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HIV Following Oral Pre-Exposure Prophylaxis (PrEP) Initiation

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Key Takeaways

- **HIV following oral PrEP initiation is infrequent, with higher incidence in those without continuous insurance enrollment before PrEP initiation**
- **Part of proper PrEP utilization includes efficient diagnostic algorithms and tools to identify people with HIV so the individuals do not start PrEP but instead start a complete antiretroviral therapy (ART) regimen as soon as possible**
- **An integral part of PrEP effectiveness is the ability to adhere to and persist on PrEP when needed; a majority of PrEP users within this cohort meeting the analysis' definitions for HIV had PrEP on hand at the time they met the definition, suggesting challenges unexplained by access, which demands further research into the unmet needs of HIV prevention**

Introduction

- Once-daily oral tenofovir-based combinations used as PrEP are effective biomedical HIV prevention strategies but must only be prescribed to individuals confirmed to be HIV-negative[1]
  - Still, low adherence and/or persistence can lead to decreased efficacy
- This study described the characteristics of and HIV incidence in commercially insured oral PrEP users in the United States
  - PrEP usage pattern results were previously presented[2]
  - This poster presents further results focused on FTC/TDF unless otherwise noted

Methods

- This retrospective study used IQVIA PharMetrics® Plus (IQVIA Inc, Durham, North Carolina) data (January 1, 2015-March 31, 2020) to identify adults newly initiated (index date) with at least a 30-day supply of emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) as a proxy for daily PrEP
- PrEP users had ≥6 months of continuous enrollment pre-index (baseline); those diagnosed with HIV, other ART use, or less than a 30-day supply of FTC/TDF at baseline were excluded
- PrEP user demographics and clinical characteristics were described at baseline
- Newly identified HIV was defined as a PrEP user with an International Classification of Diseases (ICD) diagnosis code for HIV and an ART dispensing post-index date
- Time to newly identified HIV from the index date and from the latest PrEP dispensing was reported, as well as the proportion of those with PrEP on hand at the time HIV definition was met based on how many days of supply they had

Sensitivity Analyses

- An alternate definition of newly identified HIV was applied: ≥2 dispensings of ART on separate days post-index date regardless of documented ICD diagnosis code for HIV
- HIV ≤30 days after PrEP initiation was excluded to minimize the possibility that individuals were living with HIV before starting PrEP
- The requirement of ≥6 months pre-index date of continuous enrollment was removed, which accounted for the possibility that PrEP initiation may be associated with initial healthcare system engagement

Risk Factor Analysis

- A risk factor analysis identifying and quantifying factors associated with HIV was performed among PrEP users (FTC/TDF or FTC/tenofovir alafenamide [TAF])
  - Demographics and baseline clinical characteristics were considered as potential risk factors of HIV during follow up
  - Stepwise logistic regression and non-parametric bootstrap procedures were used to select risk factors; odds ratios, confidence intervals, and *P* values were calculated from a multivariable logistic regression model

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Results

- In total, 24,232 users of FTC/TDF for PrEP were identified (Table 1)

Table 1. Baseline Demographics and Clinical Characteristics of PrEP Users

Characteristic	FTC/TDF (N=24,232)
Observation period, mean ± SD (median), days[a]	504 ± 408 (390)
Demographics[b]	
Age, mean ± SD (median), years	35.0 ± 11.3 (32)
Male, n (%)	22,869 (94.4)
Region, n (%)	
South	10,217 (42.2)
Midwest	5137 (21.2)
Northeast	5260 (21.7)
West	3617 (14.9)
Year of index date, n (%)[c]	
2015	2146 (8.9)
2016	4397 (18.1)
2017	4901 (20.2)
2018	5877 (24.3)
2019	5972 (24.6)
2020	939 (3.9)
STI diagnosis, n (%)[d]	
Any STI	2326 (9.6)
Human papillomavirus	796 (3.3)
Unspecified venereal diseases	641 (2.6)
Syphilis	537 (2.2)
Gonorrhea	425 (1.8)
Chlamydia	324 (1.3)

FTC/TDF, emtricitabine/tenofovir disoproxil fumarate; STI, sexually transmitted infection.
[a]The observation (follow-up) period spanned from the index date until the earliest of either end of continuous eligibility or end of data availability. [b]Evaluated on the index date. [c]The index date was defined as the date of the first dispensing for FTC/TDF. [d]Evaluated during the 6-month baseline period, excluding the index date.

- Mean (median) length of follow up was 504 (390) days
- By 3 months after PrEP initiation, 0.3% of FTC/TDF users had met the primary definition of HIV diagnosis, which increased to 0.5% by 12 months after initiation; removal of the 6-month continuous enrollment requirement resulted in a multi-fold increase in newly identified HIV (Table 2)

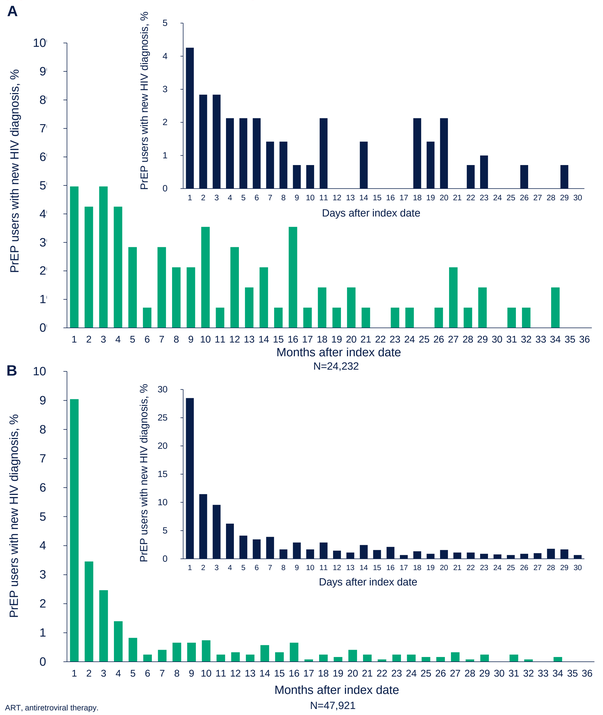
Table 2. HIV Incidence Rate on FTC/TDF

Newly identified HIV incidence rates	≥6 months continuous pre-index enrollment (N=24,232)	Continuous pre-index enrollment not required (N=47,921)
Defined by ART initiation and HIV diagnosis[a]		
Incidence by time period after the index date, %		
3 months	0.3	2.2
6 months	0.4	2.4
9 months	0.4	2.4
12 months	0.5	2.5
Incidence at any time during follow up, n (%)	141 (0.6)	1,216 (2.5)
Time from index date to HIV, mean ± SD (median), days[b]	235 ± 306 (95)	69 ± 184 (9)
Time from latest PrEP dispensing to HIV, mean ± SD (median), days[b]	149 ± 240 (29)	39 ± 127 (6)
PrEP users without HIV within 30 days after PrEP initiation, n (%)	24,176 (99.8)	47,043 (98.2)
Incidence by time period after the index date, %		
3 months	0.1	0.4
12 months	0.3	0.7
Incidence at any time during follow up, n (%)	85 (0.4)	338 (0.7)
Time from index date to HIV, mean ± SD (median), days[b]	385 ± 314 (315)	228 ± 296 (88)
Time from latest PrEP dispensing to HIV, mean ± SD (median), days[b]	243 ± 272 (141)	124 ± 220 (39)
Defined by ART initiation[c]		
Incidence by time period after the index date, %		
3 months	0.4	2.4
6 months	0.6	2.6
9 months	0.6	2.7
12 months	0.7	2.9
Incidence at any time during follow up, n (%)	214 (0.9)	1,423 (3.0)
Time from index date to HIV, mean ± SD (median), days[c]	254 ± 330 (97)	110 ± 254 (14)
Time from latest PrEP dispensing to HIV, mean ± SD (median), days[c]	152 ± 253 (33)	51 ± 140 (9)
PrEP users without HIV within 30 days after PrEP initiation, n (%)	24,155 (99.7)	47,028 (98.1)
Incidence by time period after the index date, %		
3 months	0.1	0.5
12 months	0.4	1.0
Incidence at any time during follow up, n (%)	137 (0.6)	530 (1.1)
Time from index date to HIV, mean ± SD (median), days[b]	394 ± 341 (332)	282 ± 355 (112)
Time from latest PrEP dispensing to HIV, mean ± SD (median), days[b]	235 ± 285 (115)	125 ± 209 (46)

ART, antiretroviral therapy; FTC/TDF, emtricitabine/tenofovir disoproxil fumarate.
[a]HIV incidence by ART initiation and HIV diagnosis was defined as the earliest date between an HIV diagnosis and ≥1 dispensing of an ART, and individuals required both a diagnosis and dispensing to be considered as having HIV (base case). [b]Evaluated among the subgroup with incidence of HIV during follow up. [c]HIV incidence by ART initiation was defined as the number of individuals meeting the definition of HIV (sensitivity analyses).

- Mean (median) time to HIV from index date was 235.48 (95) days (Figure 1A), and time from the latest PrEP dispensing was 149 (29) days
- 60.3% of FTC/TDF users with newly identified HIV had PrEP on hand at the time HIV definition was met (base analysis definition)
- With the 6-month pre-index coverage requirement removed, the mean (median) time to HIV from index date was 69 (9) days (Figure 1B)

Figure 1. Percent of PrEP Users After the Index Date by Month for the First 36 Months and (Inset) by Day Within the First 30 Days Who Met the Definition of New HIV Diagnosis Defined as a PrEP User With an ICD Diagnosis Code for HIV and an ART Dispensing Post-index Date With (A) ≥6-Month Continuous Enrollment and (B) Continuous Enrollment Not Required

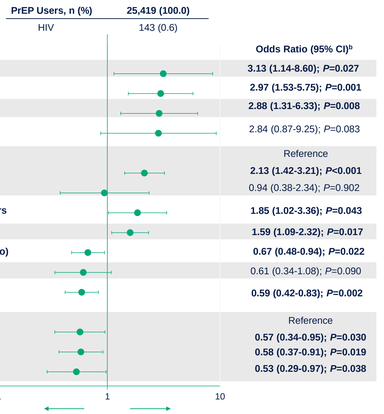


ART, antiretroviral therapy.

Risk Factor Analysis

- This analysis also identified characteristics considered as risk factors for HIV (Figure 2)
- The strongest associations between risk factors and HIV were with high-risk sexual behavior (OR, 3.13; 95% CI, 1.14-8.60; *P*=0.027), syphilis (OR, 2.97; 95% CI, 1.53-5.75; *P*=0.001), gonorrhea (OR, 2.88; 95% CI, 1.31-6.33; *P*=0.008), and other non-gonococcal urethritis (OR, 2.84; 95% CI, 0.87-9.25; *P*=0.083)
- PrEP users enrolled in a health maintenance organization had 2 times the odds of HIV compared with those enrolled in a preferred provider organization (OR, 2.13; 95% CI, 1.42-3.21; *P*<0.001)
- PrEP users in the Midwest, Northeast, and West had approximately 40% lower odds of HIV compared with those in the South

Figure 2. Odds Ratio Estimates (95% CI) for Risk Factors of HIV



HIV incidence by ART initiation and HIV diagnosis was defined as the earliest date between an HIV diagnosis and ≥1 dispensing of an ART, and patients required both a diagnosis and dispensing at any time during the observation period to be considered as having HIV. Analysis included users of both FTC/TDF and FTC/TAF. Significant estimates (*P*<0.05) are indicated by bold text. [a]Potential risk factors included the following baseline patient characteristics with ≥0.5% prevalence in either cohort: age, sex, region, insurance plan type, Quan-CCI score, high-risk sexual behavior, medication use, healthcare resource use, comorbidities, and sexually transmitted infections. Univariate associations were assessed for each potential risk factor, and those with *P* value >0.1 were discarded. Among the remaining covariates, risk factors were selected using stepwise logistic regression with the AIC. Non-parametric bootstrap procedures with 499 replications randomly re-sampled the data with replacement, and risk factors were evaluated in each bootstrap sample; selected risk factors were present in ≥50% of replication samples. [b]Odds ratios, CIs, and *P* values were calculated from a logistic regression model. AIC, Akaike information criterion; ART, antiretroviral therapy; ER, emergency room; FTC, emtricitabine; HMO, health maintenance organization; OP, outpatient; POS, point-of-service; PPO, preferred provider organization; Quan-CCI, Quan Charlson Comorbidity Index; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

Discussion

- PrEP is highly efficacious at preventing HIV acquisition but requires strict adherence and persistence while a need for HIV prevention endures[1]
- Proper initiation on PrEP must include efficient screening/diagnostic algorithms and tools to identify and ensure people with HIV do not start PrEP but instead appropriately start a complete multi-class ART regimen as soon as possible[3]

Limitations

- Pharmacy dispensings are not a guarantee that PrEP users took the medication as prescribed, and coding inaccuracies may exist in administrative claims data
- Laboratory values were not available to confirm HIV diagnosis or time of acquisition
- Information on post-exposure prophylaxis (PEP) was not directly available in the data; very few individuals used non-PrEP ART a single time, suggesting that PEP use was uncommon in the study population
- This study focused on commercially insured PrEP users in the United States; therefore, findings may not be generalizable to users with no insurance or with public insurance (eg, Medicare, Medicaid)

Conclusions

- HIV following oral PrEP initiation was infrequent, with higher incidence observed in those without continuous insurance enrollment before PrEP initiation
- A majority of PrEP users within this analysis meeting the definition of HIV had PrEP available to them at the time, suggesting challenges unexplained by PrEP access (ie, diagnosis, adherence, persistence, etc)
- Further research is needed to limit HIV acquisition despite access to oral PrEP

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