103. Persistence on F/TDF for HIV Pre-exposure Prophylaxis: Insights from Real-world Evidence

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Session: O-20. HIV PrEP Prevention: Improving Uptake and Persistence

Background: **Background**: Daily F/TDF is highly effective for HIV pre-exposure prophylaxis (PrEP). Prior studies have found that women and people of younger age have lower adherence and lower persistence on PrEP, yet real-world evidence describing persistence associated with other clinical characteristics and the patterns of persistence is limited.

Methods: **Methods**: We identified 313,526 HIV-1 negative individuals in the United States who initiated F/TDF for PrEP between January 1, 2012 and December 31, 2019 from a de-identified prescription claims database. PrEP users were defined as non-persistent if a gap in prescription fills >30 days was detected. We used survival analyses to estimate the persistence rate by year of PrEP initiation, and Cox regressions adjusting for multiple demographic and clinical characteristics to determine hazard ratios and corresponding 95% confidence interval of non-persistence for PrEP.

Results: **Results:** Among the 313,526 PrEP users with a median age at PrEP initiation of 35 years of age (interquartile range, IQR, 26–43), 88% were men (median days of persistence = 118, IQR 30–316 days) and 12% were women (median 30 days, IQR 30–92 days). PrEP persistence at 30, 60 and 90 days increased over time, reaching the highest levels in 2019 (Figure). In a multivariate analysis, younger age, female sex, and non-white race were associated with higher risk of non-persistence (Table). We also observed associations of a 5% lower rate of non-persistence if PrEP was prescribed by internal medicine or infectious disease physicians than by family medicine physicians, and a 13% lower rate of non-persistence associated prescriptions ordered from mail-order pharmacies than prescriptions of retail pharmacies. Finally, history of bone fracture or renal dysfunction prior to PrEP initiation were associated with a 13% and 9% higher rate of non-persistence, respectively.

Figure. F/TDF for PrEP persistence rates over time.

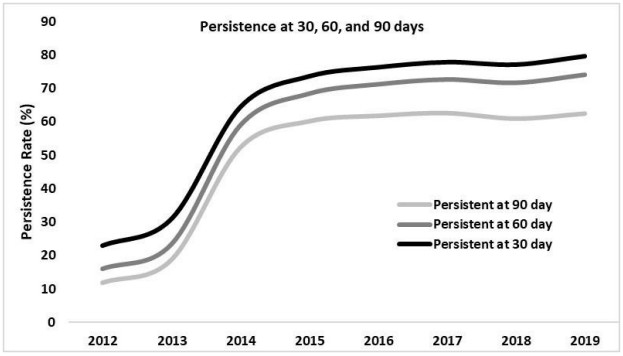

Table. Hazard ratios and corresponding 95% confidence intervals of non-persistence on F/TDF PrEP since initiation, 2012–2019

	N (%)		HR (95%)
All	**313526**		
Age at PrEP initiation			
12-17	2434	0.8%	1.82 (1.74-1.90)
18-25	64898	20.7%	1.35 (1.34-1.36)
26-39	175364	55.9%	Reference
40+	70830	22.6%	0.88 (0.87-0.89)
Gender			
Male	275814	88.0%	Reference
Female	37700	12.0%	2.04 (2.01-2.07)
Race/ethnicity			
White	86355	27.5%	Reference
Black	17548	5.6%	1.11 (1.09-1.13)
Hispanic	19523	6.2%	1.11 (1.09-1.13)
Asian/Other	5281	1.7%	1.06 (1.02-1.09)
Region			
Northwest	80366	25.6%	Reference
Midwest	46991	15.0%	0.97 (0.96-0.98)
South	99204	31.6%	1.03 (1.02-1.04)
West	86892	27.7%	0.99 (0.97-1.00)
Prescriber specialty			
Family Medicine	75646	24.1%	Reference
Internal/Infectious Medicine	96912	30.9%	0.95 (0.94-0.96)
Nurse Practitioner/Physician Assistant	113790	36.3%	1.05 (1.04-1.06)
Pharmacy			
Retail	262758	83.8%	Reference
Mail Order	27467	8.8%	0.87 (0.86-0.88)
Payer Type			
Commercial	276826	88.3%	Reference
Cash/Medicare/Medicaid	36700	11.7%	1.30 (1.28-1.32)
History of STD	14005	4.5%	0.99 (0.97-1.01)
History of Bone Fracture	266033	84.9%	1.13 (1.11-1.14)
History of Renal Dysfunction	3664	1.2%	1.09 (1.05-1.13)

* Additionally adjusted for year of PrEP initiation and multiple comorbidities prior to the initiation of PrEP.

Conclusion: This study demonstrates that persistence on F/TDF for PrEP has improved over time, and identifies several characteristics associated with non-persistence, including age, sex, race/ethnicity, prescriber specialty, type of pharmacy, and history of bone fracture or renal dysfunction. These findings can help to inform interventions aimed at improving PrEP persistence in people at risk of HIV.

Disclosures: Li Tao, MD, PhD, Gilead Sciences Inc (Employee) Valentina Shvachko, n/a, Gilead Sciences Inc (Employee) Robertino Mera, MD, PhD, Gilead Sciences Inc (Employee) Moupali Das, MD, MPH, Gilead Sciences Inc (Employee) Christoph Carter, MD, PhD, Gilead Sciences Inc (Employee) David Magnuson, PharmD, Gilead Sciences Inc (Employee)

104. Evaluation of a Prep Referral System: From Sexual Health Center to Federally Qualified Health Center Prep Clinic

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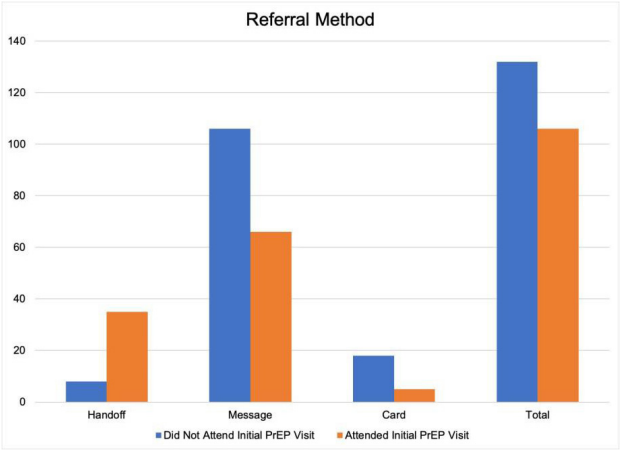
Session: O-20. HIV PrEP Prevention: Improving Uptake and Persistence

Background: In the United States, less than one-quarter of those who are eligible for pre-exposure prophylaxis (PrEP) have been prescribed the medication. Innovative strategies of PrEP delivery are needed to facilitate access and overcome barriers to care. The objective of this study was to evaluate the referral process from a sexual health center (SHC) to a co-located PrEP clinic as an alternative model of PrEP care.

Methods: An initial report was generated from the electronic health record (EHR) to determine the number of patients seen at the SHC in 2019. Charts were then manually reviewed to determine whether a PrEP clinic referral was made. For those referred, we determined the method of the referral: PrEP clinic navigator met the patient at the SHC (*handoff*), the navigator was messaged in the EHR to then schedule the appointment (*EHR message*), or the patient was provided a card with the navigator's contact information (*card*). We also determined whether patients had subsequent visits at the PrEP clinic or SHC.

Results: From January to December 2019, there were 3570 unique patients seen at the SHC, and 240 (6.7%) were referred to the PrEP clinic. Of 240 referred patients, median age was 29 years; 95 (40%) were non-Hispanic Black and 25 (11%) were Latinx. The majority (n=198, 83%) were male, 32 (13%) were cisfemale, and 9 (4%) were transfemale. An STI was diagnosed on the day of the clinic visit for 116 (49%) patients. Of those who were MSM, 75 (51%) had been diagnosed with an STI in the previous 6 months. In total, 106 referred patients attended an initial PrEP visit and the proportion attending the visit by method of referral was 81%, 38%, and 22% for handoff, EHR message, and card, respectively (p< .0001). Of the 108 patients who attended an initial PrEP visit, 66 (61%) had a subsequent PrEP visit. Of those who did not attend a PrEP visit, 36 (27%) had a subsequent visit at the SHC.

Figure 1. Method of Referral from SHC to PrEP Clinic



Conclusion: Despite co-location of these two clinics, there are significant drop-offs along the PrEP care continuum for this referral system. Navigator-facilitated handoff was the most effective method of referral from SHC to PrEP Clinic, but further efforts are needed to understand barriers to referral. Implementation of rapid PrEP provided at the SHC may be one possible solution to engaging additional patients in PrEP services.

Disclosures: **Meredith E. Clement, MD, FHI360** (Consultant)**Gilead** (Research Grant or Support)**Janssen** (Scientific Research Study Investigator)

105. Null Effect of Financial Incentives or Social Media Support on Prep Adherence in a Randomized Controlled Trial of Young Men Who Have Sex with Men of Colour

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Session: O-20. HIV PrEP Prevention: Improving Uptake and Persistence

Background: Pre-exposure prophylaxis (PrEP) using emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) effectively reduces HIV transmission, with efficacy being dependent on adherence. We evaluated the effect of either social media-based support or financial incentives on PrEP adherence among young MSM of color in Washington, DC

Methods: MSM aged 18–29 were randomized 1:1:1 to standard of care (SOC) PrEP (Control group), SOC PrEP + invitation to a bidirectional Facebook group supervised by two clinicians (Social Media group), or SOC PrEP + $50 gift card at each of two follow-up visits (Financial Incentive group). Participants were asked to return at 3 and 6 months. Adherence was monitored with predefined dried blood spots (DBS) TFVdp levels with < 490, 490–979, 980–1749 and ≥1750 fmol/punch correlating with average of < 2, 2–4, 4–6, and 7 doses per week

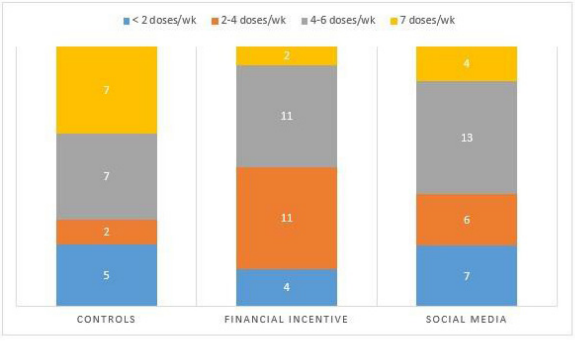
Results: We enrolled 53 MSM. Average age was 22.5 years and 72% of participants were Black. At enrollment, 96% had previously heard of PrEP, 17% had ever taken PrEP but none had taken PrEP in the prior 6 months. 92% of participants reported condomless anal sex in the prior 3 months, 36% with an HIV-positive man or man of unknown HIV status (Table 1). 81% of participants returned for their 3-month visit and 70% for their 6-month visit. Mean self-reported PrEP adherence over the previous 3 months was 78% with no difference in adherence between the three groups at either visit. Based on DBS TFVdp levels, protective PrEP adherence (≥4 doses/week) was measured in 46% of the Financial Incentive group and in 57% of the Social Media group compared to in 67% of the Control group (p=0.38). Only 16% of TFVdp levels corresponded to taking PrEP 7 days a week (Figure 1). There was no change in sexual risk activity over the course of the study. 38 sexually transmitted infections were diagnosed in 26 participants (Figure 2). No participant tested positive for HIV. 3 months after study completion, 9 participants were still taking PrEP

Table I. Sexual risk behaviors over the previous 3 months for study participants assessed at baseline visit, as well as 3 month and 6 month follow up visits

	Social Media Group n (%)	Financial Incentive Group, n (%)	Control Group n (%)	p-value
Baseline Visit, n=53	18	18	17	
Had anal sex with a male partner in the last 3 months	17 (94)	17 (94)	17 (100)	0.999
Had condomless anal sex with a male partner in the last 3 months [a]	16 (94)	16 (94)	17 (100)	0.999
Had condomless anal sex with a male partner of HIV-positive or unknown status in the last 3 months [b]	5 (31)	7 (44)	7 (41)	0.814
3 Month Visit, n=43	15	16	12	
Had anal sex with a male partner in the last 3 months	15 (100)	15 (94)	12 (100)	0.999
Had condomless anal sex with a male partner in the last 3 months [a]	13 (87)	11 (73)	12 (100)	0.206
Had condomless anal sex with a male partner of HIV-positive or unknown status in the last 3 months [b]	7 (54)	6 (55)	5 (42)	0.839
6 Month Visit, n=36	15	12	9	
Had anal sex with a male partner in the last 3 months	15 (100)	10 (83)	9 (100)	0.162
Had condomless anal sex with a male partner in the last 3 months [a]	15 (100)	9 (90)	8 (89)	0.305
Had condomless anal sex with a male partner of HIV-positive or unknown status in the last 3 months [b]	7 (47)	2 (22)	4 (50)	0.473

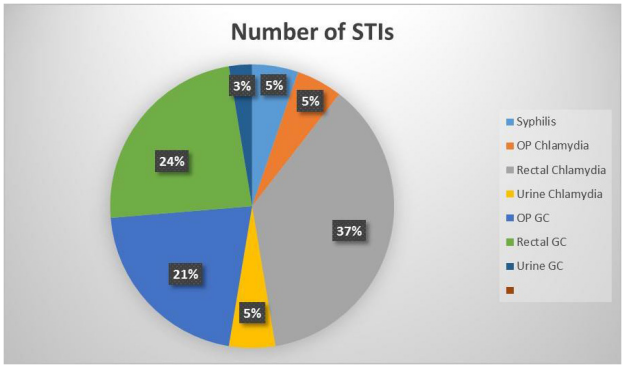
* These p-values were obtained using Fisher's exact tests.
[a] Among participants who had anal sex with a male partner in the last 3 months.
[b] Among participants who had condomless anal sex with a male partner in the last 3 months.

Figure 1. PrEP Adherence.



Adherence calculated with <490, 490-979, 980-1749 and ≥1750 fmol/punch correlating with average of < 2, 2-4, 4-6, and 7 doses per week

Figure 2. Number of sexually transmitted infections by specific etiology and site diagnosed



Conclusion: Our study showed no impact of either offering financial incentives or providing access to a supervised Facebook-based support group on PrEP adherence. Financial compensation based on level of PrEP adherence and using a more age-appropriate social media platform may have a greater impact on adherence

Disclosures: **All Authors**: No reported disclosures

106. META-INSTI: Metabolic Adverse Events Following Integrase Strand Transfer Inhibitor Administration in Spontaneous Adverse Event Reports

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Session: O-21. HIV Treatment and Complications

Background: Unexpected metabolic effects of integrase inhibitors (INSTIs) have been reported in the literature. The FDA Adverse Event Reporting System (FAERS) is a publicly available database that captures spontaneously reported adverse events. Analysis of these data allows for the determination of whether rare or unknown events represent a cause for concern. The objective of this study was to evaluate the relationship between INSTIs and metabolic adverse events using the FAERS database.

Methods: FAERS data were queried from quarter 4 2007 through quarter 4 2019 and limited to adults. The Standardized MedDRA Query (SMQ) for hyperglycemia/new onset diabetes mellitus (H/DM) was used to identify metabolic adverse events of interest. Weight gain was defined as increased weight or increased BMI and was analyzed as a separate event. Reporting odds ratios (ROR) and 95% Confidence Intervals (CIs) were calculated for the INSTI class and for individual agents.

Results: Over 10.1 million FAERS reports were identified. H/DM was noted in 732,591 reports (7.2%); 109,566 (1.1%) reported weight gain. Consumers (49%) and physicians (23%) were the most common reporters. The most frequent countries of occurrence were the US, Great Britain, and Japan. The mean (SD) age was 57 (17) years with 63% females. Any INSTI was mentioned as a primary and/or secondary suspect agent in 18,400 (0.18%) reports (bictegravir: 1,414 [0.01%]; dolutegravir: 7,840 [0.08%]; elvitegravir: 4,034 [0.04%]; raltegravir: 5,551 [0.05%]). RORs (95% CI) for H/DM and weight gain for any INSTI were 1.20 (1.15, 1.27) and 2.16 (1.96, 2.38). For individual agents, RORs (95% CI) for H/DM and weight gain were bictegravir: 1.23 (1.10, 1.37) and 6.82 (5.50, 8.41); dolutegravir: 1.28 (1.19, 1.39) and 1.86 (1.58, 2.18); elvitegravir: 0.76 (0.56, 1.02) and 1.63 (1.37, 1.92); raltegravir: 1.00 (0.90, 1.11) and 3.29 (2.77, 3.91). H/DM was noted in 159 bictegravir and 712 dolutegravir reports.

Conclusion: Overall, H/DM was associated with bictegravir and dolutegravir; weight gain was associated with all INSTIs. Clinicians should be aware of the potential relationship with INSTIs and concerning metabolic effects and institute appropriate monitoring. Future clinical studies to evaluate these findings are warranted.

Disclosures: Milena M. Murray, PharmD, MSc, BCIDP, AAHIVP, Merck (Speaker's Bureau)

107. Impact of Switching to an Antiretroviral Regimen Containing Tenofovir Alafenamide on Weight Gain and Development of Metabolic Side Effects

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Session: O-21. HIV Treatment and Complications

Background: Tenofovir is a common backbone of many antiretroviral (ARV) regimens for the treatment of HIV. Although limited, data has shown that tenofovir alafenamide (TAF) may contribute to weight gain. Our study evaluated the impact on weight gain and metabolic effects of people living with HIV (PLWH) who were switched to ARV regimens containing TAF in the real-world setting.

Methods: Single center retrospective cohort study. Included were PLWH who were on an ARV regimen not containing TAF, who were switched to a TAF containing regimen between January 1, 2016 and September 30, 2018. The control group contained patients on a TAF free ARV regimen throughout the study period. The primary outcome was change in weight from baseline at 12 months post switch. Secondary outcomes were change in BMI, development of new diabetes, hypertension, and/or hypercholesteremia.