TAF-FTC versus TDF-FTC PrEP for MSM and TGW **DISCOVER Trial**



TAF-FTC versus TDF-FTC HIV PrEP for MSM and TGW DISCOVER: Study Design

- **Background:** Phase 3, multinational, double-blind, active-controlled trial assess safety and efficacy of tenofovir alafenamide-emtricitabine (TAF-FTC) versus tenofovir DF-emtricitabine (TDF-FTC) for HIV PrEP
- Inclusion Criteria
 - Enrolled high-risk* cisgender MSM and transgender women (TGW)
 - Prior TDF-FTC HIV PrEP allowed
 - No history of HIV or HBV
 - eGFR ≥60 mL/min
- Treatment Arms (5,387 enrolled)
 - Daily dosing for TAF-FTC
 - Daily dosing for TDF-FTC
 - Provided counseling and condoms at entry and every 3 months
- Primary Endpoint
 - 100% incident HIV infection after 48 weeks
 - 50% incident HIV infection after 96 weeks

*Based on self-reported sexual activity (in the past 12 weeks) or recent history (within 24 weeks of enrollment) of bacterial STIs

Tenofovir alafenamide-Emtricitabine (TAF-FTC) (n = 2,694) Tenofovir DF-Emtricitabine (TDF-FTC)

(n = 2,693)



Source: Mayer KH, et al. Lancet 2020;396:239-54.

TAF-FTC versus TDF-FTC HIV PrEP for MSM and TGW DISCOVER: Baseline Demographics & Risk Factors

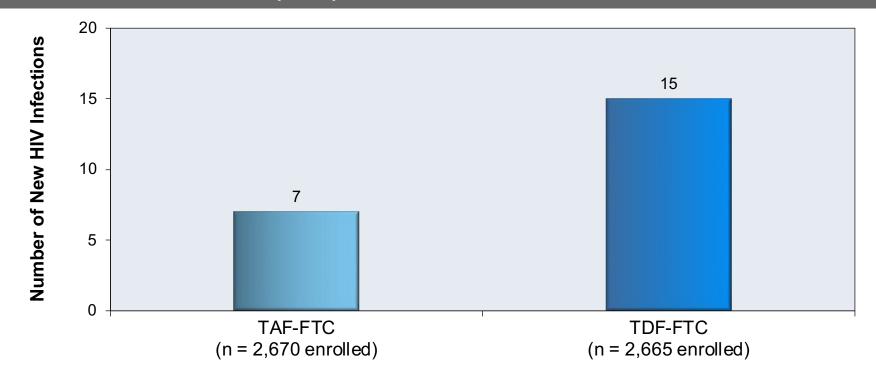
TAF-FTC (n = 2,694)	TDF-FTC (n = 2,693)
34 (28-43)	34 (28-44)
2,264 (84%)	2,247 (84%)
240 (9%)	234 (9%)
45 (2%)	29 (1%)
1,616/2,602 (62%)	1,569/2,597 (60%)
274 (10%)	262 (10%)
343 (13%)	333 (12%)
230 (9%)	263 (10%)
1,785/2,680 (67%)	1,786/2,677 (67%)
465 (17%)	440 (16%)
	(n = 2,694) 34 (28-43) 2,264 (84%) 240 (9%) 45 (2%) 1,616/2,602 (62%) 274 (10%) 343 (13%) 230 (9%) 1,785/2,680 (67%)

Abbreviations: TDF-FTC = tenofovir DF-emtricitabine; TAF-FTC = tenofovir alafenamide-emtricitabine; RAI = receptive anal intercourse



TAF-FTC versus TDF-FTC for HIV PrEP in MSM and TGW DISCOVER: Results

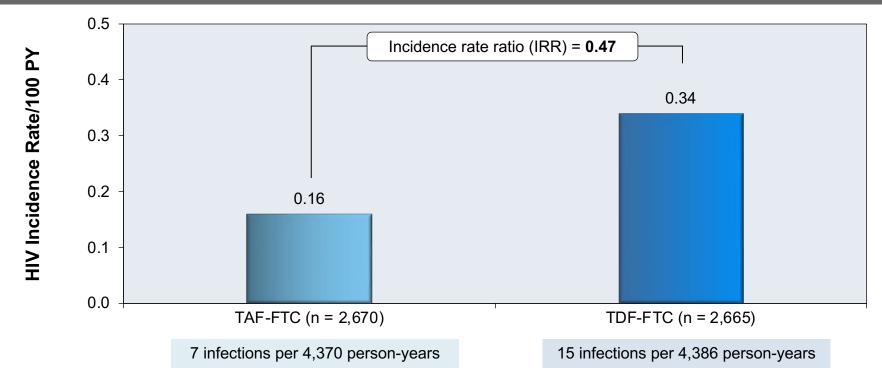
HIV Seroconversions at Primary Analysis





TAF-FTC versus TDF-FTC for HIV PrEP in MSM and TGW DISCOVER: Results

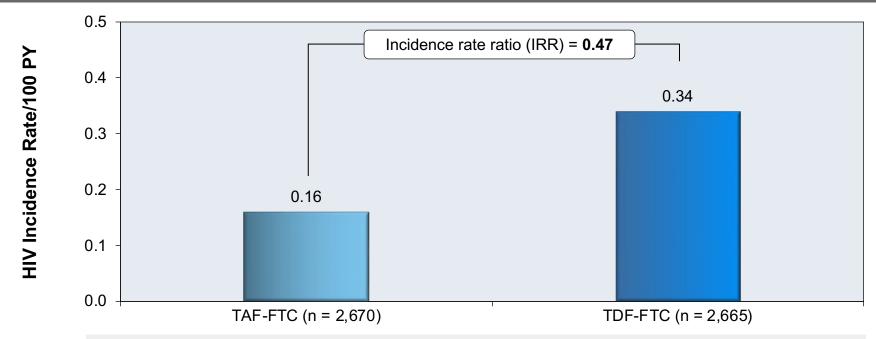
Primary Endpoint Result: HIV Incidence Rate





TAF-FTC versus TDF-FTC for HIV PrEP in MSM and TGW DISCOVER: Results

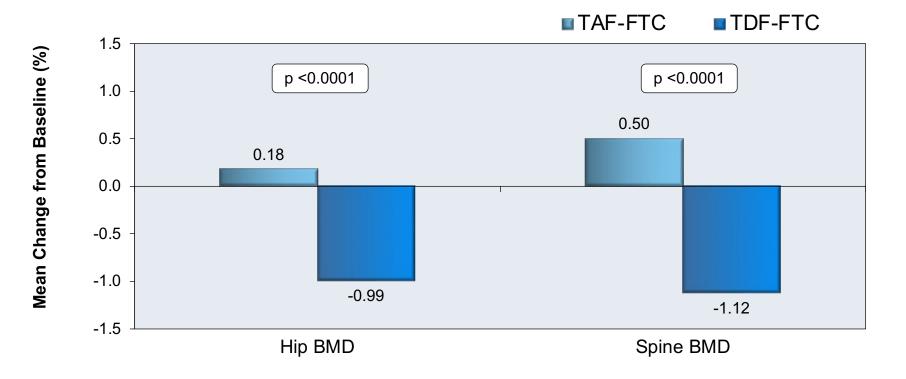
Primary Endpoint Result: HIV Incidence Rate



NOTE: Excluding baseline HIV infections (1 TAF-FTC, 4 TDF-FTC) the IRR was 0.55; there was 1 new infection in each arm that occurred in persons who had adequate drug levels

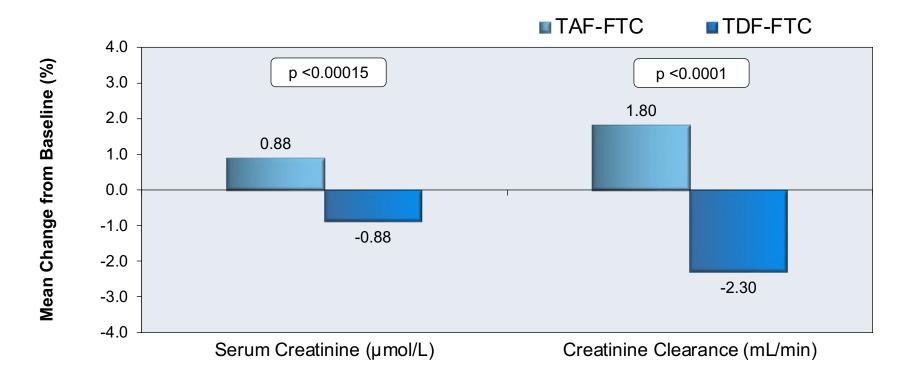


TAF-FTC versus TDF-FTC HIV PrEP for MSM and TGW DISCOVER: Bone Mineral Density





TAF-FTC versus TDF-FTC HIV PrEP for MSM and TGW DISCOVER: Renal Function





TAF-FTC versus TDF-FTC HIV PrEP for MSM and TGW DISCOVER: Adverse Effects and Sexually Transmitted Infections

	TAF-FTC (n = 2,694)	TDF-FTC (n = 2,693)
Drug-Related Adverse Effects (AEs)		
AEs leading to stoppage, n (%)	36 (1%)	49 (2%)
Mean change (%), spine BMD	0.50*	-1.12
Mean change (%), hip BMD	0.18*	-0.99
Mean change (mL/min), eGFR	1.8*	-2.3
Sexually Transmitted Infections (STIs)		
Gonorrhea (any site), n (n/100 person-years)	1053 (47.1)	1059 (45.3)
Chlamydia (any site), n (n/100 person-years)	1049 (41.9)	1071 (41.6)
Syphilis, n (n/100-person years)	365 (10.3)	370 (9.5)
Abbreviations: BMD = bone mineral density; GFR = glomerular filtration rate		

Source: Mayer KH, et al. Lancet 2020;396:239-54.



TAF-FTC versus TDF-FTC HIV PrEP for MSM and TGW DISCOVER: Conclusions

Interpretation: "Daily emtricitabine and tenofovir alafenamide shows non-inferior efficacy to daily emtricitabine and tenofovir disoproxil fumarate for HIV prevention, and the number of adverse events for both regimens was low. Emtricitabine and tenofovir alafenamide had more favourable effects on bone mineral density and biomarkers of renal safety than emtricitabine and tenofovir disoproxil fumarate."



Acknowledgments

The National HIV Curriculum is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$1,021,448 with 0% financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by HRSA, HHS, or the U.S. Government. For more information, please visit HRSA.gov. This project is led by the University of Washington's Infectious Diseases Education and Assessment (IDEA) Program.





