2088

Real-world Geographic Variations of HIV Diagnosis Rates Among Individuals Prescribed and Not Prescribed Oral HIV Pre-Exposure Prophylaxis Regimens in the United States

Li Tao,[1] Christoph Carter,[1] Moupali Das,[1] Jennifer Thorburn,[2] Amanda Kong,[2] Debra Irwin,[2] Julie Paone[2] — [1]Gilead Sciences, Inc., Foster City, CA; [2]Aetion, Inc., New York, NY

Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404
800-445-3235

Scan for plain language summary

Introduction

- HIV pre-exposure prophylaxis (PrEP) is a highly effective prevention strategy for people at risk of sexually acquired HIV[1]
  - The U.S. Food & Drug Administration approved emtricitabine/tenofovir disoproxil fumarate (F/TDF) for PrEP for adults in 2012 and expanded approval to adolescents weighing ≥ 35 kg in 2018[2]
  - Emtricitabine/tenofovir alafenamide (F/TAF) for PrEP was approved for adults and adolescents weighing ≥ 35 kg in 2019, excluding those who are at risk of HIV-1 from receptive vaginal sex[2]
- Declines in the diagnoses of new HIV infections have been reported in geographic areas with higher uptake of PrEP among persons who would benefit from PrEP (PWBP)
- Due to heterogeneity of diagnosis of HIV infection and variability in PrEP uptake among PWBP across the US, additional studies are important to help understand the impact of PrEP in real-world settings

Objective

- To understand the impact of PrEP in differing geographies by examining the rates of new HIV diagnoses in PWBP prescribed with oral PrEP regimens and the rates in individuals not using PrEP in the US

Methods

- The rate of new HIV infections among PWBP not using PrEP in each state was estimated with a previously described model[3] using a combination of published reports and a claims database

Table 1

$$\text{Incidence Rates} = \frac{(N - n)}{PT - PT_{HIV} - PT_{PrEP}}$$

	Label	Data Source
N	No. of HIV diagnoses in each state	HIV Surveillance Report, 2019[4]
n	No. of HIV diagnoses without PrEP indications (excluding people aged < 19 y and other risk categories: hemophilia, blood transfusion, and risk factor not reported or not identified)	HIV Surveillance Report, 2019[4]
PT	Total PT for individuals with PrEP indications	Estimated no. of adults with PrEP indication (MSM, PWID, HET) by state obtained from Smith et al[5]
PT_{PrEP}	On-PrEP PT for individuals with PrEP indications	Obtained from IQVIA® LRxDx Data[a] for individuals prescribed with PrEP by state
PT_{HIV}	PT with HIV infection for individuals with PrEP indications	HIV Surveillance Report, 2019[4]

[a]IQVIA Inc., Durham, NC. HET = heterosexually active adults; LRxDx = Longitudinal Prescription and Diagnosis; MSM = men who have sex with men; PT = person time; PWID = people who inject drugs. Modified from Mera et al[3] (previously calculated rates by metropolitan statistical area).

- HIV rates for individuals prescribed daily oral F/TAF or F/TDF (including brand and generic) for PrEP between 03 Oct 2019 (F/TAF approval) and 30 Jun 2021 were analyzed
  - Eligible participants included adults (aged ≥ 18 years) without HIV receiving an oral PrEP regimen (F/TDF or F/TAF) who were identified from a pharmacy claims database (IQVIA LRxDx) linked with medical claims from physicians' offices across the US
  - Individuals previously diagnosed with HIV or treated with HIV agents, diagnosed with chronic hepatitis B or treated with chronic hepatitis B agents, or treated with postexposure prophylaxis were identified and excluded using a PrEP algorithm
  - For participants prescribed PrEP, new infections included new HIV diagnoses and addition of HIV treatment within 10 days of PrEP discontinuation

Results

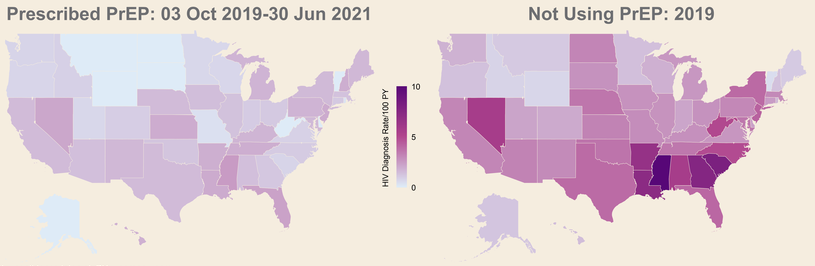
Table 2. Baseline Demographics

		Prescribed PrEP 03 Oct 2019-30 Jun 2021 n = 104,354	US Census 2019[6] n = 328,239,523
Age categorized on cohort entry date, n (%)[a]	25-34 y	33,426 (32)	45,030,415 (14)
	35-44 y	24,515 (24)	40,978,831 (13)
	45-54 y	17,974 (17)	42,072,620 (13)
	≥ 55 y	13,888 (13)	92,540,210 (29)
Race/ethnicity, n (%)[b]	White	36,804 (35)	235,377,662 (73)
	Hispanic/Latinx	7909 (8)	58,479,370 (18)
	Black or African-American	7242 (7)	45,612,523 (14)
	Asian/Other	1922 (2)	40,666,687 (13)

[a]No individuals prescribed PrEP were aged ≥ 85 y; [b]Participants prescribed PrEP with unknown race and ethnicity not included in this table (n = 50,477 [48%]).

Figure 1. Estimated HIV Diagnosis Rates by State

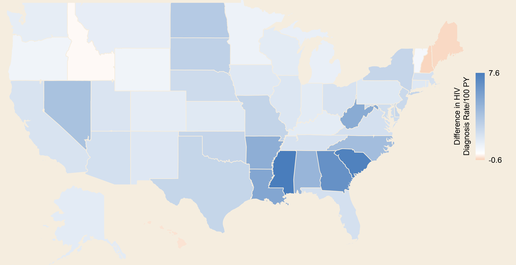
- **Overall, the US HIV diagnosis rate was 61% lower among PWBP prescribed PrEP (1.33/100 PY [95% CI 1.24, 1.42]) vs those not using PrEP (3.38 [3.35, 3.42])**



CI = confidence interval; PY = person-years.

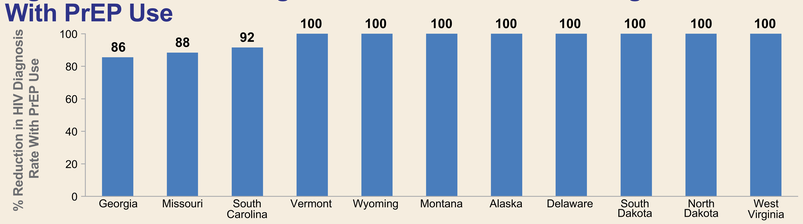
- New HIV diagnosis rates by state among individuals not using PrEP ranged from 0.41 (95% CI 0.22, 0.78) in Vermont to 9.96 (9.53, 11.54) in Mississippi
- HIV diagnosis rates by state among PWBP prescribed PrEP ranged from 0 in Alaska, Delaware, Montana, North Dakota, South Dakota, Vermont, West Virginia, and Wyoming to 2.40 in Mississippi

Figure 2. Differences in HIV Diagnosis Rates With vs Without PrEP Use by State



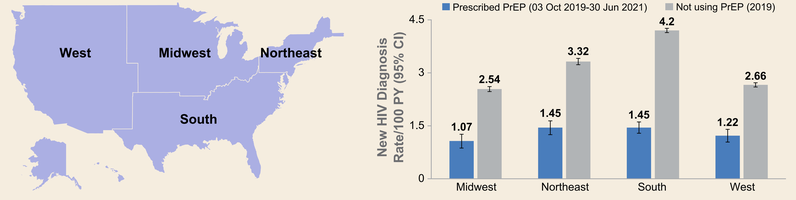
- The greatest disparities in PrEP use and HIV diagnosis rates were observed in the Southeastern states

Figure 3. States With Highest % Reductions in HIV Diagnosis Rates With PrEP Use



- 11 states had > 85% lower HIV diagnosis rates among PWBP prescribed PrEP vs those not using PrEP

Figure 4. HIV Diagnosis Rates by Region



Study Limitations

- Due to the challenges in defining a key population with PrEP indication in administrative records, a mathematical projection based on multiple data sources was used instead; this method included certain assumptions and projections about PWBP as a group which may not apply to individuals, and may not reflect real-world rates of PrEP use
- This study is not a comparative analysis within the same population at the same period
- Real-world data cannot assess PrEP adherence, how individuals use PrEP, or how many PrEP candidates may not be receiving treatment; these considerations warrant future study

Conclusions

- This study suggests that substantial reductions in HIV diagnosis rates have occurred in people prescribed PrEP in the US
- Large geographic variations were found in HIV diagnosis rates, with the largest differences by PrEP prescription status occurring in the Southeastern states, underscoring the need for PrEP expansion and its potential impact on the HIV epidemic in that region
- Furthermore, the findings demonstrate an approach of estimating HIV rates for PWBP prescribed PrEP and not using PrEP
  - Variations in PrEP utilization across geographic regions may be useful in supporting targeted delivery of HIV prevention services in the US
  - Further research is warranted in those states with the largest discrepancies in HIV diagnosis rates and PrEP utilization

References: **1.** Mayer K, et al. *Lancet*. 2020;396:239-54; **2.** Centers for Disease Control and Prevention: US Public Health Service: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2021 Update: a Clinical Practice Guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf; **3.** Mera R, et al. *J Int AIDS Soc*. 2019;22:e25433; **4.** Centers for Disease Control and Prevention. HIV Surveillance Report, 2019; vol 32. http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html; May 2021; **5.** Smith DK, et al. *Ann Epidemiol*. 2018;28:850-7.e9; **6.** United States Census Bureau. American Community Survey 5-Year Data (2009-2020). https://www.census.gov/data/developers/data-sets/acs-5year.2019.html; 17 Mar 2022.

Acknowledgments: We extend our thanks to the participants, their families, and all participating investigators. This study was funded by Gilead Sciences, Inc. Editing and production assistance were provided by Clint Earnheart of BioScience Communications, New York, NY, funded by Gilead. **Disclosures:** **L. Tao, C. Carter, M. Das:** Gilead; **J. Thorburn, A. Kong, D. Irwin, J. Paone:** Gilead, Aetion.

Scan using the IDWeek Mobile App to view the poster

Presented at IDWeek 2022, 19-23 Oct, Washington, DC