

Health Care Resource Utilization And Cost Of Heavily Treatment Experienced (HTE) People Living With HIV (PLWH) In US Commercial And Medicare Advantage Health Plans

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Background

- Human immunodeficiency virus (HIV) continues to represent a significant healthcare burden in the United States although advancements in antiretroviral therapy (ART) have made significant improvements to the health of most people living with HIV (PLWH).
- A subset of PLWH are heavily treatment experienced (HTE) and have limited remaining ART options due to multidrug resistance, intolerance, and potential interactions with concomitant medications. These patients may not be able to achieve virologic suppression which can lead to disease progression.¹ Limited research exists on this subset of patients in the US.
- The objectives of this study were to describe the clinical characteristics, healthcare resource utilization (HCRU) and cost of HTE and Non-HTE PLWH in US commercial and Medicare Advantage health plans.

Methods

Study design and Data Sources

- This retrospective cohort study used administrative claims from the Optum Research Database (ORD) between July 1, 2013 and March 31, 2019 (study period) including medical and pharmacy claims, and enrollment information linked to socioeconomic and Social Security administration death data

Patient population

- Adult (≥18 years) commercial and Medicare Advantage health plan enrollees with ≥1 non-diagnostic medical claim for HIV-1 during the study period
- ≥1 pharmacy claim for ART between January 1, 2014 and March 31, 2018 (identification period)
- Continuous enrollment 6 months before (baseline) and 12 months after (unless evidence of death sooner) the first ART regimen (follow-up). The index date was assigned to the first ART agent filled meeting identification criteria.
- Two mutually exclusive cohorts were defined based on HTE and Non-HTE status during the study period (Figure 1). The HTE criteria included ART combinations typically reserved for PLWH at advanced stages based on clinical judgement.

Figure 1. Cohort Identification Criteria^a

HTE Heavily Treatment Experienced	Non-HTE Treatment Experienced
<ul style="list-style-type: none"> Dolutegravir BID Darunavir BID Enfuvirtide Etravirine + maraviroc or one of the above ≥2 Pharmacy claims of core agents plus any other ARTs 	<ul style="list-style-type: none"> Any Antiviral regimen in the 6 month pre-period Did not meet HTE criteria

^aCore included medications from the following ART classes: Non-nucleoside Reverse Transcriptase Inhibitors, Protease, Fusion or Entry Inhibitors, Integrase strand transfer Inhibitors, or any combinations of these. BID: Twice daily

Measures

- Demographics and clinical characteristics, all-cause and HIV-related healthcare utilization and cost were assessed during the 6-month baseline and fixed 12-month follow-up period. Mortality was assessed during variable follow up, to the earliest of death, end of continuous enrollment or the end of the study period.
- Average daily pill burden was based on the number of fills and days' supply for all medications during the fixed 12-month follow-up period.

Statistical analysis

- All study measures were summarized descriptively.
- Differences in HTE vs Non-HTE patients were assessed using chi-square or two-sample t-tests.
- Differences in mortality were assessed using the Kaplan-Meier log rank test.

Results

Patient Characteristics

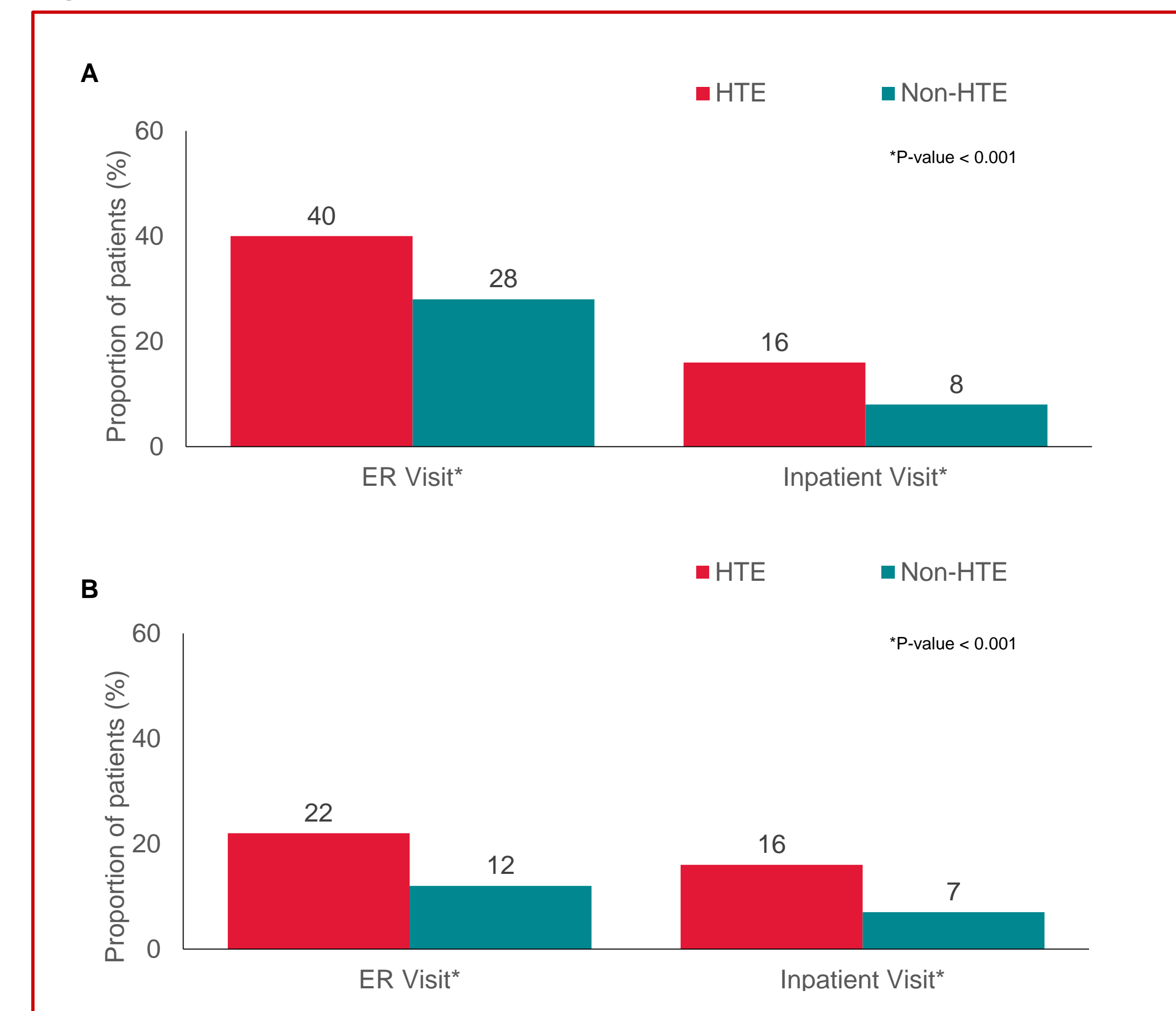
- Among 9,901 patients meeting the selection criteria, 2,297 (23.2%) had an HTE regimen and 7,604 (76.8%) were treatment-experienced but Non-HTE. (Table 1)
- Compared to Non-HTE patients, HTE patients were:
 - Older on average with nearly 70% aged 50 and older
 - More likely to be enrolled in Medicare than commercial plans
 - Living with more AIDS defining conditions at baseline
 - Particularly herpes simplex (4.4%), encephalopathy (1.3%), kaposi's sarcoma (1.2%), pneumonia (1.1%) and esophageal candidiasis (0.9%)
 - More likely to die in the one year of follow-up

Table 1. Patient demographics

Demographics	HTE (N=2,297)	Non-HTE (N=7,604)	P-Value
Age (years), mean (SD)	53 (10)	49 (11)	<0.001
Age Category, n (%)			<0.001
18–34	101 (4%)	897 (12%)	
35–49	621 (27%)	2,959 (39%)	
50–64	1,272 (55%)	3,184 (42%)	
≥65	303 (13%)	564 (7%)	
Sex (male), n (%)	1,918 (84%)	6,508 (86%)	0.014
Race/Ethnicity, n (%)			<0.001
White	1,140 (50%)	4,116 (54%)	
African-American/Black	592 (26%)	1,855 (24%)	
Hispanic	265 (12%)	1,114 (15%)	
Other ^a	300 (13%)	519 (7%)	
Insurance type, n (%)			<0.001
Commercial	1,391 (61%)	6,212 (82%)	
Medicare Advantage	906 (39%)	1,392 (18%)	
Any AIDS Defining Conditions at baseline, n (%)	224 (10%)	427 (6%)	<0.001
Mortality, n (%)	135 (6%)	218 (3%)	<0.001
All-Cause Healthcare Utilization, n (%) Pre-Period			
Ambulatory (Office/Outpatient Visits)	2,184 (95%)	7,217 (95%)	0.744
Emergency Room	591 (26%)	1,291 (17%)	<0.001
Inpatient Stay	262 (11%)	298 (4%)	<0.001

^aIncludes other less commonly reported races/ethnicities.

Figure 2. 12-month Follow-up (A) All-Cause and (B) HIV-related Healthcare Utilization



Healthcare Utilization

- The majority of patients in both cohorts had at least one all-cause ambulatory visit in a year (99%) and at least one HIV-related ambulatory visit (≥96%) and were not statistically different
- A higher proportion of HTE patients had all-cause (Figure 2A) and HIV-related (Figure 2B) ER and Inpatient visits compared to Non-HTE patients in the follow-up period

Pill Burden

- The mean (SD) daily pill burden for HTE patients was double that of Non-HTE patients:
 - HTE cohort: 9.7 (7.7) pills/day for all medications, 4.2 (2.5) pills/day for ART medications only and 5.5 (7.0) pills/day for non-ART medications only.
 - Non-HTE cohort: 5.1 (5.9) pills/day for all medications, 1.9 (1.5) pills/day for ART medications only and 3.2 (5.4) pills/day for non-ART medications only.

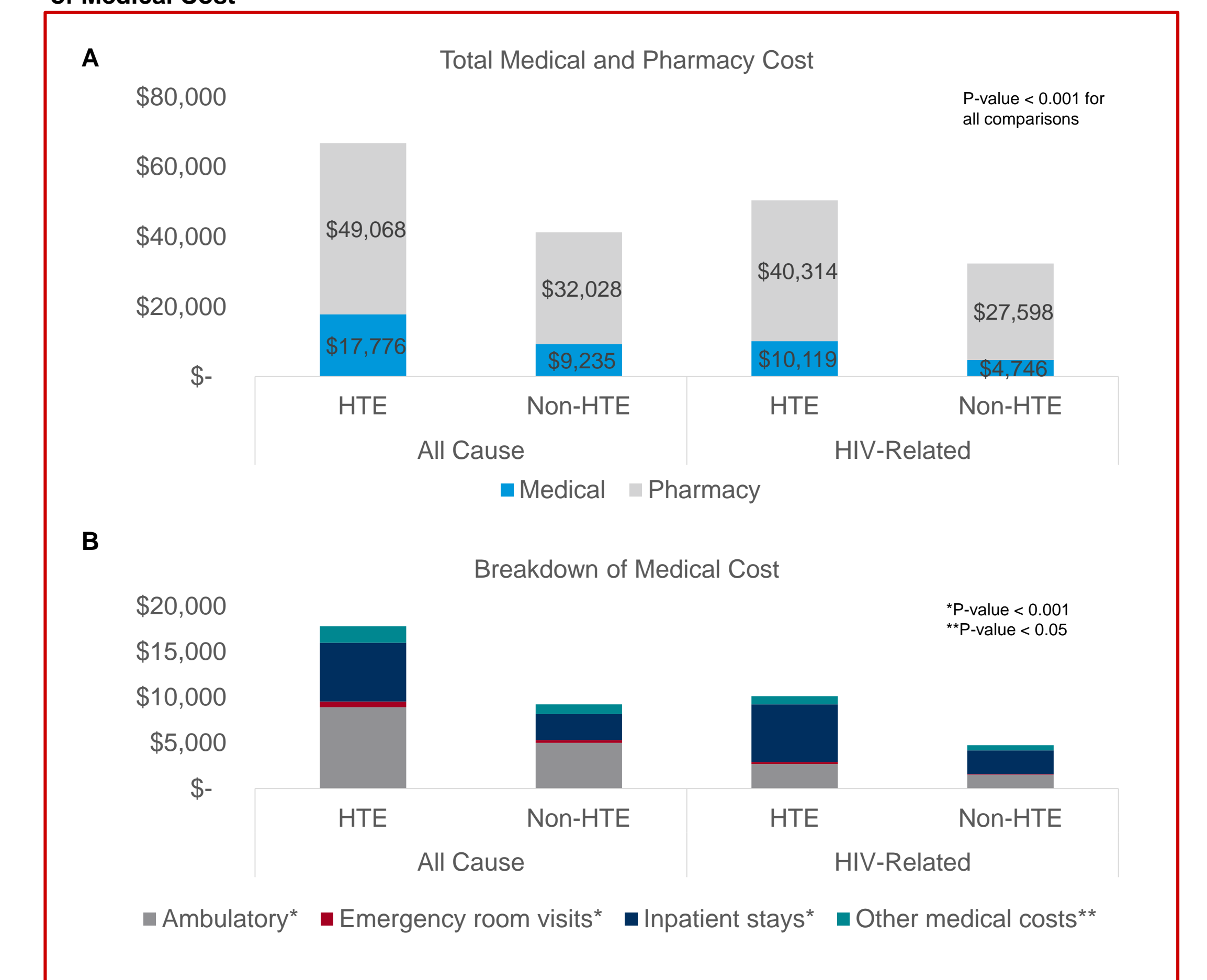
AIDS defining conditions

- Among patients with no AIDS defining conditions during baseline, a higher proportion of HTE patients developed one during the following up period (HTE: 9%, Non-HTE: 5%; p-value <0.001)

CD4 Laboratory Results

- A greater proportion of HTE patients (22%) had CD4 counts < 200 copies/mL compared to Non-HTE patients (8%) (p-value <0.001), for the subset of patients with available CD4 results near the index date (HTE: 1,117, Non-HTE: 2,394).

Figure 3. 12-month Follow-up (A) Total All-Cause and HIV-Related Total Cost and (B) Breakdown of Medical Cost



Healthcare Cost

- HTE patients cost on average \$25,583 more than Non-HTE patients in a one year period for all-cause medical and pharmacy cost. This was also true for HIV-related cost with a difference of \$18,090 on average. (Figure 3A)
- Medical costs were higher for HTE patients in all categories for both all-cause and HIV-related, the highest differences seen in ambulatory and inpatient costs. (Figure 3B)

Conclusions

- The HTE population is complex subgroup of PLWH.
- HTE patients have a high disease burden with more AIDS defining conditions, higher mortality, more frequent ER and Inpatient visits along with higher healthcare cost than Non-HTE experienced patients.
- These patients are also more likely to have CD4 counts below 200 copies/mL which could be contributing to some of these differences. Additional research is underway to better understand how this potentially impacts these results.

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