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Characteristics of Truvada for Pre-Exposure Prophylaxis Users in the US (January 2012 – September 2013)

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Background

- Truvada® (TVD) was approved in July 2012 by the US FDA for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the risk of sexually acquired HIV-1 in adults at high risk
- Registrational studies in the US accrued only men who have sex with men and transgender women while serodiscordant heterosexual couple studies were carried out in Africa
- The objective of this study is to explore the characteristics of the US PrEP population and their prescribers

Materials and Methods

- By examining an electronic source of nationally representative de-identified patient level data from approximately 55% of all US retail pharmacies that dispensed TVD for PrEP, a standard algorithm was designed to determine which patients were receiving Truvada for PrEP between January 2012 and September 2013 was used
- Since there is no diagnosis code for PrEP, this involved examining all diagnosis codes where Truvada was prescribed, and excluding diagnosis codes for other possible Truvada uses including HIV Treatment, Post-exposure prophylaxis, and/or hepatitis B treatment
- De-identified patient-level data including detailed drug information, medical claims, and patient demographics were analyzed
- Logistic regression was used to estimate the odds of a given characteristic and their change over time. All analyses were carried out using STATA 13 (College Station, Tx)

Algorithm for PrEP Indication

- Among all exposure periods (eras) that belong to TVD; sequential exclusions:
 - **Exclude** all eras where there is concomitant use of any other antiretroviral or anti Chronic Hepatitis B specific treatment
 - **Exclude** all eras where there is a prior diagnosis of :
 - HIV disease (ICD9 = 042)
 - asymptomatic HIV infection (V08)
 - HIV-2 infection (079.53) or
 - nonspecific serologic evidence of HIV (795.71)
 - **Exclude** all eras where there is a prior diagnosis of opportunistic infection: (*Candidiasis 112, of bronchi, trachea, esophagus 112.84, or lungs 112.4, Toxoplasmosis 130.X, Coccidioidomycosis 114, Cryptococcosis 117.5, Cryptosporidiosis 007.4, CMV retinitis 078.5, Kaposi's sarcoma (176), Mycobacterium avium complex (031.2, 031.), Pneumocystis carinii pneumonia 136.3*)
 - **Exclude** all eras where there is a prior diagnosis of chronic hepatitis B infection (70.22, 70.23, 70.32, 70.33)
 - **Exclude** all eras with specific codes of E920.5 (contaminated needle stick) and /or V078 V079 (prophylaxis). Those correspond to Post Exposure Prophylaxis eras

Assign PrEP to any eras that do not fulfill requirements above as long as those subjects had existing diagnosis and procedures information

Results

- A total of 2,319 unique individuals who started TVD for PrEP between 01 Jan 2012 and 30 Sep 2013 were included in the analysis
 - 48.8% of PrEP users were women
 - Mean age was 38.2 ± 12.2 years
 - Males were significantly older (39.5 ± 12.0) than females (36.8 ± 12.3). $p < 0.0001$
 - 12.3% of individuals were under 25 years old
 - The proportion of males under 25 was 8.0% (95% CI 6.5 – 9.5) significantly lower than that of women 16.8% (95% CI 14.6 – 19.0). $p < 0.0001$

Table 1. PrEP Demographics by US Regions

	Overall	Midwest	Northeast	South	West
Unique PrEP users n (%)	2,319*	373 (16%)	570 (25%)	729 (32%)	604 (27%)
Mean age in years (SD)	38 (12)	37 (12)	37 (12)	40 (12)	38 (12)
Younger <25 y/o	12.3%	16.4%	12.3%	9.7%	12.4%
Female	48.8%	53.6%	51.4%	51.4%	39.2%
Medicaid	9.9%	15.3%	15.3%	6.6%	5.1%

* 43 subjects did not have region information

Results (cont'd)

Figure 1. PrEP by U.S. Regions

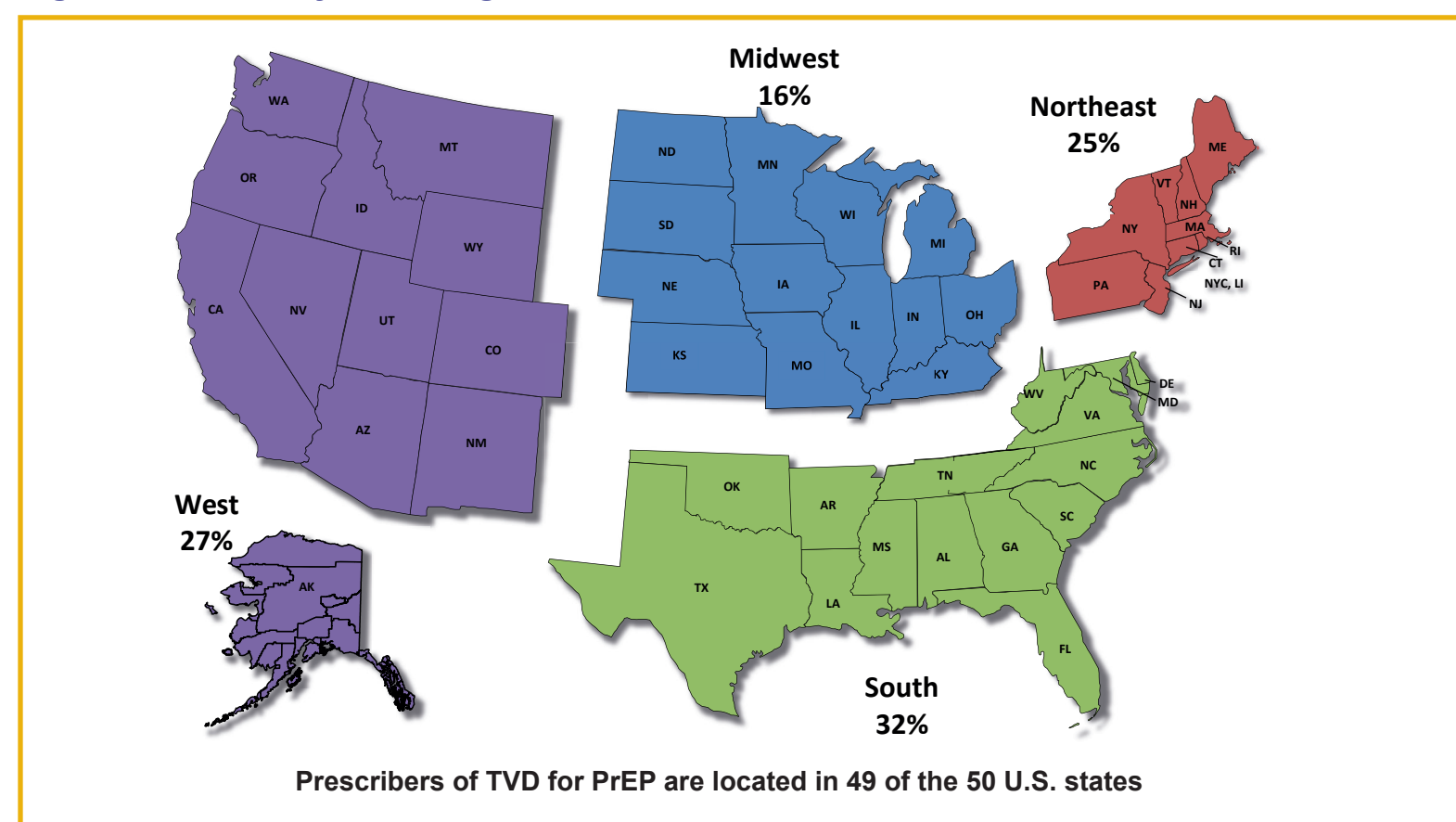
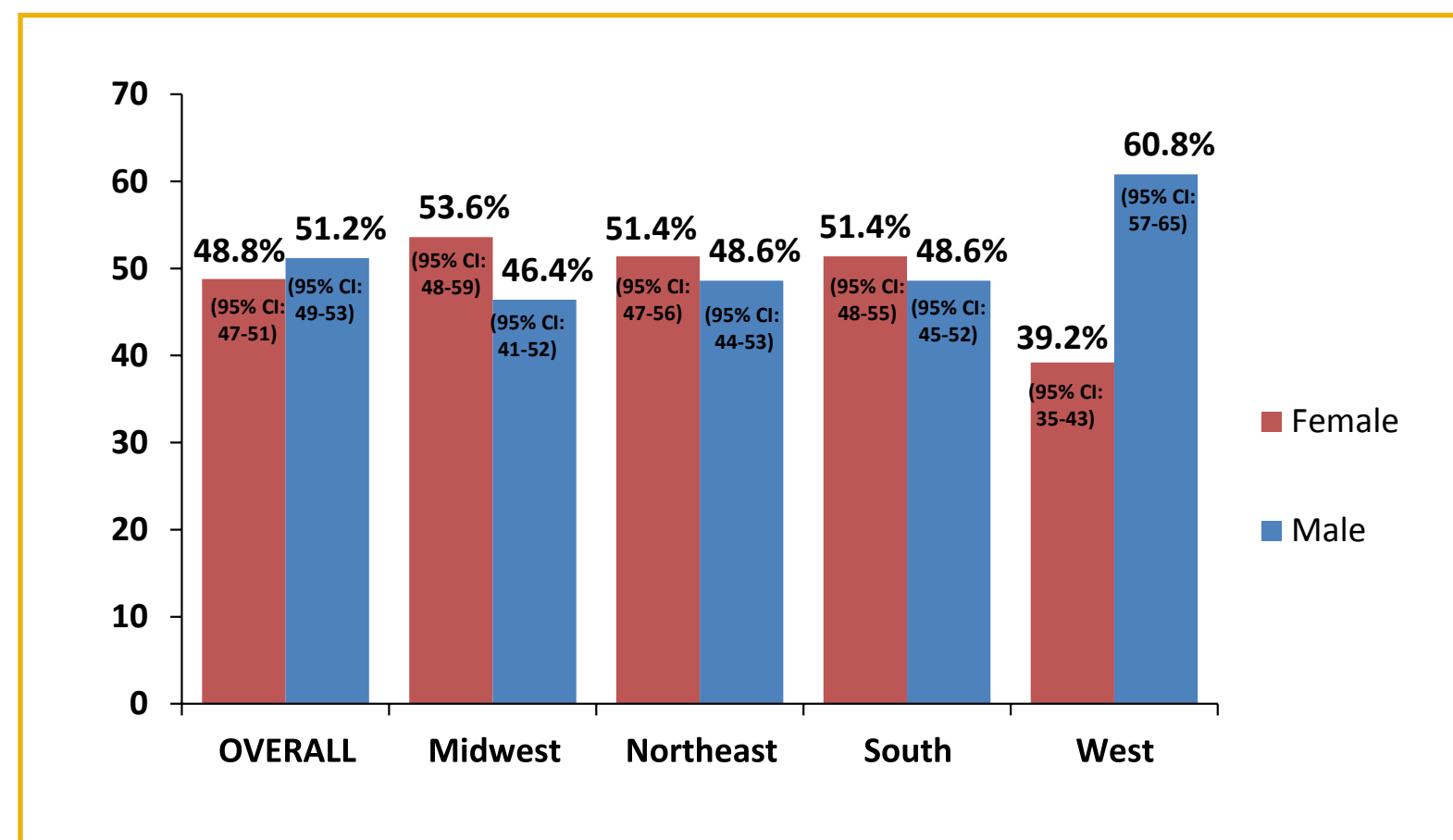


Figure 2. PrEP Demographics by Gender



PrEP Prescriptions

- Overall distribution of TVD for PrEP prescriptions by prescriber specialty:
 - Family Practice (18%)
 - Internal Medicine (16%)
 - Infectious Diseases (11%)
 - Nurse Practitioners (9%)
 - Physician Assistants (9%)
- Among women who initiated TVD for PrEP
 - 49% received it from Nurse Practitioners and 43% Infectious Diseases specialists

PrEP Users compared to HIV positive patients in the US

- Uninfected individuals receiving TVD for PrEP were:
 - 1.8 times more likely to be female (95% CI 1.6 – 1.9)
 - 1.4 times more likely to be younger than 25 years old (95% CI 1.3 – 1.7)
 - 3.6 times more likely to be treated by a non-ID physician (95% CI 3.2 – 4.1)

Conclusions

- The population of TVD for PrEP users in the US is quite different from HIV+ subjects. They are more likely to be women, younger and be treated by Primary care clinicians