Estimated Background HIV Diagnosis Rates Among People Who Could Benefit From Pre-Exposure Prophylaxis at the Metropolitan Statistical Area Level in the United States, 2012-2019

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Introduction

♦ Identifying areas of high background HIV incidence (bHIV) in people who are not taking pre-exposure prophylaxis (PrEP) is critical, both for PrEP studies using counterfactual study designs, and to facilitate and evaluate effective implementation of HIV prevention interventions in real-world settings

♦ Although the annual number of HIV diagnoses in the US has decreased over the past 10 years, heterogeneity in HIV diagnosis rates across geographies remains[1,2]

♦ Data providing greater granularity in HIV diagnosis rates among people who could benefit from PrEP (PWBP) but are not on PrEP are lacking

Objectives

♦ To estimate bHIV between 2012 and 2019 in PWBP who are not taking PrEP to identify areas of high HIV transmission at the metropolitan statistical area (MSA)[a] level

♦ To compare bHIV in PWBP in PURPOSE 2 study (NCT04925752) sites with those in the DISCOVER study (NCT02842086) to demonstrate how this approach can inform site selection in future PrEP clinical trials and support targeted delivery of PrEP interventions

[a]An MSA consists of ≥ 1 county containing a city of ≥ 50,000 inhabitants or a United States Census Bureau-defined urbanized area and having a total population ≥ 100,000 (75,000 in New England); counties containing the principal concentration of population—the largest city and surrounding densely settled area—are components of the MSA.[3]

Methods

♦ Number of new HIV diagnoses, number of individuals with a PrEP indication, and person-time (PT) on PrEP or after HIV diagnosis obtained from published surveillance data and pharmacy claims data (IQVIA® Longitudinal Prescription and Diagnosis [LRxDx] Data, IQVIA Inc., Durham, NC) were used to calculate estimated bHIV in a multivariate Poisson regression model for PWBP in 108 MSAs and across states between 2012 and 2019[4]

Table 1

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

	Label	Data source
N	No. of HIV diagnoses in each MSA	HIV Surveillance Report, 2019[1]
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[1]
PT	Total PT for individuals with PrEP indications	1. Estimated no. of adults with PrEP indication (MSM, PWID, and HET) by state obtained from Smith et al[5] 2. MSA population obtained from US Census Bureau and proportions obtained for state population 3. Adults who would benefit from PrEP were mapped to MSA
PT_PrEP	On-PrEP PT[a] for individuals with PrEP indications	Obtained from claims data (SHA by 2020) for individuals prescribed with PrEP by MSA
PT_HIV	PT with HIV infection for individuals with PrEP indications	HIV Surveillance Report, 2019[1]

HET = heterosexually active adults; MSM = men who have sex with men; PWID = people who inject drugs; SHA = System of Health Accounts. Modified from Mera R et al[4] (previously calculated rates by MSA).

– [a]On-PrEP PT was calculated among eligible participants: adults (aged ≥ 18 years) without HIV receiving an oral PrEP regimen (emtricitabine/tenofovir disoproxil fumarate or emtricitabine/tenofovir alafenamide)

Results

Figure 1. Estimated bHIV in PWBP by MSA Selected by DISCOVER and PURPOSE 2 Sites: 2012-2019

● **PURPOSE 2 and DISCOVER**
● **PURPOSE 2 only**
● **DISCOVER only**
● **Neither**

Overall bHIV in all MSAs
4.42 — 3.14

CI = confidence interval; PY = person-years.

♦ Overall, bHIV/100 PY among PWBP decreased from 4.42 (95% CI 4.38, 4.47) in 2012 to 3.14 (3.10, 3.17) in 2019

♦ bHIV among PWBP in MSAs with PURPOSE 2 sites were, however, consistently higher (from 4.69 [95% CI 4.56, 4.81] in 2012 to 3.58 [3.49, 3.67] in 2019) vs areas with DISCOVER-only sites (from 3.77 [3.53, 4.01] in 2012 to 2.83 [2.63, 3.03] in 2019)

Study Limitations

♦ Real-world data are limited:
  – bHIV calculations at the MSA level are based on proportional bHIV estimates at the state level and US Census data, and may be subject to variability
  – Subgroup analyses based on gender or age are beyond the capabilities of the mathematical calculations

Figure 2. Estimated bHIV in PWBP by State and MSA Selected by DISCOVER and PURPOSE 2 Sites: 2019

MSA bHIV: ○ 4 ○ 8 ○ 12 ○ 16
State bHIV: 10 / 5 / 0
● PURPOSE 2 and DISCOVER
● PURPOSE 2 only
● DISCOVER only
● Neither

♦ The same approach was used to estimate bHIV at the state level

♦ Although some areas had a lower state-level bHIV, specific localities were identified within the state that had high bHIV among PWBP

♦ For example, in Illinois, state-level bHIV/100 PY was 2.65 (95% CI 2.50, 2.80), but as high as 6.04 (5.67, 6.40) in the MSA with a PURPOSE 2 site

Conclusions

♦ Considerable variation was found in bHIV at the MSA level among PWBP who were not taking PrEP, including a concentration of MSAs in the Southeastern US with high rates of new HIV diagnosis

♦ The methodology used for leveraging existing surveillance data to identify areas of high bHIV with greater precision may provide a valuable approach to support future counterfactual clinical trial designs

♦ Further, these data can help facilitate more targeted delivery of interventions and resources to support PrEP uptake and persistence at MSAs with high bHIV

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