BACKGROUND
- The February 2013 Department of Health and Human Services (DHHS) guidelines for the use of antiretroviral therapy (ART) in human immunodeficiency virus (HIV) recommend four specific “preferred” ART regimens for ART-naïve patients: (1) efavirenz (EFV) plus tenofovir/emtricitabine (TDF/FTC), (2) ritonavir-boosted darunavir plus tenofovir/emtricitabine (ATV/r + TDF/FTC), (3) ritonavir-boosted darunavir plus tenofovir/didanosine (TDF/DDI), or (4) ritonavir plus tenofovir/rilpivirine (RAL + TDF).
- Guideline-preferred ART regimens have been studied in randomized controlled trials and have been shown to confer the benefits of ‘optimal and durable virologic efficacy, favorable tolerability and toxicity profiles, and ease of use.’
- Adherence is critical to the success of ART in suppressing viral load and avoiding virologic failure and development of drug resistance.

OBJECTIVE
- To compare ART adherence between February 2013 guideline-preferred first-line ART regimens, among Medicaid-insured HIV patients.

METHODS

Data Source
- This study used data from the 2004–2011 Truven Health Analytics MarketScan® Multi-State Medicaid Database. The database includes the administrative claims and encounter records for individuals covered under Medicaid programs in 15 states of varying sizes and demographic compositions across the U.S.
- This database was selected because Medicaid is the largest source of health insurance for HIV patients living in the U.S.1
- Sample Selection Criteria
  - HIV patients meeting all of the following inclusion criteria were selected into the study sample:
    - Initiated a first-line preferred ART regimen according to February 2013 guidelines2 between January 1, 2007, and September 30, 2011 (the date of ART initiation was designated the index date)
    - Aged 18–64 years on the index date
    - Had continuous enrollment with pharmacy benefits for six months preceding, and at least three months following, the index date
    - Not eligible for Medicare and no evidence of pregnancy, hepatitis B infection, or HIV-related ART prescriptions any time before the index date.

Study Population
- The study population comprised an index date (the date of ART initiation), a six-month baseline period, and a variable-length follow-up period of at least three months.
- The duration of the follow-up period equaled the number of days from the index date until the earliest of the following events:
  - First occurrence of a prescription claim for an ART that was not part of the initiated ART regimen
  - A gap of 30 days or more in any agent from the ART regimen
  - Disenrollment from Medicaid benefits

Study end date of December 31, 2011

Classification of Initiated ART
- Outpatient prescription claims for HIV-related ART were evaluated during the first 14 days after the index date (index date included) to establish initiation ART regimen.
- Patients initiating EFV/TDF/FTC, ATV/r + TDF/FTC, or RAL + TDF/FTC were considered to have initiated preferred ART regimens.

Outcomes
- ART adherence:
  - Measured as the proportion of days covered (PDC), which was calculated as the proportion of days that patients had all components of their ART regimen ‘on hand’ during the follow-up period.
  - ART adherence was dichotomized at ≥ 80 percent (versus < 80 percent) and ≥ 95 percent (versus < 95 percent) according to guideline recommendations and clinical evidence.3

Statistical Analysis
- Adherence 280 percent and 295 percent was evaluated using logit regression.
- Adherence analyses excluded patients who were persistent for 30 days or less, as most ART prescriptions had 30 days of supply. The sample included 100 percent adherence for these patients.
- The multivariable models adjusted for the following covariates: age, sex, race, capitation, rural versus urban residence, index year, baseline process of overall health status (number of unique three-digit International Classification of Disease, Ninth Revision, Clinical Modification diagnoses, number of unique National Drug Codes, number of outpatient office visits, total healthcare expenditures, any hospitalization, any visit to gastroenterology, infectious disease specialist), baseline comorbidities (renal disease, comorbidity of any condition associated with low CD4, hepatitis C, depression, other mental disorders, diagnosed substance abuse), and Medicaid state.

RESULTS

Table 1. Baseline Demographic and Clinical Characteristics

<table>
<thead>
<tr>
<th>Clinical Characteristics</th>
<th>EFV/TDF/FTC</th>
<th>ATV/r + TDF/FTC</th>
<th>RAL + TDF/FTC</th>
<th>DRV/r + TDF/FTC</th>
<th>DRV/r + TDF/FTC</th>
<th>RAL + TDF/FTC</th>
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</thead>
<tbody>
<tr>
<td>Age in years</td>
<td>41.2 (11.2)</td>
<td>40.8 (11.2)</td>
<td>40.1 (10.3)</td>
<td>42.1 (8.8)</td>
<td>41.2 (11.2)</td>
<td>40.8 (11.2)</td>
</tr>
<tr>
<td>Male (N, %)</td>
<td>698 (55.4%)</td>
<td>239 (48.0%)</td>
<td>63 (44.1%)</td>
<td>38 (48.1%)</td>
<td>698 (55.4%)</td>
<td>239 (48.0%)</td>
</tr>
<tr>
<td>Female (N, %)</td>
<td>501 (44.6%)</td>
<td>259 (52.0%)</td>
<td>90 (55.9%)</td>
<td>21 (51.9%)</td>
<td>501 (44.6%)</td>
<td>259 (52.0%)</td>
</tr>
<tr>
<td>Race (N, %)</td>
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<tr>
<td>Caucasian</td>
<td>597 (49.1%)</td>
<td>193 (38.7%)</td>
<td>57 (39.2%)</td>
<td>24 (30.4%)</td>
<td>597 (49.1%)</td>
<td>193 (38.7%)</td>
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<tr>
<td>Black</td>
<td>359 (29.3%)</td>
<td>116 (23.3%)</td>
<td>26 (17.9%)</td>
<td>11 (13.8%)</td>
<td>359 (29.3%)</td>
<td>116 (23.3%)</td>
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<tr>
<td>Other</td>
<td>343 (27.8%)</td>
<td>99 (19.7%)</td>
<td>40 (27.9%)</td>
<td>24 (30.4%)</td>
<td>343 (27.8%)</td>
<td>99 (19.7%)</td>
</tr>
<tr>
<td>Capitation* (N, %)</td>
<td>753 (59.8%)</td>
<td>320 (64.3%)</td>
<td>89 (62.2%)</td>
<td>36 (45.6%)</td>
<td>753 (59.8%)</td>
<td>320 (64.3%)</td>
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<td>Medicaid state (N, %)</td>
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<td>California</td>
<td>440 (35.2%)</td>
<td>180 (36.0%)</td>
<td>45 (31.3%)</td>
<td>14 (17.2%)</td>
<td>440 (35.2%)</td>
<td>180 (36.0%)</td>
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<tr>
<td>Florida</td>
<td>187 (15.0%)</td>
<td>85 (17.1%)</td>
<td>25 (17.5%)</td>
<td>9 (11.4%)</td>
<td>187 (15.0%)</td>
<td>85 (17.1%)</td>
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<td>Massachusetts</td>
<td>92 (7.4%)</td>
<td>35 (7.0%)</td>
<td>10 (7.0%)</td>
<td>6 (7.5%)</td>
<td>92 (7.4%)</td>
<td>35 (7.0%)</td>
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<tr>
<td>New York</td>
<td>233 (18.6%)</td>
<td>101 (20.2%)</td>
<td>32 (22.4%)</td>
<td>14 (17.2%)</td>
<td>233 (18.6%)</td>
<td>101 (20.2%)</td>
</tr>
<tr>
<td>Ohio</td>
<td>64 (5.1%)</td>
<td>20 (4.0%)</td>
<td>8 (5.6%)</td>
<td>4 (5.0%)</td>
<td>64 (5.1%)</td>
<td>20 (4.0%)</td>
</tr>
</tbody>
</table>

CONCLUSION

Among patients initiating a February 2013 DHHS guideline-preferred first-line ART regimen, the odds of adherence were not the same for all regimens. Further research should explore the reasons for differences in adherence levels between “preferred” ART regimens.

REFERENCES