A Retrospective Analysis of Treatment-Naïve People With HIV With or Without Mental Health Disorders Initiating Single-Tablet Regimens vs. Multi-Tablet Regimens: A Claims Analysis of US Medicaid Population

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Conclusions

- In this analysis of real-world data representing approximately 80% of the Medicaid population, nearly two-thirds of PWH in the sample initiating either MTRs (65.5%) or STRs (61.6%) had concurrent diagnoses for MHD
- PWH with concurrent MHD initiating MTR vs. STR were significantly younger, more likely to be female, and had higher rates of substance use; however, race and comorbidity patterns were similar for both groups
- MTR initiators among PWH both with or without concurrent MHD experienced significantly higher HCRU vs. STR initiators, as demonstrated by a greater proportion of patients with IP hospitalizations and ED visits ($p<0.05$) for both those with and without MHD.
- Among PWH both with or without concurrent MHD, MTR vs. STR treatment resulted in significantly higher adjusted odds of:
  - IP hospitalizations [PWH/MHD, AOR=1.49 (1.41–1.56); PWH/No-MHD, AOR=1.6 (1.43–1.79)]
  - ED visits [PWH/MHD, AOR=1.39 (1.32–1.45); PWH/No-MHD, AOR=1.35 (1.25–1.47)]

Plain Language Summary

- In this claims analysis of PWH who are covered by Medicaid insurance (i.e., "joint federal and state program that helps cover medical costs for some people with limited income and resources), two out of every three PWH had one or more mental health issues
- All PWH who start MTR, whether they had co-existing mental health issues or not, were usually younger, female and had substance use disorder vs. those in the STR group
- PWH with or without mental health issues had nearly 50–60% greater chance of hospitalization and 35–40% greater chance of ED visits after starting MTR vs. STR

Introduction

- Several studies have reported a high prevalence of mental health disorders (MHD) in people with HIV (PWH) and an association with adverse health outcomes such as delayed entry into medical care, increased healthcare resource utilization (HCRU), greater healthcare expenditures, higher productivity losses, and poorer health-related quality of life (HRQoL)[1–3]
- The widespread adoption of highly efficient antiretroviral therapy (ART) in the past two decades has resulted in increased life expectancy in PWH[1]
- Historically, ARTs comprised of a multi-tablet regimen (MTR) which may result in poor treatment adherence due to the high pill burden. However, once-daily fixed dose combination therapies formulated as single-tablet regimen (STRs) have largely replaced MTRs
- Considering the prevalence of concurrent MHD among PWH, research examining HCRU outcome differences among PWH with or without concurrent MHD who initiate STRs vs. MTRs is needed

Objectives

- To examine the baseline characteristics and HCRU associated with use of MTRs vs. STRs among PWH with and without concurrent MHD in the US Medicaid population

Methods

Study Design and Data Source

- A retrospective cohort analysis of claims data sourced from Anlitiks All Payor Claims Data (APCD) from 01/01/16–06/30/23 (the study period) of treatment-naïve Medicaid PWH with MHD (PWH/MHD) or PWH without MHD (PWH/no-MHD) initiating MTRs or STRs
- The APCD provides insight into the healthcare utilization of over 80% of the US population eligible for health insurance. It gathers patient claims data from all state Medicaid programs through claims clearinghouses, which manage transactions between payers and providers

Study Population

- The study population consisted of patients ≥18 years old initiating MTR or STR between January 2017–June 2022 (i.e., patient identification period), and continuously enrolled for ≥12 months pre- and post-index (i.e., ≥1 medical and pharmacy claim). The index dates for the two cohorts are defined below
  - ***STR:*** the first date for the STR ART prescription fill claim during the identification period with no evidence of prior ART during the baseline period
  - ***MTR:*** the first date of the claim for the final medication completing the MTR prescription combination (a window of 10 days between fills for the agents comprising an MTR was allowed) or the same date for all drugs in the regimens if they were given on the same date

Study Measures and Definitions

- Baseline measures (pre-index): Demographic characteristics (e.g., age, sex, race, and geographic region)
- Clinical and comorbidity characteristics e.g., substance use, HIV diagnosis rate, time from HIV diagnosis to treatment (in days), total time from HIV diagnosis to treatment, Charlson comorbidity index (CCI; excluding HIV) were examined
- Follow-up outcome measures (post-index): HCRU outcomes defined as the proportion of patients with ≥1 all-cause IP and ED visits during follow-up period

Statistical Methods

- Demographics, clinical characteristics, and follow-up outcome measures were reported as frequencies and percentages for categorical variables; mean, standard deviation (SD) and 95% confidence intervals (CIs) for continuous variables
- Non-parametric comparisons were made using Chi-square or Fisher's exact tests for categorical variables, and t-tests or Wilcoxon-rank sum tests for continuous variables
- Multivariate logistic regression models adjusting for age, gender, region, Substance use disorder (SUD), and Quan-Charlson score (excluding HIV disease) compared the HCRU differences between the STR and MTR groups and reported them as adjusted odds ratios with 95% CIs

Results

- Of the 1,065,802 patients who initiated ART, 590,462 and 494,326 patients were eligible for selection into MTR and STR, respectively. Patient selection and attrition table is provided in **Figure 1**

PWH & MHD: MTR (n=7874) vs. STR (n=46,024)

Demographic, Clinical and Comorbidity Characteristics **(Table 1)**

- MTR initiators were younger (43.6 vs. 47.2 years; $p<0.05$), more likely to be female (46.43% vs. 35.7%; $p<0.05$), and more likely to be substance users (32.1% vs. 29.4%; $p<0.05$) than STR initiators
- MTR group had a higher proportion of PWH with CCI score ≥5 was observed in MTR cohort (MTR=4.2% vs. STR=3.33%; $p<0.05$)

All-cause HCRU **(Figure 2 & 3)**

- Overall, MTRs were associated significantly with higher rates of IP hospitalizations and ED visits
- PWH using MTR had higher adjusted odds of requiring any (≥1) all-cause IP hospitalizations and ED visits after controlling for potential confounders

PWH & No-MHD: MTR (n=3,612) vs. STR (n=23,452):

Demographic, Clinical and Comorbidity Characteristics (Table 1)

- MTR initiators were younger (39.2 vs. 43.3 years; $p<0.05$), and more likely to be female (42.3% vs. 29.7%; $p<0.05$) compared to STR initiators
- The proportion of patients with CCI score ≥5 (MTR=1.47% vs. STR=1.04%; $p=0.022$) were similar for both groups

All-cause HCRU (Figure 2 & 3)

- Overall, MTRs had higher proportion of PWH with IP hospitalization and ED visit ($p<0.05$), both had similar number of visits PPPM for IP and ED visits [IP visits (MTR=0.8 vs. STR= 0.78) and ED visits (MTR=0.34 vs. STR= 0.32)]
- PWH using MTR had higher adjusted odds of requiring any (≥1) all-cause IP and ED visits after controlling for potential confounders

Table 1. Demographic, Clinical and Comorbidity Characteristics

Parameters	PWH & MHD		P-value	PWH & No-MHD		P-value
	STRs, n=46,024	MTRs, n=7874		STRs, n=23,452	MTRs, n=3612	
Age						
Mean (SD)	47.2 (13.5)	43.6 (14.4)	<0.05	43.3 (14.9)	39.2 (15.1)	<0.05
Sex, n (%)						
Male	29,590 (64.3%)	4218 (53.6%)	<0.05	16,484 (70.3%)	2083 (57.7%)	<0.05
Geographic region, n (%)						
Northeast	14,563 (31.6%)	2418 (30.7%)	0.09	7658 (32.7%)	1,109 (30.7%)	<0.05
Midwest	7269 (15.8%)	1167 (14.8%)	0.02	3612 (15.4%)	426 (11.8%)	<0.05
South	14,746 (32%)	2248 (28.6%)	<0.05	7453 (31.8%)	1216 (33.7%)	<0.05
West	8089 (17.6%)	1722 (21.9%)	<0.05	3152 (13.4%)	585 (16.2%)	<0.05
Unknown/US territories	1357 (2,95%)	319 (4.1%)	<0.05	1577 (6.7%)	276 (7.6%)	<0.05
Documented claims for HIV diagnosis within 12 months before the index date						
n (%)	34,616 (75.2%)	3883 (49.3%)	<0.05	15,535 (66.2%)	1511 (41.8%)	<0.05
Non-HIV Quan-Charlson Comorbidity Index ≥5, n (%)						
≥5	1533 (3.3%)	330 (4.2%)	<0.05	244 (1.04%)	53 (1.5%)	<0.05
Non-HIV Quan-Charlson Comorbidity Score						
Mean (SD)	0.95 (1.56)	0.98 (1.71)	<0.05	0.5 (1.1)	1.23 (0.53)	<0.05
Substance use, n (%)						
Any SUD	13,535 (29.4%)	2528 (32.11%)	<0.05	2097 (8.9%)	320 (8.9%)	0.87

P-values reported using two sample independent t-test for comparing means and Chi-square test for comparing categories; P-values ≤0.05 considered statistically different.
The assessment of substance use encompassed Alcohol Use Disorder, Opioid Use Disorder, Substance-related disorder, and Medication for Opioid Use Disorder. We determined the number of patients and proportions based on whether they were diagnosed with one or more of the following: Alcohol Use Disorder, Opioid Use Disorder, Substance-related disorder, or had a National Drug Code (NDC) associated with Medication for Opioid Use Disorder.

Figure 1. Attrition Table

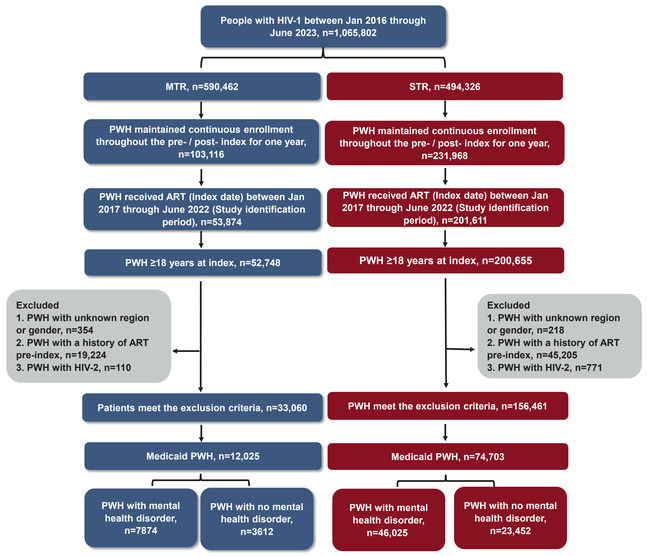


Figure 2. Healthcare Resource Utilization

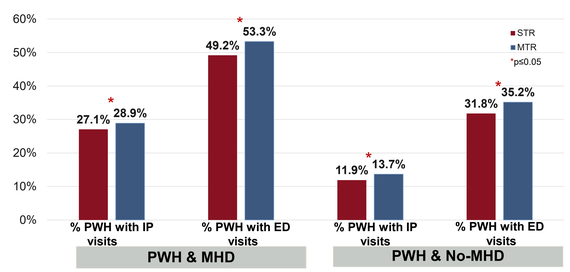
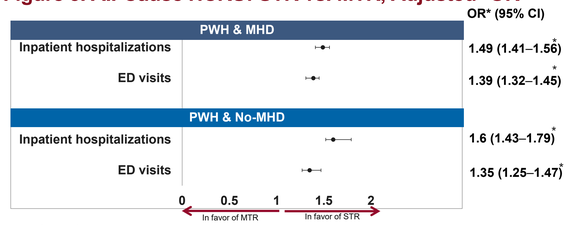


Figure 3. All-Cause HCRU: STR vs. MTR, Adjusted† OR



*ps0.05; reference: STR.
†Covariates in adjusted model: age, gender, region, substance related disorder, Quan-Charlson (excluding HIV)

References:

1. Christensen S, et al. *PLoS One*. 2019;14(11):e0224279. **2.** Avina RM, et al. *Healthcare (Basel)*. 2022;10(5):804. **3.** Rothbard AB, et al. *Psychiatr Serv*. 2009;60(7):974-7.

Abbreviations: AOR, Adjusted† Odds Ratio; APCD, all payor claims data; ART, antiretroviral therapy; CCI, Charlson comorbidity index; ED, emergency department; HCRU, healthcare resource utilization; HIV, human immunodeficiency virus; HRQoL, health-related quality of life; ICD-10, international classification of diseases, tenth revision; IP, inpatient; IQR, interquartile range; MHD, mental health disorders; MTR, multi-tablet regimen; NA, not available; NDC, national drug code; OR, odds ratio; PWH, people with HIV; SD, standard deviation; STR, single-tablet regimen; SUD, Substance use disorder; US, United States.

Disclosures: This study was funded by Gilead Sciences, Inc.

Acknowledgments: Thanks to Sharyu Deshmukh and Vamshidhar Taduka for their exceptional programming support, as well as to Richa Goyal and Goutam Solanki from the Anlitiks team for their valuable assistance during the preparation of the poster.

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Annual Meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR); May 5–8, 2024; Atlanta, GA, USA