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 concurrent 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-v2 infection (079.53) or non-specific serologic evidence of HIV (795.71).
  - Exclude all eras where there is a prior diagnosis of opportunistic infection: (Candidiasis 112.0, 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, 031.1), 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).
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- Assign PrEP to any eras that do not fulfill requirements above as long as those subjects had existing diagnosis and procedures information.

Results

Table 1. PrEP Demographics by US Regions

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<td>373 (16%)</td>
<td>570 (25%)</td>
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* 43 subjects did not have region information.

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.

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