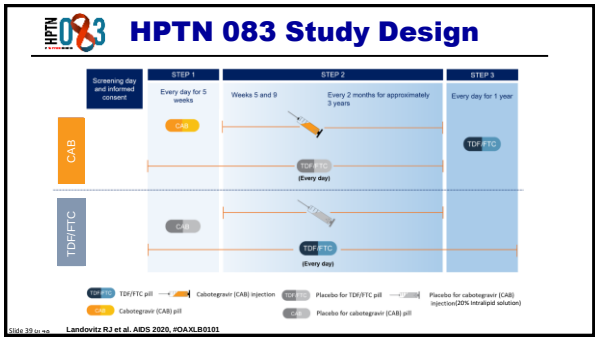
ARS Question #5

Your best advice is:

1. He must strive for 100% adherence to daily oral TDF/FTC
2. Try TAF/FTC daily
3. "T's and S's" is just fine with TDF/FTC
4. Drive to Canada to acquire CAB LA + RPV LA for treatment, split it apart and use the CAB LA for prevention
5. I have a headache stop asking me hard questions

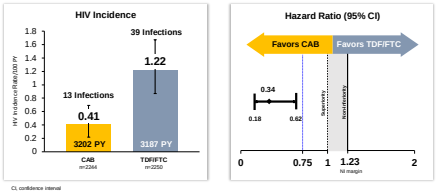
Slide 37 of 48





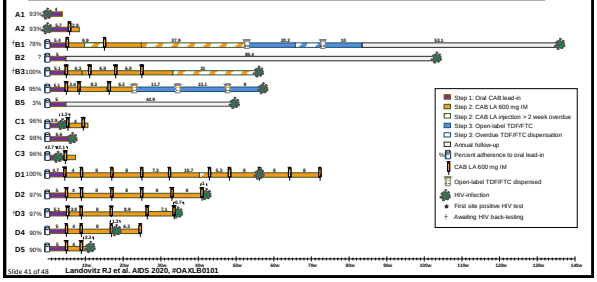
HIV Incidence
CAB vs. TDF/FTC

52 HIV infections in 6389 PY of follow-up
1.4 (IQR 0.8-1.9) years median per-participant follow-up
Pooled incidence 0.81 (95%CI 0.61-1.07) per 100 PY



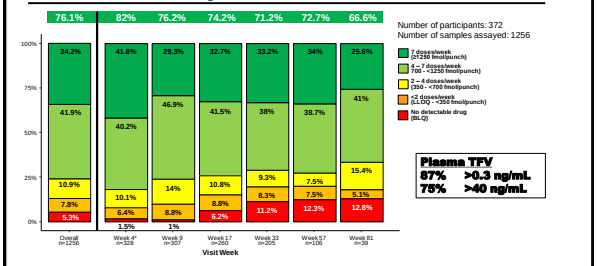
 Landovitz RJ et al. AIDS 2020, #OAXLB0101

13 Incident HIV Infections
Cabotegravir



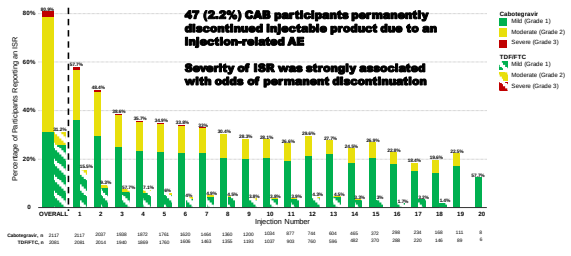
 Landovitz RJ et al. AIDS 2020, #OAXLB0101

DBS TFV-DP
Randomly selected "adherence" subset



 Landovitz RJ et al. AIDS 2020, #OAXLB0101

Injection Site Reactions



Landovitz RJ et al. AIDS 2020, #OAXLB0101

Slide 43 of 48

Grade 2+ Adverse Events
Reported in ≥5%

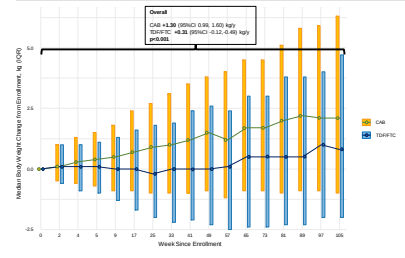
	TOTAL (n=4566)	TDF-FTC (n=2284)	CAB (n=2282)	p-value
Participants with grade 2+ AEs, n (%)	4202 (92.1%)	2106 (92.3%)	2096 (91.9%)	
Creatinine clearance decreased	3204 (70.2%)	1642 (72.0%)	1562 (68.5%)	0.01
CPK increased	937 (20.5%)	460 (20.2%)	477 (20.9%)	0.52
Nasopharyngitis	828 (18.1%)	388 (17.0%)	440 (19.3%)	0.04
Creatinine increased	775 (17.0%)	412 (18.1%)	363 (15.9%)	0.06
Upper Respiratory Infection	510 (11.2%)	255 (11.2%)	255 (11.2%)	0.99
Musculoskeletal discomfort	507 (11.1%)	253 (11.1%)	254 (11.1%)	0.95
Lipase increased	495 (10.9%)	252 (11.0%)	243 (10.7%)	0.68
Headache	448 (9.8%)	216 (9.5%)	232 (10.2%)	0.42
AST/SGOT increased	382 (8.4%)	197 (8.6%)	185 (8.1%)	0.53
ALT/SGPT increased	347 (7.6%)	191 (8.4%)	156 (6.8%)	0.05
Blood glucose increased	323 (7.1%)	117 (5.1%)	206 (9.0%)	<0.001
Amylase increased	316 (6.9%)	166 (7.3%)	150 (6.6%)	0.36
Diarrhoea	306 (6.7%)	158 (6.9%)	148 (6.5%)	0.56
Rash	253 (5.5%)	139 (6.1%)	114 (5.0%)	0.11
Hypoglycaemia	241 (5.3%)	123 (5.4%)	118 (5.2%)	0.75
Pyrexia*	181 (4.0%)	62 (2.7%)	121 (5.4%)	<0.001

*70% of pyrexia events in CAB were within 7 days of an injection (event probability 0.65%)
16% of pyrexia events in TDF/FTC were within 7 days of an injection (event probability 0.05%)

Landovitz RJ et al. AIDS 2020, #OAXLB0101

Slide 44 of 48

Changes in Weight
Median of changes from baseline (IQR)





Cabotegravir Is Not Associated With Weight Gain in Human Immunodeficiency Virus–uninfected Individuals in HPTN 077

HPTN 077: Over 41 weeks

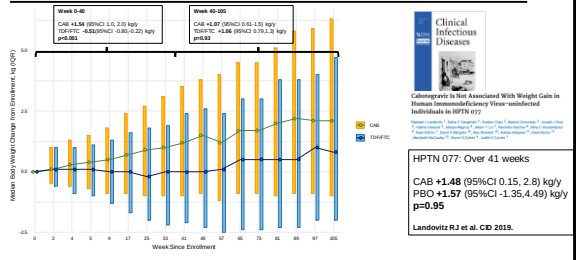
CAB **+1.48** (95%CI 0.15, 2.8) kg/y
PBO **+1.57** (95%CI -1.35,4.49) kg/y
p=0.95

Landovitz RJ et al. CID 2019.

Landovitz RJ et al. AIDS 2020, #OAXLB0101

Slide 45 of 48

Changes in Weight
Median of changes from baseline



Cabotegravir Is Not Associated With Weight Gain in Human Immunodeficiency Virus–uninfected Individuals in HPTN 077

HPTN 077: Over 41 weeks

CAB **+1.48** (95%CI 0.15, 2.8) kg/y
PBO **+1.57** (95%CI -1.35,4.49) kg/y
p=0.95

Landovitz RJ et al. CID 2019.

Slide 46 of 48 **Landovitz RJ et al. AIDS 2020, #OAXLB0101**

Thank you!

Slide 47 of 48

Suggested Further Reading

Pilkington V et al.,
How safe is TDF/FTC as PrEP? A systematic review and meta-analysis of the risk of adverse events in 13 randomised trials of PrEP. Journal of Virus Eradication. 2018 Oct;4(4):215.

Khan S et al.,
Tenofovir Disoproxil Fumarate-Associated Fanconi Syndrome in an Human Immunodeficiency Virus (HIV)-Uninfected Man Receiving HIV Pre-Exposure Prophylaxis. InOpen forum infectious diseases 2017 Jul 1 (Vol. 4, No. 3). Oxford University Press.

Gandhi M et al.,
Hair levels of PrEP drugs measure adherence and are associated with renal decline among men/transwomen in an open label PrEP study. AIDS (London, England). 2017 Oct 23;31(16):2245.

Gandhi M et al.,
Association of age, baseline kidney function, and medication exposure with declines in creatinine clearance on pre-exposure prophylaxis: an observational cohort study. The lancet HIV. 2016 Nov 1;3(11):e521-8.

Nanayakkara D et al.,
Effect of Vitamin D Supplementation on Bone Turnover Markers during HIV Pre-exposure Prophylaxis using Tenofovir Disoproxil Fumarate-Emtricitabine in Men who have Sex with Men. AIDS research and human retroviruses. 2019 Mar 23(ja).

Mulligan K et al.,
Effects of emtricitabine/tenofovir on bone mineral density in HIV-negative persons in a randomized, double-blind, placebo-controlled trial. Clinical infectious diseases. 2015 Apr 23;61(4):572-80.

Glidden DV et al.,
Brief Report: Recovery of Bone Mineral Density After Discontinuation of Tenofovir-Based HIV Pre-exposure Prophylaxis. Journal of acquired immune deficiency syndromes (1999). 2017 Oct;76(2):177-82.

Overton ET et al.,
Vitamin D and calcium attenuate bone loss with antiretroviral therapy initiation: a randomized trial. Annals of internal medicine. 2015 Jun 16;162(12):815-24.

Dominguez S et al.,
Efficacy and safety of tenofovir double-dose in treatment-experienced HIV-infected patients: The tenoplus study. Journal of medical virology. 2007 Feb;79(2):105-10.

Molina JM et al.,
Efficacy, safety, and effect on sexual behaviour of on-demand pre-exposure prophylaxis for HIV in men who have sex with men: an observational cohort study. The lancet HIV. 2017 Sep 1;4(9):e402-10.

Chow EP et al.,
Antiseptic mouthwash against pharyngeal Neisseria gonorrhoeae: a randomised controlled trial and an in vitro study. Sex Transm Infect. 2017 Mar 1;93(2):88-93.

Clement ME et al.,
Long-acting injectable cabotegravir for the prevention of HIV infection. Curr Opin HIV AIDS. 2020 Jan; 15 (1): 19-26.

Slide 48 of 48

2020 Ryan White HIV/AIDS Program CLINICAL CONFERENCE

Question-and-Answer Session

rlandovitz@mednet.ucla.edu