Figure 1. PrEP Cascade at VAMHCS by year. Non-statistically significant (P=0.33) when comparing engagement in care between different years.

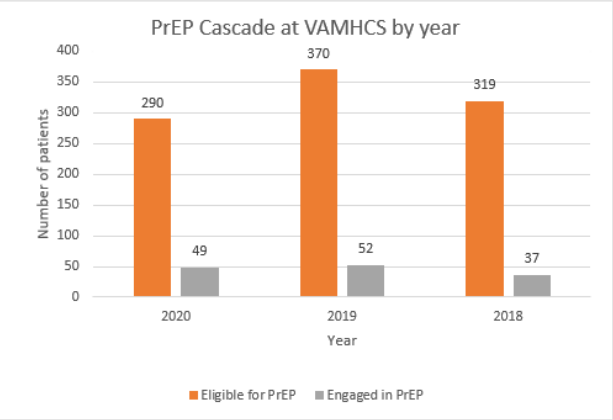
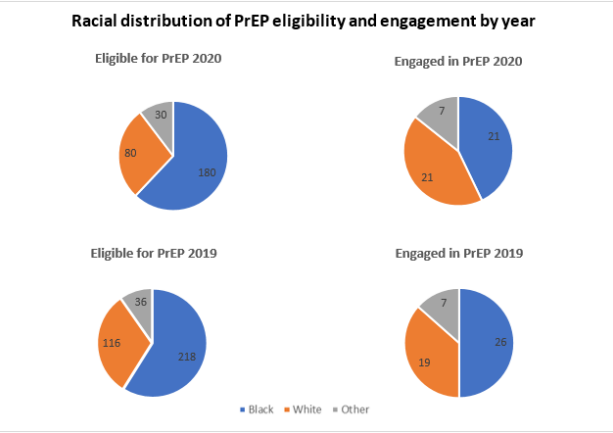


Figure 2. Racial distribution of PrEP eligibility and initiation by year at the VAMHCS.



Conclusion. While during the coronavirus pandemic in 2020, fewer Veterans sought STI testing at the VAMHCS, the number of positive STI results remained steady, leading to a higher positivity rate. The rate of initiation of PrEP did not differ between 2020, 2019 and 2018. Racial inequities in initiation of PrEP increased in 2020.

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852. Bridging the Gap in PrEP Provider Training: An Implementation Science Study

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Session: P-49. HIV: Prevention

Background. Training healthcare providers in a variety of clinical settings to deliver pre-exposure prophylaxis (PrEP) is a key component of the Ending the HIV Epidemic (EHE) initiative. Self-efficacy, the individual's belief in their ability to carry out the steps of PrEP delivery, is a core part of provider training and necessary for successful PrEP implementation. We characterized self-efficacy among providers from family planning (FP) clinics that do not provide PrEP to inform provider training strategies.

Methods. We surveyed providers (any clinical staff who could screen, counsel, or prescribe PrEP) from FP clinics in 18 Southern states (Feb-June 2018, N=325 respondents from 224 clinics not providing PrEP) using contraception- and PrEP-specific self-efficacy questions (overall and grouped into PrEP delivery steps: screening, initiation, and follow-up). We compared self-efficacy scores (5-point Likert scale) by prescriber status, between PrEP delivery steps, and used linear mixed models to analyze provider-, clinic-, and county-level covariates associated with overall PrEP self-efficacy.

Results. Among 325 FP providers, self-efficacy scores were lowest in the PrEP initiation step, higher in follow-up, and highest in screening ($p < 0.0001$, Table). Mean overall PrEP self-efficacy scores were significantly higher among prescribers compared to non-prescribers ($p < 0.0001$). However, providers reported lowest self-efficacy regarding insurance navigation for PrEP with no significant difference by prescriber status. The mixed model demonstrated overall PrEP self-efficacy was positively associated with favorable PrEP attitudes among non-prescribers, PrEP knowledge among prescribers, and contraception self-efficacy in both groups, but was not associated with availability of insurance navigation on-site or other covariates (Figure).

Provider Self-Efficacy along the PrEP Delivery Model stratified by prescriber status

Provider Self-Efficacy Survey Topics and Questions[1]	All Providers N = 325 (mean, SD)	Non-prescribers N = 176 (mean, SD)	Prescribers N = 149 (mean, SD)	*P*-value[2]
PrEP Screening	3.57 (0.81)	3.25 (0.81)	3.94 (0.64)	<0.0001
A. Patient Engagement HIV risk assessment per CDC PrEP guidelines. PrEP readiness assessment. PrEP side-effects counseling. PrEP adherence counseling. Patient referral to subspecialists for PrEP/HIV.	3.67 (0.84)	3.38 (0.86)	4.02 (0.66)	<0.0001
B. Initial Clinical Evaluation Test for HIV. Screen for acute HIV. Kidney function assessment. Test for and interpret active hepatitis B virus results. PrEP medication interactions assessment.	3.46 (0.91)	3.12 (0.90)	3.86 (0.75)	<0.0001
PrEP Initiation PrEP prescription. PrEP insurance navigation.	2.33 (0.95) 2.34 (1.26) 2.31 (1.03)	2.01 (0.76) 1.73 (0.82) 2.30 (1.01)	2.70 (1.02) 3.07 (1.31) 2.32 (1.05)	<0.0001
PrEP Follow-up Medication adherence counseling and side-effect assessment. Appropriate interval laboratory testing.	3.29 (1.15)	3.07 (1.12)	3.55 (1.13)	<0.0001
Overall PrEP Self-Efficacy	3.35 (0.78)	3.05 (0.75)	3.71 (0.66)	<0.0001
Contraception Self-Efficacy Pregnancy intentions and contraceptive counseling initial assessment. Pregnancy intentions and contraceptive counseling follow-up.	4.03 (0.92)	3.82 (1.03)	4.28 (0.70)	<0.0001

Table: Provider Self-Efficacy along the PrEP Delivery Model stratified by prescriber status (n = 325). Self-efficacy scores for each step of the PrEP Delivery Model represent the means of scores corresponding to questions within each step. Overall PrEP Self-Efficacy scores represent the means of all steps within the model. 1. Survey question text is abridged in this table to highlight question topic. 2. *P*-values comparing non-prescriber and prescriber self-efficacy scores were calculated using unpaired t-tests. *P*-values described in the abstract text comparing self-efficacy scores between the steps of the PrEP Delivery Model were calculated using paired t-tests.

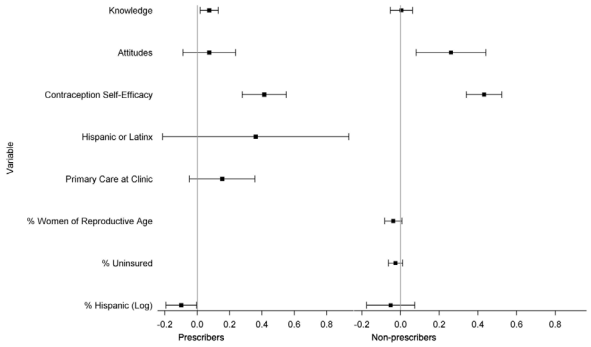

Figure. Linear Mixed Model Results for Self-Efficacy among Providers from Non-PrEP Providing Family Planning Clinics in the Southern United States February-June 2018. Variables were selected for inclusion using a backward selection approach. Variables missing in the model results above were not selected. The percent and prevalence rate variables are the percents or log transformed percents or rate among the county population where the provider's clinic is located and based on data from the U.S. Census Bureau 2010 Census and AIDSVu. The points indicate linear mixed model estimates and whiskers indicate unadjusted 95% confidence intervals.

Conclusion. FP providers reported low confidence in their ability to perform the steps that comprise PrEP initiation. Provider training focused on elements of PrEP initiation are critical to improve PrEP implementation and EHE initiatives. Alternatively, programs employing referral or telehealth models to support the PrEP initiation step can successfully bridge this gap.

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853. Real-World Persistency of Patients Receiving Tenofovir-Based Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the US

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Session: P-49. HIV: Prevention

Background. Once-daily oral tenofovir-based combinations as pre-exposure prophylaxis (PrEP) have shown to be an effective biomedical HIV prevention strategy for populations at-risk of acquiring HIV-1. However, low adherence can lead to poor effectiveness. This study described the characteristics of commercially-insured US PrEP users.

Methods. This retrospective study used IQVIA™ PharMetrics Plus data (1/1/2015–3/31/2020) to identify adults newly initiated (index date) on

emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) or emtricitabine/tenofovir alafenamide (FTC/TAF) as daily PrEP. Users had ≥6 months of continuous enrollment pre-index (baseline); those diagnosed with HIV or with antiretroviral therapy (ART) use during baseline were excluded. User characteristics were described during the baseline period. For FTC/TDF users, proportion of days covered (PDC), persistence, treatment breaks, and switching were described during the follow-up period, which spanned from index to the earliest of disenrollment or end of data. Non-persistence was defined as a >90-day gap from last day of supply, with re-initiation after this gap indicating treatment break. For PDC and persistence, follow-up was censored at HIV infection, defined by both multi-class ART initiation and HIV diagnosis.

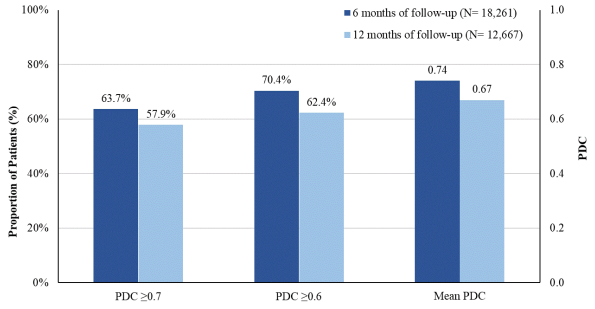
Results. In total 24,232 FTC/TDF and 1,187 FTC/TAF users were identified. Overall, mean age was 35.1 years and 94.5% were male (Table 1). Mean [median] length of follow-up was longer for FTC/TDF (504 [390] days) than FTC/TDF users (77 [70] days). On average, FTC/TDF users had 9.0 dispensings with 38.3 days of supply per dispensing over follow-up; 11.1% had ≥1 treatment break (mean length, 249 days). Among those initiated on FTC/TDF, 10.8% switched to FTC/TAF. The mean PDC for FTC/TDF users at 6 and 12 months was 0.74 and 0.67, respectively, corresponding to 63.7% and 57.9% of patients with PDC ≥0.70 (Figure 1). Persistence to FTC/TDF at 6 and 12 months was 70.2% and 57.4%, respectively (Figure 2).

Table 1. Baseline Demographics and Clinical Characteristics of PrEP Users by Regimen

Characteristics	PrEP Regimen	
	FTC/TDF (Truvada®) (N= 24,232)	FTC/TAF (Descovy®) (N= 1,187)
Observation period,[1] days, mean ± SD [median]	504 ± 408 [390]	77 ± 46 [70]
Demographics[2]		
Age, years, mean ± SD [median]	35.0 ± 11.3 [32]	36.6 ± 12.3 [33]
Male, n (%)	22,869 (94.4)	1,146 (96.5)
Region, n (%)		
South	10,217 (42.2)	680 (57.3)
Midwest	5,137 (21.2)	243 (20.5)
Northeast	5,260 (21.7)	152 (12.8)
West	3,617 (14.9)	112 (9.4)
Year of index date,[3] n (%)		
2015	2,146 (8.9)	0 (0.0)
2016	4,397 (18.1)	0 (0.0)
2017	4,901 (20.2)	0 (0.0)
2018	5,877 (24.3)	0 (0.0)
2019	5,972 (24.6)	481 (40.5)
2020	939 (3.9)	706 (59.5)
Quan-CCI,[4,5] mean ± SD [median]	0.12 ± 0.48 [0]	0.15 ± 0.58 [0]
Select comorbidities,[5] n (%)		
Hypertension	2,893 (11.9)	184 (15.5)
Obesity	1,752 (7.2)	112 (9.4)
Diabetes	962 (4.0)	60 (5.1)
Renal failure	67 (0.3)	8 (0.7)
Hepatitis B	59 (0.2)	4 (0.3)
STI diagnosis,[5] n (%)		
Any STI	2,326 (9.6)	94 (7.9)
Human papillomavirus	796 (3.3)	35 (2.9)
Unspecified venereal diseases	641 (2.6)	32 (2.7)
Syphilis	537 (2.2)	22 (1.9)

ART: antiretroviral therapy; FTC: emtricitabine; HIV: human immunodeficiency virus; PDC: proportion of days covered; TDF: tenofovir disoproxil fumarate.
Note:
1. PDC was calculated for each patient as the total number of days with the index medication (FTC/TDF) on hand during the time interval of interest (i.e., 6 and 12 months) divided by the duration of the interval of interest. The observation period spanned from the index date until the earliest of health plan disenrollment, end of data availability, or HIV infection. HIV infection was defined as the earliest date between an HIV diagnosis and the initiation of a multi-class ART regimen, where patients required both a diagnosis and dispensing to be considered as having HIV infection.

Figure 1. Proportion of Days Covered of FTC/TDF Users



ART: antiretroviral therapy; FTC: emtricitabine; HIV: human immunodeficiency virus; PDC: proportion of days covered; TDF: tenofovir disoproxil fumarate.
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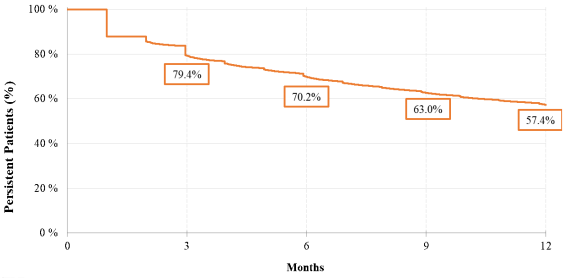
1. PDC was calculated for each patient as the total number of days with the index medication (FTC/TDF) on hand during the time interval of interest (i.e., 6 and 12 months) divided by the duration of the interval of interest. The observation period spanned from the index date until the earliest of health plan disenrollment, end of data availability, or HIV infection. HIV infection was defined as the earliest date between an HIV diagnosis and the initiation of a multi-class ART regimen, where patients required both a diagnosis and dispensing to be considered as having HIV infection.

Figure 2. Kaplan-Meier Persistence Rates of FTC/TDF Users



No. of FTC/TDF patients at risk[2]:					
	24,232	16,502	12,192	9,222	6,981

ART: antiretroviral therapy; FTC: emtricitabine; HIV: human immunodeficiency virus; PrEP: pre-exposure prophylaxis; TDF: tenofovir disoproxil fumarate.
Notes:
1. PrEP non-persistence was defined as a gap of >90 days between the end of the days of supply of a dispensing and the start date of the next fill or between the end of the days of supply of the last dispensing and the end of the observation period (censored at incidence of HIV infection). HIV infection was defined as the earliest date between an HIV diagnosis and the initiation of a multi-class ART regimen, where patients required both a diagnosis and dispensing to be considered as having HIV infection.
2. Number of patients still observed at the specific point in time.

Conclusion. Patient characteristics of PrEP users are broadly similar between regimens, though switching from FTC/TDF to FTC/TAF is common. FTC/TDF users had lower real-world PDC and persistence than in recent clinical trials (DISCOVER and HPTN 083).

Disclosures. **Alan Oglesby, MPH**, **GlaxoSmithKline (GSK)** (Employee, Shareholder) **Guillaume Germain, MSc**, **ViiV Healthcare** (Other Financial or Material Support, I am an employee of Groupe d'analyse, Ltée, a consulting company that provided paid consulting services to ViiV Healthcare for the conduct of the present study.) **Francois Laliberte, MA**, **Viiv** (Research Grant or Support) **Staci Bush, NP**, **GlaxoSmithKline (GSK)** (Employee, Shareholder) **Heidi Swygard, MD**, **ViiV Healthcare** (Employee) **Sean MacKnight, MScPH**, **Analysis Group** (Employee) **Annalise Hilts, BA**, **Analysis Group, Inc.** (Employee) **Mei Sheng Duh, MPH, ScD**, **ViiV Healthcare** (Grant/Research Support)

854. Long-term Outcomes of Participants on F/TAF for Pre-Exposure Prophylaxis: Results for 144 Weeks of Follow-Up in the DISCOVER Trial

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Session: P-49. HIV: Prevention

Background. In DISCOVER, a multinational randomized controlled trial, F/TAF demonstrated noninferior efficacy compared to F/TDF for HIV prevention with improved bone mineral density and renal safety biomarkers at the primary endpoint (when all participants had reached 48 weeks and 50% had reached 96 weeks) and at week (W) 96, the end of the blinded phase. We now report W144 outcomes for participants who were randomized to F/TAF and continued F/TAF in the open-label extension (OLE) phase.

Methods. All participants who completed the randomized blinded phase could opt to receive F/TAF for at least 48 weeks in the OLE phase. We evaluated HIV incidence in participants on F/TAF through W144 and assessed changes in hip and spine bone mineral density (BMD) and in glomerular function (eGFR) from baseline to W144.

Results. 2,080 of the 2,694 participants initially randomized to F/TAF opted into the OLE phase, and 1,933 were still on study drug through W144, thereby leading to a total of 7,885 person-years (PY) of follow-up on F/TAF. Eight participants taking F/TAF acquired HIV in the blinded phase and 3 in the OLE phase. Dried blood spot analyses on the 3 OL infections found tenofovir diphosphate levels consistent with low adherence. Genotypic resistance testing showed no relevant resistance mutations for the 3 new infections. Among participants taking F/TAF, HIV incidence was 0.16/100 PY (95% CI 0.06-0.33) at the primary endpoint, 0.16/100 PY (95% CI 0.07-0.31) through 96 weeks and 0.14/100 PY (95% CI 0.07-0.25) through 144 weeks. Participants taking F/TAF had increases in hip BMD (mean percentage change +0.54%) and in spine BMD (mean percentage change +1.02%) from baseline to W144 (Figure 1). Median eGFR increased over 144 weeks, with a median increase of 2.6 mL/min from baseline to week