Patient Characteristics, Duration on Antiretrovirals (ARVs) and Adherence in an Insured US Population Receiving ARVs in 2010-2014: A Focus on Women

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Background

- Adherence to antiretroviral (ARV) therapy is a critical factor in determining long-term outcomes for patients with HIV[1]
- Gender disparities have been observed in the use of ARV treatment, with women less likely than men to receive ARV therapy[2]
- Prior literature (January 2000-June 2011) from studies in developed countries suggests that women have lower adherence to ARV therapy than men[3]
- Recent real-world evaluations of ARV therapy adherence in women would provide additional and relevant insights that would be particularly important within the context of measuring the quality of HIV care

HIV, human immunodeficiency virus.

1. Department of Health and Human Services. Guidelines for the use of antiretroviral agents in HIV-1-infectedadults and adolescents. https://aidsinfo.nih.gov/guidelines. Accessed May 18, 2015.
2. Fleishman JA, et al. *Med Care*. 2012;50(5):419-427.
3. Puskas CM, et al. *Curr HIV/AIDS Rep*. 2011;8(4):277-287.

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Study Objective

- To describe patient characteristics, including comorbidities, duration of ARV therapy, and adherence, for women (in reference to men) in a large, insured US population receiving HIV treatment from 2010 to 2014

ARV, antiretroviral; HIV, human immunodeficiency virus.

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Methods (1/2)

- Data were obtained for commercially insured and Medicare Advantage insured patients from 2 US health insurance databases
  - Optum Research Database (ORD): large, proprietary database that contains administrative, medical, and pharmacy claims data (1993-present). Membership is representative of commercially insured and Medicare Advantage insured US patients
  - Impact National Benchmark Database (Impact): comprehensive, de-identified database that includes data collected from 16 different US health care plans
- Eligible patients were ≥18 years old and had evidence of HIV diagnosis,* no evidence of HIV-2 infection,† a pharmacy claim for any ARV‡ during the identification period of January 2010 to December 2014 (date of the first claim set as the index date), and continuous enrollment with both medical and pharmacy coverage for ≥6 months before the index date (baseline defined as the 6 months prior to the index date)

HIV, human immunodeficiency virus; ARV, antiretroviral.
*HIV diagnosis defined as ICD-9-CM codes 042, 795.71, or V08.
†HIV-2 infection defined as ICD-9-CM code 079.53.
‡Patients with claims for only nucleos(t)ide reverse transcriptase inhibitors during the identification period were excluded.

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Methods (2/2)

- Analyses were performed for the total population, and by gender; statistical comparisons were not performed
  - Sociodemographic and clinical characteristics were assessed; comorbidities were described by the Quan-Charlson Comorbidity Index (excluding HIV/AIDS)[1] and the Agency for Healthcare Research and Quality (AHRQ) Clinical Classification Software[2]
  - Utilization of ARV regimens (a regimen included all ARVs filled within ≤14 days of the index date) was described
  - Duration of treatment episodes (defined as therapy with the same regimen until a change in anchor medication, gap of ≥90 days, end of patient follow-up, or end of study) was described
  - Adherence was evaluated from ARV initiation through either end of enrollment or December 31, 2014 (whichever came first); multiple adherence measures were employed

HIV, human immunodeficiency virus; AIDS, acquired immunodeficiency syndrome; ARV, antiretroviral.

1. Quan H, et al. *Am J Epidemiol*. 2011;173(6):676-682.
2. AHRQ Clinical Classification Software for ICD-9-CM. http://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccs.jsp. Accessed April 17, 2015.

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Population Characteristics

Parameter	Women (n = 3,949)	Men (n = 21,371)	Total (N = 25,320)
Age, years			
Mean (SD)	45.2 (11.2)	45.3 (10.8)	45.3 (10.8)
18-44, n (%)*	1,910 (48.4)	9,503 (44.5)	11,413 (45.1)
45-64, n (%)*	1,869 (47.3)	11,186 (52.3)	13,055 (51.6)
65+, n (%)*	170 (4.3)	682 (3.2)	852 (3.4)
Geographic location, n (%)*			
Northeast	1,442 (36.5)	6,878 (32.2)	8,320 (32.9)
Midwest	453 (11.5)	2,837 (13.3)	3,290 (13.0)
South	1,867 (47.3)	9,118 (42.7)	10,985 (43.4)
West	186 (4.7)	2,534 (11.9)	2,720 (10.7)
Prior therapy, n (%)			
ARV treatment naïve	1,358 (34.4)	7,550 (35.3)	8,908 (35.2)
ARV treatment experienced	2,591 (65.6)	13,821 (64.7)	16,412 (64.8)
Insurance type, n (%)			
Commercial	3,573 (90.5)	20,246 (94.7)	23,819 (94.1)
Medicare Advantage	376 (9.5)	1,125 (5.3)	1,501 (5.9)
Data source, n (%)			
ORD	2,550 (64.6)	14,911 (69.8)	17,461 (69.0)
Impact	1,399 (35.4)	6,460 (30.2)	7,859 (31.0)

SD, standard deviation; ARV, antiretroviral; ORD, Optum Research Database.
*One woman and 4 men were from geographic locations classified as “Other”; these patients accounted for <0.1% of the respective subpopulation and the total population.

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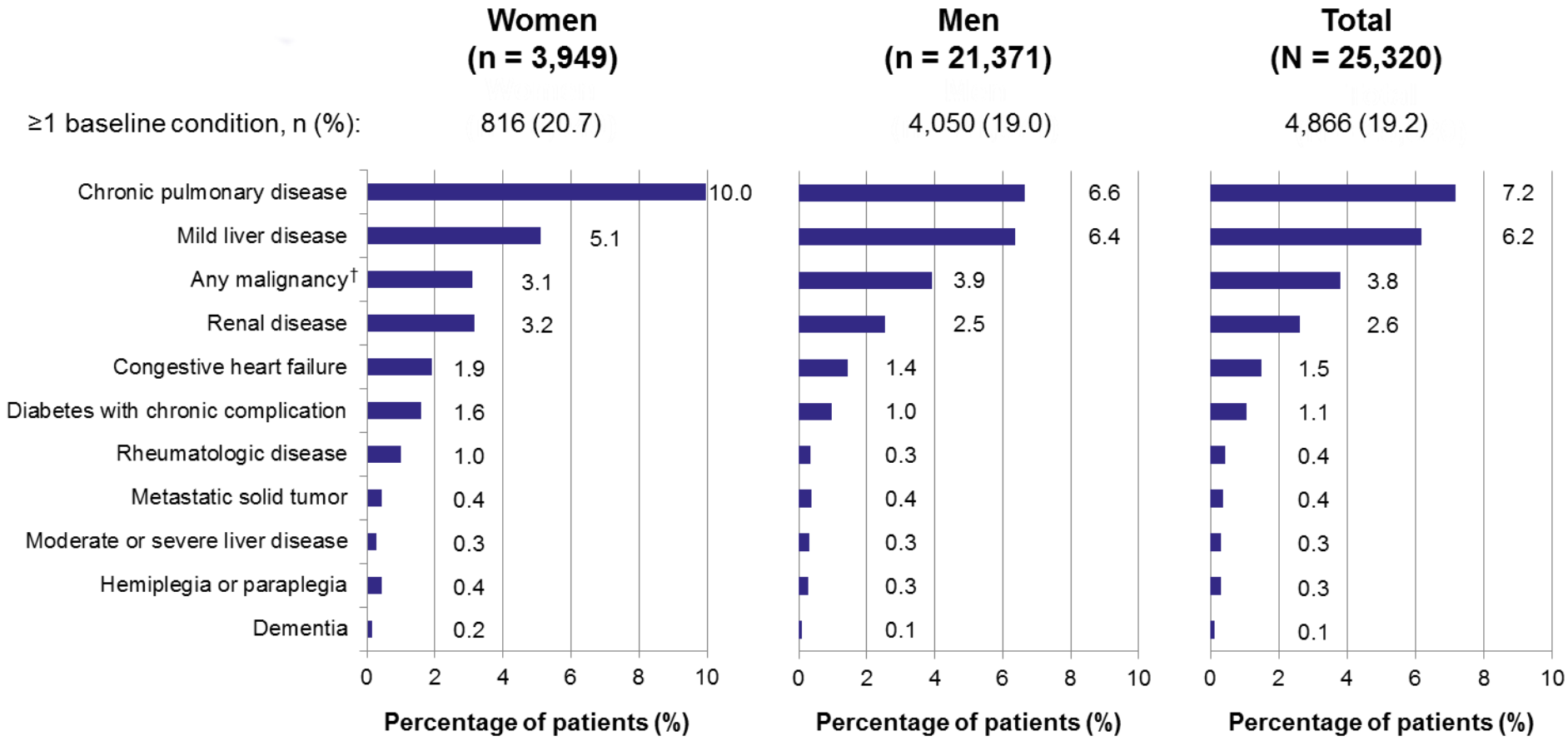
Results: Baseline Comorbidities (1/2)

Quan-Charlson Comorbidity Index, excluding HIV/AIDS*



HIV, human immunodeficiency virus; AIDS, acquired immunodeficiency syndrome.
*Conditions listed from highest to lowest proportion in the total population.
†Including leukemia and lymphoma.

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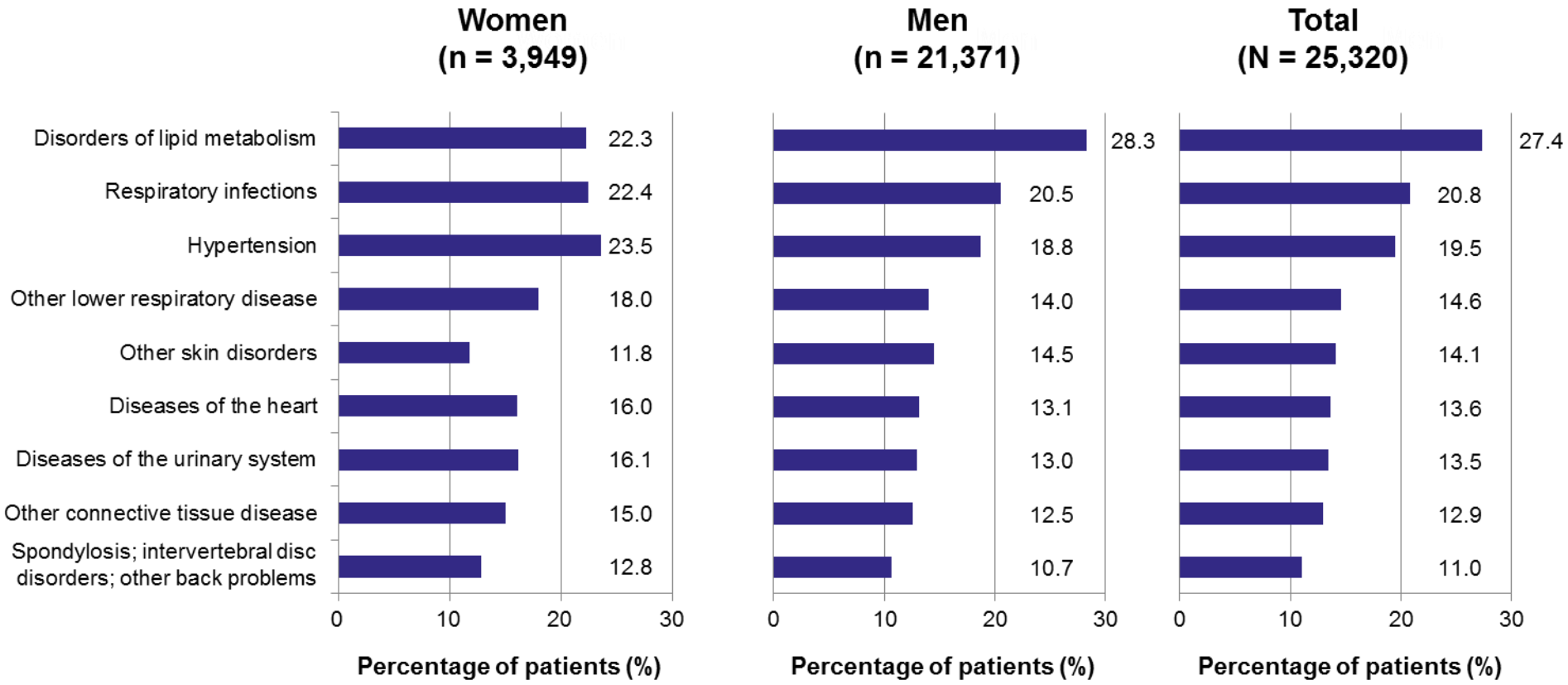
Results: Baseline Comorbidities (2/2)

AHRQ Clinical Classification Software, excluding viral infections*



AHRQ, Agency for Healthcare Research and Quality.
*Conditions listed from highest to lowest proportion in the total population. Only the top 10 most common conditions observed in the total population are presented.

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Results: Treatment Characteristics

- There were 6,681 treatment episodes* for women (n = 32,390 for men; n = 39,071 for the total population)
- The mean ± SD post-index follow-up was 727.1 ± 538.9 days for women (759.1 ± 562.6 days for men; 753.6 ± 558.7 days for the total population)
- 36.4% of women had >1 treatment episode during follow-up (29.6% of men; 30.7% of the total population)
- The mean ± SD treatment duration for any treatment episode was 418.9 ± 469.9 days for women (504.2 ± 514.0 days for men; 489.6 ± 507.8 days for the total population)†

Table. Most Common ARVs (Observed in >5% of Treatment Episodes in Total Population)‡,§

ARV, %	Women (n = 6,681)¶	Men (n = 32,390)¶	Total (n = 39,071)¶
Efavirenz	30.2	37.1	36.0
Raltegravir	17.6	17.9	17.8
Atazanavir	19.4	14.5	15.4
Darunavir	13.4	13.3	13.4
Lopinavir	12.5	7.9	8.7
Nevirapine	4.8	6.5	6.2
Etravirine	4.8	5.3	5.3
Rilpivirine	5.4	5.2	5.2

SD, standard deviation; ARV, antiretroviral; N(t)RTI, nucleos(t)ide reverse transcriptase inhibitor; BA, boosting agent.
*Treatment episodes were defined as therapy with the same regimen until an ARV‡ switch, gap of ≥90 days, end of patient follow-up, or end of study period.
†Median (interquartile range) treatment duration was as follows: women, 218 (68-621) days; men, 306 (95-752) days; total population, 290 (91-725) days.
‡Excludes N(t)RTIs and BAs.
§Not mutually exclusive.
¶Number of treatment episodes.

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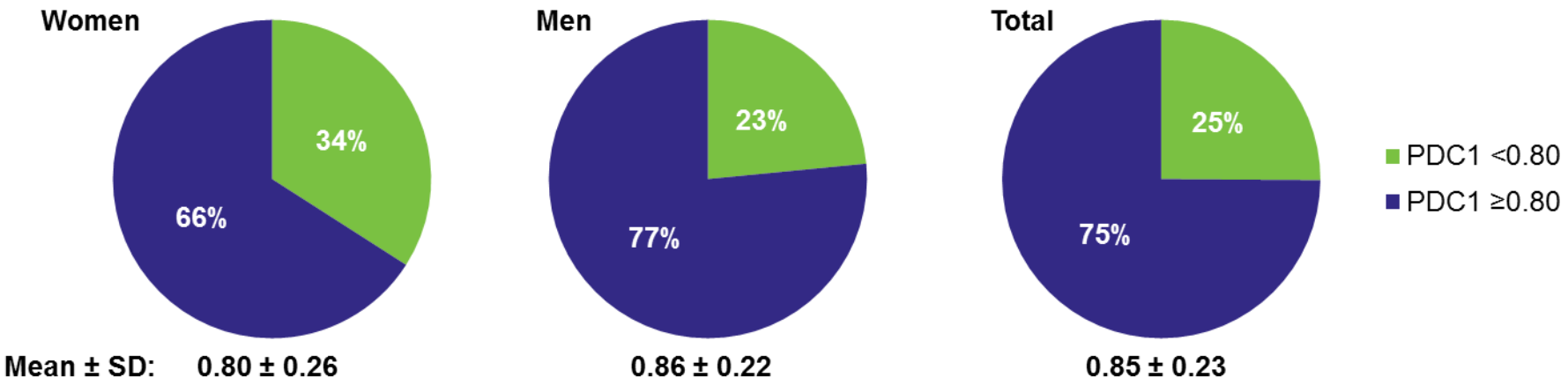
Results: Adherence Measures (1/3)

PDC1



- PDC1 represents the proportion of time during the follow-up period that a patient theoretically is in possession of ≥1 ARV
- PDC1 was calculated by dividing the number of days on which ≥1 ARV (regardless of medication class) was available (based on filled prescriptions) by the number of days between the index date and end of the follow-up period*
- By this definition, a PDC = 1 is considered perfect compliance, while a PDC <1 is considered less than fully compliant

One in 3 (34%) women and nearly 1 in 4 (23%) men had a PDC1 <0.80

PDC1, Proportion of Days Covered by any ARV; SD, standard deviation; ARV, antiretroviral.
*Calculation excluded boosting agents.

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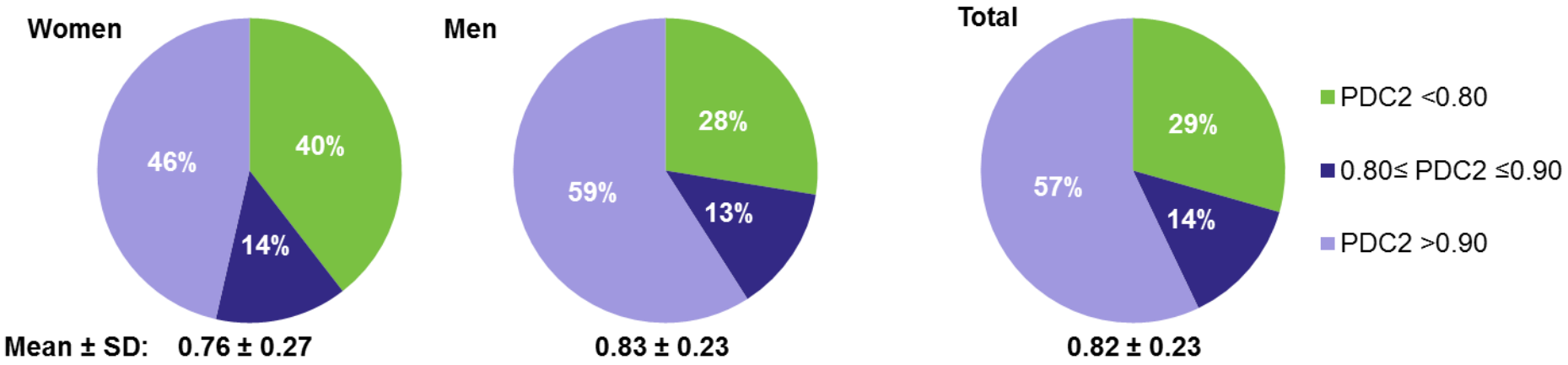
Results: Adherence Measures (2/3)

PDC2



Mean ± SD: 0.76 ± 0.27 | 0.83 ± 0.23 | 0.82 ± 0.23

- Similar to PDC1, PDC2 was calculated by dividing the number of days on which ≥2 ARVs were available by the number of days between the index date and end of the follow-up period*

40% of women had a PDC2 <0.80; more than half (54%) had a PDC2 ≤0.90. For men, 28% and 41% had a PCD2 <0.80 and ≤0.90, respectively

PDC2, Proportion of Days Covered by ≥2 ARVs; SD, standard deviation; PDC1, Proportion of Days Covered by any ARV; ARV, antiretroviral.
*PDC2 was calculated for patients with ≥2 ARVs per regimen with overlapping days (women, n = 3,925; men, n = 21,271; total, n = 25,196). Calculation excluded boosting agents.

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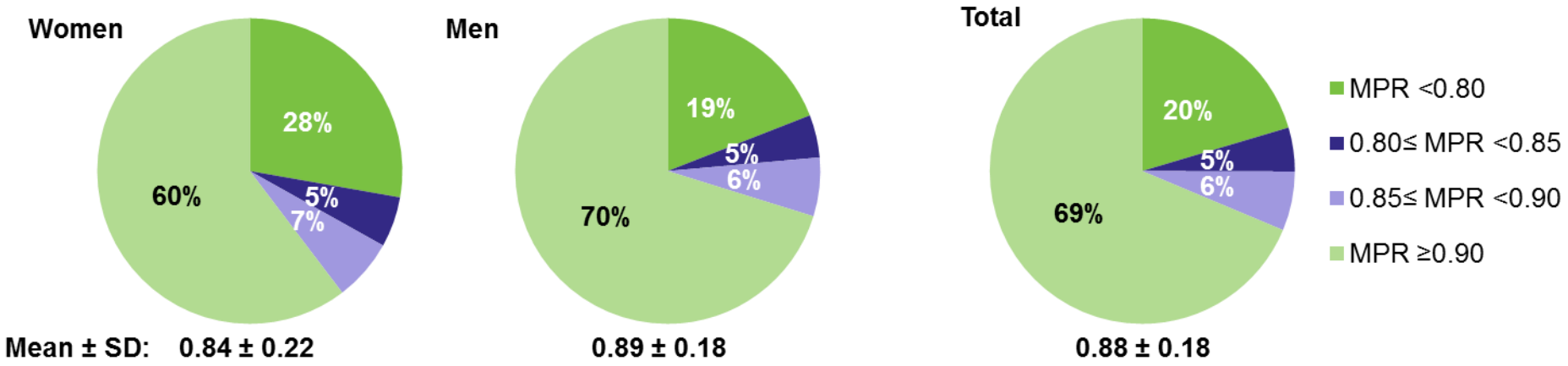
Results: Adherence Measures (3/3)

MPR



- MPR was calculated by summing the number of days supplied of any ARV medication for all but the last fill in the follow-up period, divided by the number of days between the first and the last refill*
- By this definition, an MPR = 1 is considered perfect compliance, while an MPR <1 is considered less than fully compliant

28% of women had an MPR <0.80, and 40% had an MPR <0.90

MPR, Medication Possession Ratio; SD, standard deviation; ARV; ARV, antiretroviral.
*MPR was calculated for patients with ≥2 ARV fills (women, n = 3,731; men, n = 20,444; total, n = 24,175). Calculation excluded boosting agents.

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Limitations and Considerations

- This study utilized administrative claims data from a US commercially insured and Medicare Advantage insured population. Results may not be generalizable to uninsured populations, untreated HIV/AIDS patients, or other populations that are limited by the sample criteria
- Patients included in the study had varying follow-up lengths. Additionally, those who initiated treatment in more recent years (eg, 2014) had the potential for less observation time in the dataset versus patients who initiated treatment in earlier years (eg, 2010)
- Analyses performed for the total population and by gender were descriptive and statistical comparisons were not performed. Additionally, the sample size for women was smaller than that of men
- While various inclusion/exclusion criteria (eg, exclusion of BAs in calculations) were applied, it is unknown if changes to certain criteria would impact results
- Claims-based analyses of adherence are centered on prescription fill and refill information, which represents medication receipt, but may not accurately capture all measures of adherence that are unobservable in such databases (eg, patient medication-taking behaviors and compliance following receipt)

HIV, human immunodeficiency virus; AIDS, acquired immunodeficiency syndrome; BA, boosting agent.

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Conclusions

- Findings from this study provide insights into possible variations in real-world characteristics and adherence by gender within a large, insured HIV population receiving ARV therapy
  - Baseline comorbidities were observed for both genders
  - ARVs (excluding N(t)RTIs and BAs) observed in >5% of treatment episodes for both genders were efavirenz, raltegravir, atazanavir, darunavir, lopinavir, and rilpivirine
  - The average follow-up was 2.0 years for women and 2.1 years for men, while the average treatment duration for any treatment episode was 1.2 and 1.4 years, respectively
  - Women appeared to have lower levels of adherence than men among the various adherence measures evaluated in this study
    - More than 1 out of 4 women were observed to have an adherence level <0.80, regardless of the measure used (PDC1, PDC2, or MPR)
    - When higher adherence thresholds were employed, 40% of women had an MPR <0.90 and over half had a PDC2 ≤0.90
- Given that claims-based adherence analyses reflect medication receipt but do not assess patient medication-taking behaviors, findings warrant additional research to further elucidate adherence and outcomes by gender

HIV, human immunodeficiency virus; ARV, antiretroviral; N(t)RTI, nucleos(t)ide reverse transcriptase inhibitor; BA, boosting agent; PDC1, Proportion of Days Covered by any ARV; PDC2, Proportion of Days Covered by ≥2 ARVs; MPR, Medication Possession Ratio.

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