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HIV Pre-Exposure Prophylaxis: Adherence, Retention, and Discontinuation Rates Between Single and Multiple Tablet Regimens

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Background

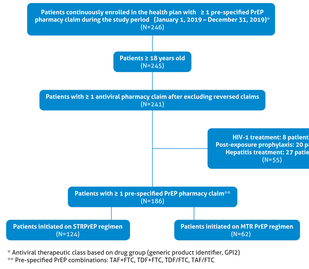
- The CDC estimates the number of current pre-exposure prophylaxis (PrEP) users in the US to be 152,000-157,000[1] despite there being more than 1 million Americans who could benefit from PrEP. [2]
- In June 2019, the US Preventive Services Task Force (USPSTF) recommended "clinicians offer PrEP with effective antiretroviral therapy to persons who are at high risk of HIV acquisition" (Grade A).[3]
- Medications considered "effective PrEP" include:
  - tenofovir disoproxil fumarate (TDF) + emtricitabine (FTC)
  - tenofovir alafenamide fumarate (TAF) + emtricitabine (FTC)
  - Viread (TDF) + Emtriva (FTC)
  - Vemlidy (TAF) + Emtriva (FTC)
  - Truvada (TDF/FTC)
  - Descovy (TAF/FTC)
- Per the Affordable Care Act (ACA) Mandate, commercial and expanded Medicaid health plans must require zero cost share for members of USPSTF Grade A recommendations. To allow time for insurers to implement the PrEP coverage changes, this rule starts June 2020. Additionally, by 2021, this coverage will be extended to include all necessary lab work and clinical visits. These changes may significantly increase per member expenditures for health plans.
- One cost-minimization strategy may be within the USPSTF defined research gap of single and multi-tablet drug regimens for PrEP.

Objective

- To assess differences in rates of adherence, retention, discontinuation, and drug costs between single-tablet regimen (STR) and multi-tablet regimen (MTR) PrEP within a small health plan.

Methods

- This study is a retrospective analysis of PrEP pharmacy claims from a small, self-insured, staff-model managed care organization after implementing a zero cost-share program for MTR.
- PrEP pharmacy claims were assessed from January 1, 2019 to December 31, 2019.
  - The index date was defined by the first PrEP claim for MTRs and the fill date for the last therapy in the regimen for STRs.
  - There was a financial incentive for patients to switch from STR to MTR (lower copay), but it was not required by the plan.
- Primary outcomes
  - Adherence was assessed over a 6-month period and reported as medication possession ratio (MPR).
  - Retention was assessed as the number of patients continuing on PrEP during the follow up period.
  - Discontinuation was defined as drug possession ≤ 120 consecutive days.
  - A cost-minimization analysis was performed to compare member and health plan costs between the two therapeutically equivalent products.



[*] Antiviral therapeutic class based on drug group (generic product identifier, GPI2)
[**] Pre-specified PrEP combinations: TAF+FTC, TDF+FTC, TDF/FTC, TAF/FTC

No significant difference was observed in patient adherence between MTR and STR for PrEP.

Table 1. Demographics (n=186)

	Before Program Implementation n= 122	After Program Implementation n= 64
Age, years, mean (SD) [median]	30.5 (7.6) [29]	27.9 (6.8) [26]
Age range, n (%)		
18 – 29	70 (57.4%)	44 (68.8%)
30 – 39	37 (30.3%)	16 (25%)
40 – 49	12 (9.8%)	3 (4.7%)
50 – 59	2 (1.6%)	1 (1.6%)
60+	1 (0.8%)	0 (0%)
Sex, n (%)		
Female	3 (2.5%)	1 (1.6%)
Male	119 (97.5%)	63 (98.4%)
Regimen, n (%)		
STR	120 (98.4%)	4 (6.3%)
MTR	2 (1.6%)	60 (93.8%)

Table 2. Clinical Outcomes

	Before Program Implementation n= 122		After Program Implementation n= 64	
	STR	MTR	STR	MTR
Mean MPR, %				
Annual	68.8	24.7	28.8	32.6
Variable	135.6	100	142.8	158.3
Annual MPR range, n (%)				
> 80	48 (39.3%)	0 (0%)	4 (6.3%)	1 (1.6%)
60 – 80	19 (15.6%)	0 (0%)	0 (0%)	1 (1.6%)
< 60	53 (43.4%)	2 (1.6%)	0 (0%)	58 (90.6%)
Variable MPR range, n (%)				
> 80	117 (96%)	2 (1.6%)	4 (6.3%)	60 (93.8%)
60 – 80	1 (0.8%)	0 (0%)	0 (0%)	0 (0%)
< 60	2 (1.6%)	0 (0%)	0 (0%)	0 (0%)
Retention, n (%)				
Yes	45 (36.9%)	2 (1.6%)	3 (4.7%)	57 (89%)
No	75 (61.5%)	0 (0%)	1 (1.6%)	3 (4.7%)
Discontinuation, n (%)				
Yes	35 (28.7%)	2 (1.6%)	1 (1.6%)	1 (1.6%)
No	85 (69.7%)	0 (0%)	3 (4.7%)	59 (92.2%)

Table 3. Cost Outcomes

	Before Program Implementation n= 122		After Program Implementation n= 64	
	STR	MTR	STR	MTR
Total Cost, n (mean)	$970,628.67 ($3776.77)	$6,443.91 (2,147.97)	$252,971.90 ($848.90)	$135,341.64 ($723.80)
Patient Paid, n (mean) [percent of total cost]	$15,595 ($60.68) [1.6]	$100 ($33.33) [1.6]	$3,240 ($10.87) [1.3]	$1,755 ($9.39) [1.3]
Plan Paid, n (mean) [percent of total cost]	$955,033.67 ($3,716.08) [98.4]	$6,343.91 ($2114.64) [98.4]	$249,731.90 ($838.03) [98.7]	$133,586.64 ($714.37) [98.7]

Results

- Prior to program implementation, majority of patients receiving PrEP therapy were started on STR (STR 98.4%, MTR 1.6%). After the program started, more patients were started on MTR compared to STR (STR 6.3%, MTR 93.8%).
- Inconclusively, MPR was greater for MTR after program initiation, and patients on STR were less likely to be retained on therapy compared to the MTR population.
- After program initiation, 0.3% patient costs were shifted from the patient to the health plan.

Limitations

- Did not perform testing for statistical significance.
- The pharmacy claims data is retrospective and is an incomplete representation of all patient care (e.g., pharmaceutical drug samples and manufacturer assistance programs were not included in the analysis).
- Generalizability to other populations may be limited due to study sample size and exclusivity of the health plan

Conclusion

- Patients receiving MTR were less likely to discontinue therapy and were more likely to be retained on MTR, supporting greater adherence and persistence with MTR compared to STR. This finding is contrary to conventional thought that STR has greater adherence compared to MTR.
- MTR is the lower cost option compared to STR.
- Further research is needed to examine reasons for discontinuation and non-adherence.

References

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