

Utilization of Oral Pre-exposure Prophylaxis (PrEP) After FTC/TAF Approval in the United States

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BACKGROUND

Two oral medications are approved for PrEP in the US: emtricitabine/tenofovir disoproxil fumarate and tenofovir alafenamide (FTC/TDF, FTC/TAF).

In the DISCOVER trial FTC/TAF exhibited favorable safety outcomes (creatinine clearance, bone mineral density) compared to FTC/TDF.

This study describes socio-demographic and clinical characteristics of individuals new to PrEP after the approval of FTC/TAF in the US (October 2019) to better understand PrEP prescribing and dispensing patterns in clinical practice.

METHODS

Data source: EMR and dispensing data from Trio Health HIV Research Network (10/2019-11/2021).

Included: HIV-negative adults newly prescribed or dispensed oral PrEP (≥1-month supply) with ≥3 months follow-up.

Excluded: indications of hepatitis B or post-exposure prophylaxis prior to PrEP.

Comorbidities, socio-demographic and clinical characteristics were compared among those prescribed and (separately) those dispensed FTC/TAF vs FTC/TDF (t-test, chi-square) at the same facilities.

Classification and regression trees analysis (CART) was utilized to evaluate predictors of prescribing and dispensing FTC/TAF.

Variables used in CART analysis: age, race, payer, liver function tests at baseline (ALT > upper limit of normal (ULN), AST > ULN), baseline eGFR category (<60, 60-89, 90+ mL/min/1.73m³), documented "high-risk behavior" at baseline (based on ICD-10), baseline BMI.

Gender was not used in the model due to high proportion of unspecified gender.

RESULTS

In the prescription cohort (N=2213), most individuals were prescribed FTC/TAF (1821 [82%] vs. FTC/TDF 392 [18%]). A similar distribution was observed for the dispense cohort (N=1794; FTC/TAF 1551 [86%]; FTC/TDF 243 [14%]).

In both cohorts, most participants had commercial insurance and FTC/TAF individuals were more likely to be white and male.

In the prescription cohort, "high-risk behavior" and clinical characteristics, including mean BMI, age, eGFR were similar for FTC/TAF and FTC/TDF among those with available data [Table].

Individuals dispensed FTC/TAF were more likely to be overweight at baseline (39% vs. 29%; p=.019), with "high-risk behavior" (75% vs. 63%, p<.001), age >50 (16% vs. 11%, p=.041), and less likely to be age ≤25 (13% vs 18%, p=.018).

Based on CART analysis, primary predictors of prescribing FTC/TAF were payer and race [Figures 1, 3]. The model accuracy was 82%.

Predictors of dispensing FTC/TAF were more complex: top 3 predictors of dispensing FTC/TAF were age, "high-risk behavior" and payer. Other less important predictors were baseline BMI, eGFR, and liver function tests [Figures 2, 4]. The model successfully predicted 87% of cases.

CONCLUSIONS

Socio-demographic characteristics were key predictors of both prescribing and dispensing behaviors.

Individual safety risk factors (e.g., age and renal function) did not appear to factor into prescribing decisions for FTC/TAF vs. FTC/TDF.

Perception of individual risk for HIV acquisition based on sexual behavior emerged as an important predictor of FTC/TAF dispenses. This finding will need further evaluation in upcoming research.

Table. Characteristics of Individuals Prescribed and Dispensed PrEP After October 2019

n (%); mean (std)	Prescription Cohort (n=2213)		Dispense Cohort (n=1794)	
	FTC/TDF n=392	FTC/TAF n=1821	FTC/TDF n=243	FTC/TAF n=1551
Gender				
Male	257 (66)	1312 (72)*	124 (51)	1024 (66)*
Female	64 (16)*	35 (2)	26 (11)*	16 (1)
Transgender	4 (1)	16 (1)	0 (0)	1 (0)
Unspecified or non-binary	67 (17)	458 (25)†	93 (38)	510 (33)
Race				
White	190 (48)	1020 (56)†	108 (44)	928 (60)*
Black	79 (20)†	266 (15)	28 (12)	182 (12)*
Asian, American Indian, or Pacific Islander	41 (10)	175 (10)	20 (8)	128 (8)
Payer				
Unspecified	82 (21)	360 (20)	87 (36)*	313 (20)
Commercial	264 (67)	1173 (64)	116 (48)	949 (61)*
Medicare	5 (1)	40 (2)	2 (1)	34 (2)
Medicaid	49 (13)†	148 (8)	24 (10)	106 (7)
Ryan White	0 (0)	3 (0)	0 (0)	3 (0)
Other plan or self-pay	35 (9)*	103 (6)	9 (4)	34 (2)
Unknown	39 (10)	354 (19)‡	92 (38)†	425 (27)
Age				
18-25 years	61 (16)	326 (18)	44 (18)	195 (13)*
26-50	282 (72)	1250 (69)	173 (71)	1112 (72)
51+	49 (13)	245 (13)	26 (11)	244 (16)*
"High-risk Behavior" ¹	279 (71)	1372 (75)	154 (63)	1156 (75)*
eGFR ² (>90 mL/min/1.73m ³)	257 (74)	1105 (73)	133 (75)	892 (70)
Underweight <18.5 kg/m ²	13 (4)	43 (3)	9 (6)	40 (4)
Normal 18.5-24.9	118 (39)	490 (39)	64 (41)	403 (37)
Overweight 25-30	102 (34)	465 (37)	45 (29)	419 (39)*
Obese >30	68 (23)	266 (21)	37 (24)	219 (20)

*p<0.05; †p<0.01; ‡p<0.001 FTC/TDF vs FTC/TAF.

¹"High-risk Behavior": ICD-10 codes for "high-risk sexual behavior" and exposure to communicable diseases.

²eGFR= estimated glomerular filtration rate; eGFR values available for 84% (1865) of those prescribed and 81% (1457) of dispensed.

³BMI= body mass index; BMI available for 69% of prescribed and 71% of dispensed.

Figure 1. CART Tree For Prescription Cohort

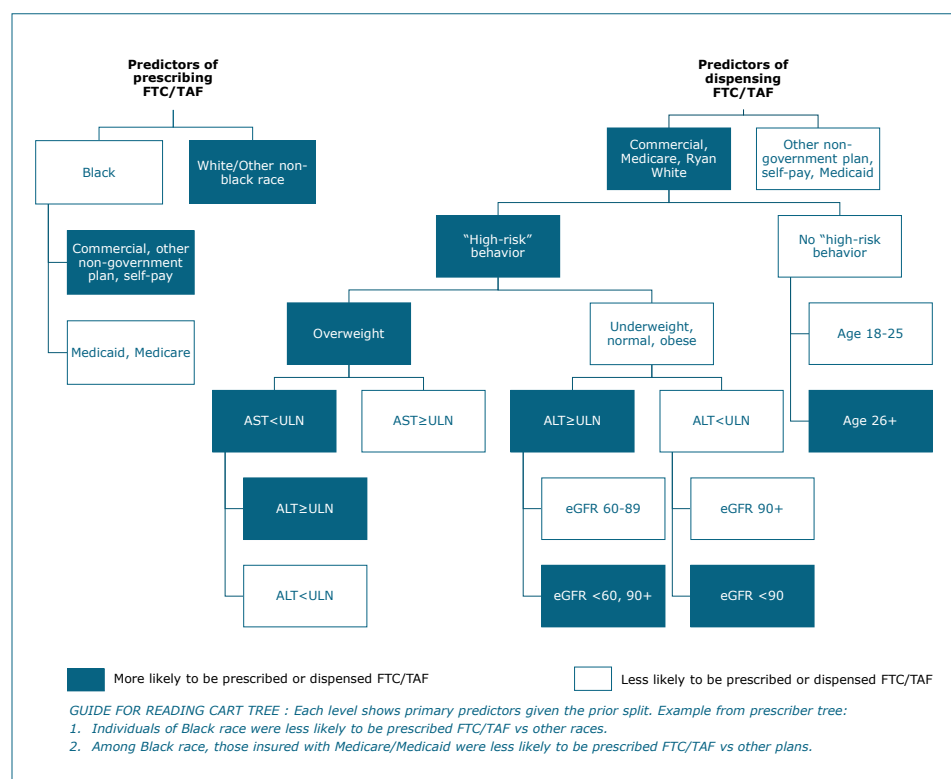


Figure 3. Predictors of Prescribing FTC/TAF by Normalized Importance to CART Model

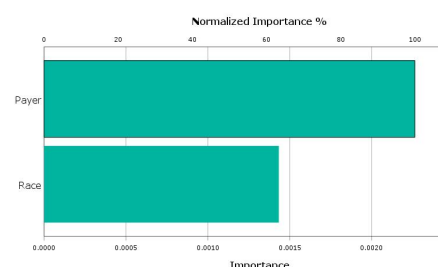


Figure 2. CART Tree For Dispense Cohort

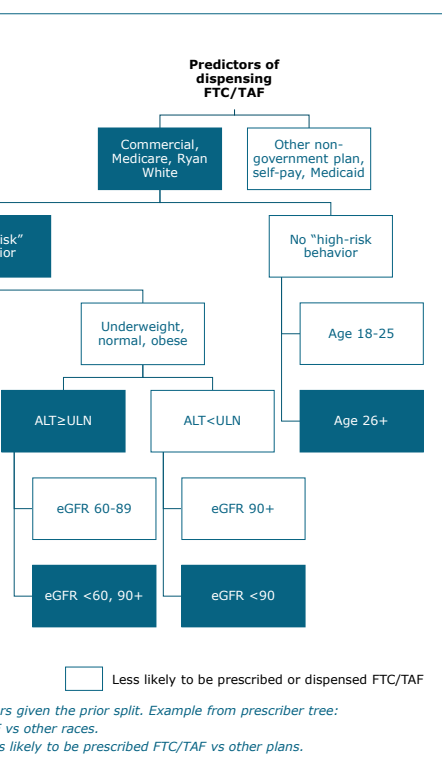
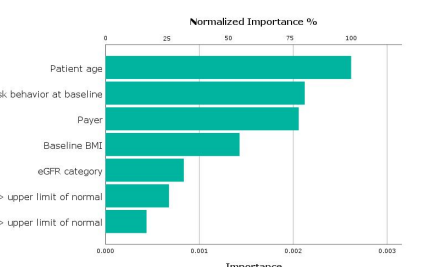


Figure 4. Predictors of Dispensing FTC/TAF by Normalized Importance to CART Model



R. Elion received grants from Gilead Sciences and Proteus, serves on the Advisory boards for Gilead Sciences and ViiV Healthcare, and is a speaker for Gilead Sciences and Janssen. J. Radtchenko is employed by Trio Health. J. Gruber and M. Dunbar are employed by Gilead Sciences. K. Mounzer advises for ViiV, Merck, Janssen, Gilead Sciences. He is on the speakers' bureau for ViiV Healthcare, Merck, Janssen, Gilead Sciences, clinical care options, and Simply Speaking. Prime and received research grants from ViiV Healthcare, Merck, Janssen, Gilead Sciences, K. Mayer is a consultant for ViiV Healthcare, Gilead Sciences, Janssen, and Merck and received research funding from these companies. G. Huhn advises to Gilead Sciences, ViiV Healthcare, Janssen, Lilly, Merck, received institutional grant support from Gilead Sciences, ViiV Healthcare, Janssen, Lilly, Ridgeback. Helps with content development to Simply Speaking, Clinical Care Options, Medscape, CME Outfitters. Drs. Mounzer, Huhn, Mayer, and Elion serve on Trio Health's Scientific Advisory Board.