MeP05.4

GS-US-380-7296

ART Persistence Among Treatment-Experienced People With HIV and Mental Health Disorders in the US

Uche Mordi[1], Benjamin Chastek[2], Mary J Christoph[1], Lisa B Le[2], Neia Prata Menezes[1], Travis Lim[1], Sunil Majethia[1], James Jarrett[3]

[1]Gilead Sciences, Inc., Foster City, CA, USA; [2]Optum, Eden Prairie, MN, USA; [3]Gilead Sciences, Uxbridge, UK

Conclusions

- Over one-third of people with HIV (PWH) in this study had baseline mental health or substance use disorders (MH/SUD) among this commercially insured population, and nearly one-third had suboptimal adherence to index antiretroviral therapy (ART) regimen
- PWH who restarted or switched to bictegravir/emtricitabine/ tenofovir alafenamide (B/F/TAF) were more likely to persist at 1 year compared to other ARTs among both those with MH/SUD or low adherence. These findings in the US support prior European studies[1]
- This study was limited by difficulties in capturing adherence data for injectable therapy using medical claims due to variations in days supplied (ie, 30 vs 60 days)

Plain Language Summary

- People with human immunodeficiency virus (PWH) who also have mental health issues or substance use issues can have trouble taking their HIV medicine regularly. This can lead to worse health for these people and a higher chance of passing on HIV
- This study looked at how many previously treated PWH that have mental health or substance [alcohol or drug] use disorders (MH/SUD) and those who had trouble taking their HIV medicine regularly stayed on commonly used HIV medication at 1 year
- More PWH who had MH/SUD or trouble taking their HIV medicine who were prescribed bictegravir/ emtricitabine/tenofovir alafenamide stayed on treatment after 1 year. They were also less likely to stop taking it over time

Introduction

- Discontinuation of ART has been linked to poor outcomes for PWH[2]
- PWH who have MH/SUD, as well as those with a history of suboptimal ART adherence, are particularly vulnerable to treatment interruptions, regimen changes, and poorer health outcomes[3]
- Independently, MH/SUD are often underrecognized comorbidities in PWH, contributing to poorer health outcomes, reduced adherence to ART, and increased risk of HIV transmission
- Understanding how regimen persistence differs after switching or restarting ART in these key populations is essential for optimizing treatment strategies and improving clinical outcomes

Objective

- Describe and compare regimen persistence after switching or restarting ART among PWH with MH/SUD and in PWH with low adherence to ART

References: **1.** Antinori A, et al. *Int J STD AIDS.* 2025;36:309-18. **2.** Nyaku M, et al. *AIDS Care.* 2019;31:599-608. **3.** Conway FN, et al. *Community Ment Health J.* 2021;57:1328-39.

Acknowledgments: This study was sponsored by Gilead Sciences, Inc.

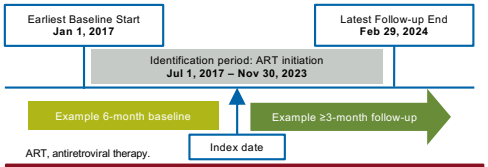
Disclosures: **BC** and **LBL** are employees of Optum. **UM**, **MJC**, **NPM**, **TL**, **SM**, **and JJ** are employees of, and own stocks/shares in, Gilead Sciences, Inc.

Correspondence: James Jarrett, PhD (James.Jarrett@Gilead.com).

Methods

- This retrospective study used medical and pharmacy claims data from the Optum Research Database, including PWH who had commercial insurance or Medicare Advantage with Part D coverage
- PWH were identified as treatment-experienced based on their first prescription claim between January 7, 2017 and November 30, 2023 (Figure 1), for one of six common ART regimens, and whether they had any prior ART claims, with or without a gap in therapy
- Primary outcome of nonpersistence was defined as the earliest of ART discontinuation (gap in all ART ≥ 90 days), ART switch or add on, or death. Time to nonpersistence was defined as time until primary outcome, with censoring for end of continuous enrolment or study period. Adherence was measured as proportion of days covered (PDC) while still persistent
- Outcomes were evaluated for:
  - Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF)
  - Dolutegravir/lamivudine (DTG/3TC)
  - Dolutegravir/abacavir/lamivudine (DTG/ABC/3TC)
  - Dolutegravir + emtricitabine/tenofovir alafenamide (DTG + F/TAF)
  - Dolutegravir + emtricitabine/tenofovir disoproxil fumarate (DTG + F/TDF)
  - Cabotegravir + rilpivirine (CAB + RPV)
- Inverse probability treatment weighting was implemented to adjust for demographic characteristics, baseline clinical measures, and baseline healthcare cost and utilization. Kaplan-Meier analysis was conducted after weighting to examine the effect of regimen selection on ART persistence at 1 year. Hazard ratios from Cox proportional hazards models were examined controlling for residual differences in covariates for the entire follow-up period

Figure 1. Patient Observation Period



Results

Study Sample

- Of 14,826 PWH who met all inclusion criteria, 5310 had baseline MH/SUD and 4090 had PDC < 85% to index regimen during their index line of therapy (Table 1)
- The mean (SD) age of patients in the MH/SUD subgroup was 54.0 years (12.3), 22.8% were female, and 44.5% were enrolled in commercial insurance (Table 1). The mean (SD) Quan-Charlson comorbidity score was 4.9 (2.3)
- The mean (SD) age among PWH with PDC < 85% was 50.7 years (13.5), 23.5% were female, and 58.0% were enrolled in commercial insurance (Table 1). The mean (SD) Quan-Charlson comorbidity score was 4.1 (2.4)

Table 1. Demographics of PWH

MH/SUD		Total (N = 5310)	B/F/TAF (n = 3178)	DTG/3TC (n= 674)	DTG/ABC/3TC (n = 680)	DTG + F/TAF (n = 477)	DTG + F/TDF (n = 84)	CAB + RPV (n =217)
Age	Mean (SD)	54.0 (12.3)	53.9 (12.3)	53.8 (12.5)	54.8 (11.9)	54.0 (12.4)	54.5 (12.8)	53.3 (13.4)
Female	%	22.8	21.9	21.1	26.6[a]	24.6	14.5	26.3
Race[b]								
White	%	46.6	47.2	48.4	44.2	44.5	38.8	48.1
Hispanic	%	12.6	13.1	12.0	10.6	12.4	14.3	12.2
Black	%	31.4	30.2	29.5	35.0[a]	34.2	40.2	33.2
Asian	%	1.5	1.7	1.6	1.2	1.8	0.0	0.1[a]
Commercial insurance	%	44.5	44.6	47.3	41.8	45.3	32.7	46.7
Baseline Charlson comorbidity score	Mean (SD)	4.9 (2.3)	4.9 (2.3)	4.7 (2.3)	5.0 (2.3)	4.9 (2.2)	4.5 (2.3)	5.2 (2.1)
PDC < 85%		**Total (N = 4090)**	**B/F/TAF (n = 2323)**	**DTG/3TC (n = 366)**	**DTG/ABC/3TC (n = 739)**	**DTG + F/TAF (n = 436)**	**DTG + F/TDF (n = 81)**	**CAB + RPV (n = 145)**
Age	Mean (SD)	50.7 (13.5)	50.1 (13.4)	50.4 (14.1)	51.3 (13.5)	51.1 (13.1)	54.2 (13.5)	54.4[a] (13.7)
Female	%	23.5	22.6	23.4	26.5	25.2	21.7	21.6
Race[b]								
White	%	37.2	36.4	32.9	35.7	41.4	47.9	51.3[a]
Hispanic	%	12.5	12.5	13.6	10.5	13.9	7.8	14.0
Black	%	39.7	40.0	42.0	43.5	35.1[a]	36.9	27.3
Asian	%	1.4	1.4	0.2[a]	1.9	2.3	0.4	0.9
Commercial insurance	%	58.0	60.0	56.0	52.9[a]	59.0	59.4	48.7
Baseline Charlson comorbidity score	Mean (SD)	4.1 (2.4)	4.1 (2.4)	3.8 (2.3)	4.4[a] (2.6)	4.0 (2.4)	4.1 (2.2)	4.8 (2.3)

[a]$P < 0.05$. [b]Other/unknown/missing and no SES data were reported but not included.
3TC, lamivudine; ABC, abacavir; B, bictegravir; CAB, cabotegravir; DTG, dolutegravir; F, emtricitabine; MH/SUD, mental health or substance use disorders; PDC, proportion of days covered; RPV, rilpivirine; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

Results (Cont.)

Index Line of Therapy

- Among PWH with MH/SUD, those on B/F/TAF (18.5 months) had the longest mean follow-up followed by DTG//ABC/3TC (18.1), DTG + F/TAF (15.8), DTG/3TC (13.4), CAB + RPV (9.3), and DTG + F/TDF (9.7)
- Among PWH with PDC < 85%, those on DTG + F/TAF had the longest mean follow-up (15.2 months) followed by B/F/TAF (14.9), DTG/ABC/3TC (14.4), DTG/3TC (10.7), CAB + RPV (8.8), and DTG + F/TDF (7.3)

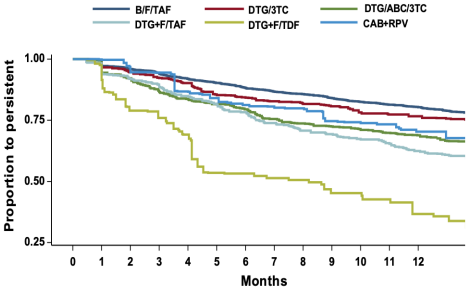
Persistence at 1 Year

- Weighted Kaplan-Meier analysis in the MH/SUD group indicated that the percent persistent at 1 year was significantly higher ($P < 0.05$) for B/F/TAF (80.3%) vs DTG/ABC/3TC (68.9%), DTG + F/TAF (62.4%), and DTG + F/TDF (36.7%), and higher but not statistically different vs DTG/3TC (76.7%) and CAB + RPV (70.4%) (Figure 2 and Table 2)
- Among PWH with PDC < 85%, those on B/F/TAF (78.6%) were more likely to be persistent at 1 year compared to DTG/ABC/3TC (66.3%), DTG + F/TAF (58.9%), and DTG + F/TDF (41.9%), and more likely but not statistically different vs DTG/3TC (70.8%) and CAB + RPV (68.5%) (Figure 3 and Table 2)

Risk of Nonpersistence

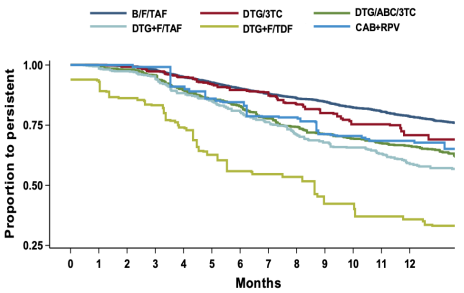
- Overall risk of nonpersistence was significantly greater ($P < 0.05$) for DTG-based regimens vs B/F/TAF in PWH with MH/SUD, and significantly greater ($P < 0.05$) for DTG/ABC/3TC, DTG + F/TAF, and DTG + F/TDF vs B/F/TAF in those with PDC < 85% (Table 3)

Figure 2. Weighted Kaplan-Meier of Persistence – MH/SUD



3TC, lamivudine; ABC, abacavir; B, bictegravir; CAB, cabotegravir; DTG, dolutegravir; F, emtricitabine; MH/SUD, mental health or substance use disorders; RPV, rilpivirine; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

Figure 3. Weighted Kaplan-Meier of Persistence – PDC < 85%



3TC, lamivudine; ABC, abacavir; B, bictegravir; CAB, cabotegravir; DTG, dolutegravir; F, emtricitabine; PDC, proportion of days covered; PWH, people with HIV; RPV, rilpivirine; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

Table 2. Weighted Kaplan-Meier Percent Persistent at 12 Months

	MH/SUD		PDC < 85%	
	%	*P*-value	%	*P*-value
B/F/TAF	80.3	Ref.	78.6	Ref.
DTG/3TC	76.7	0.094	70.8	0.036
DTG/ABC/3TC	68.9	< 0.001	66.3	< 0.001
DTG + F/TAF	62.4	< 0.001	58.9	< 0.001
DTG + F/TDF	36.7	< 0.001	41.9	< 0.001
CAB + RPV	70.4	0.084	68.5	0.140

3TC, lamivudine; ABC, abacavir; B, bictegravir; CAB, cabotegravir; DTG, dolutegravir; F, emtricitabine; MH/SUD, mental health or substance use disorders; PDC, proportion of days covered; RPV, rilpivirine; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.

Table 3. Adjusted Weighted Hazard Model of Nonpersistence

	Index Regimen	Hazard Ratio (95% CI)	*P*-value
MH/SUD	B/F/TAF	Ref.	
	DTG/3TC	1.27 (1.02, 1.57)	0.033
	DTG/ABC/3TC	1.60 (1.37, 1.88)	< 0.001
	DTG + F/TAF	2.23 (1.92, 2.60)	< 0.001
	DTG + F/TDF	4.71 (3.41, 6.49)	< 0.001
	CAB + RPV	1.40 (0.83, 2.38)	0.209
PDC < 85%	B/F/TAF	Ref.	
	DTG/3TC	1.24 (0.96, 1.59)	0.100
	DTG/ABC/3TC	1.59 (1.34, 1.88)	< 0.001
	DTG + F/TAF	1.95 (1.63, 2.33)	< 0.001
	DTG + F/TDF	4.81 (3.40, 6.81)	< 0.001
	CAB + RPV	1.60 (0.88, 2.92)	0.123

Covariates included: baseline demographics, Charlson comorbidity score, AHRQ comorbidities, AIDS-defining conditions, comedications, ambulatory count, inpatient count, and pharmacy patient paid cost index 30 days of disease HIV specified: with standard difference between treatment experience group at least 11 and sufficient sample size.

3TC, lamivudine; ABC, abacavir; AHRQ, Agency for Healthcare Research and Quality; B, bictegravir; CAB, cabotegravir; DTG, dolutegravir; F, emtricitabine; MH/SUD, mental health or substance use disorders; PDC, proportion of days covered; RPV, rilpivirine; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate.