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# Demographic, Clinical Guideline Criteria, Medicaid Expansion and State of Residency: A Multilevel Analysis of PrEP use on a Large US Sample



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**Demographic, Clinical Guideline Criteria, Medicaid Expansion and State of Residency: A Multilevel Analysis of PrEP use on a Large US Sample**

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## Abstract

**Objective:** To explore the association of clinical guideline-related variables, demographics and Medicaid expansion on PrEP uptake in one of the largest US sample of MSM and TGNB people ever analyzed.

**Methods:** We analyzed predictors of current PrEP use using demographic and HIV risk-related variables (level-1), as well as state-level variables (level-2) (i.e, Medicaid Expansion status). We further explored the role state of residence plays in PrEP uptake disparities across the US.

**Results:** We found that the odds of PrEP use were significantly greater in older age, white, cisgender men. Moreover, individuals who reported recent PEP use, a recent sexually transmitted infection diagnosis and recent drug use were significantly more likely to report PrEP use. Lastly, we found **that** the median odds of PrEP use between similar individuals from different states were 1.40 for the ones living in the Medicaid expansion states, compared to those not living in Medicaid expansion states. State of residence did not play a significant role in explaining PrEP disparities overall.

**Conclusion:** Our analysis showed that PrEP use is less common in communities standing to benefit the most from it – young MSM and TGNB of color. However, individuals meeting federal guidelines for PrEP were significantly more likely to use PrEP. Though we found a positive association between living in Medicaid expansion states and PrEP use; that variable, as well as one's state of residency, were not suitable to explain variations in PrEP use in the US.

## Article summary

### Strengths and limitations of this study

1. This study reports on patient-level risk factors of PrEP use in a sample of over 6,000 cisgender men and transgender people who have sex with men across the United States, representing all states.
2. This study uses multi-level modelling analysis to understand the role of state-level predictors alongside individual-level predictors of PrEP use.
3. This study includes the magnitude of clinical guidelines criteria predictors of PrEP use in a US national sample, and the role of Medicaid Expansion on PrEP use.
4. This study was conducted in 2017 and 2018, and the implementation of PrEP across the United States is ever growing and changing.
5. The study uses self-reported cross-sectional data, and causal inference cannot be drawn from the analysis

## Introduction

In 2012, the US Food and Drug Administration (FDA) approved the first daily HIV preexposure prophylactic (PrEP) medication in the form of tenofovir disoproxil fumarate and emtricitabine (TDF/FTC).[1] The efficacy of PrEP is unmatched, providing near-universal (i.e., 99%) protection against HIV with proper adherence.[2-4] Following its approval, the CDC estimated that as many as 1.2 million Americans would benefit from taking the regimen.[6] In 2017, the first official analysis of PrEP data in the United States was published, identifying approximately 80,000 prescriptions filled by unique HIV-negative users by the end of 2016.[7] The number represents one-fifth of all estimated candidates and about one-quarter of all eligible men who have sex with men (MSM)[6] – these numbers haven't been updated since, and there is little indication they have significantly improved .

Recent estimations of PrEP use in the general population suggest that as many as 200,000 individuals have initiated PrEP since the 2012 FDA approval through 2020,[8] a number still lower than expected.[6] To add complexity to the issue, these numbers represent initiations-only and, for PrEP to be effective, users also need to stay engaged and persist. Researchers in the US have reported PrEP discontinuation rates of up to 60% following six-months of initiation.[9-12] An analysis of persistence (i.e., continous use) data using prescription drug records in the US from 2012-2017 found that PrEP persistence was only 14-months on average, and significantly differed by race, age group and insurance status.[13] Understanding this issue is critical for communities at-risk for HIV, especially Black and Latinx MSM communities. Racial disparities in HIV outcomes are alarming in magnitude in the US with a recent report from the CDC estimating that Black MSM have a 1 in 2 chance of lifetime seroconversion, while Latinos have a 1 in 4.[16] There is an immediate need to develop solutions to mitigate both issues - the overall

uptake and persistence in PrEP, and the observed racial disparity in communities standing to benefit the most from it.

A prominent issue impacting PrEP uptake in the US is coverage, both financial coverage in the form of health insurance, and geographic coverage in the form of access to a provider who is competent and accepts your medical coverage. Issues related to having health insurance coverage or being able to afford costs associated with medical care are widely reported throughout the PrEP literature,[17-20] and they relate to an individual inability to pay for costs associated with taking PrEP. However, financial coverage is also managed at the state-level, through state-run Medicaid programs and drug assistance programs (DAP), which grant some access and affordability to PrEP. Patients enrolled in Medicaid have mixed levels of PrEP access, with enrollees with incomes under 150% of the federal poverty level (FPL) receiving PrEP for nearly free due to federal laws limiting costs.[21] In 2010, the affordable care act (ACA) provided states with the ability to expand Medicaid programs to adults aged 65 and younger with incomes 138% of the FPL (about $17,000 a year) and below.[21] Several states have chosen to expand Medicaid, and reports have linked increases in PrEP use to these expansions,[23-25] suggesting that state variation in PrEP use may explain some of the disparities observed in the population at-large. Thus far, the issue of Medicaid expansion has only been explored on the aggregate level, limiting studies to measures of association which only informs on effect size but not on the impact of the variable on the distribution of PrEP across communities. Understanding the impact of Medicaid expansion on a population-level can support a better understanding of the complexities in regional disparities in PrEP use, for example, by exploring the association of Medicaid expansion and racial disparities in PrEP uptake. Furthermore, it seems imperative to

understand whether the state of residency of a particular individual is significant to explain PrEP uptake.

Another limitation of current PrEP use reports in the US is their reliance on pharmacy claims data,[7] or multiple different sources to obtain estimates,[8] limiting one's ability to account for confounding variables, like HIV-related risk factors. They also limit a deeper exploration of complex questions by limiting the study unit to a prescription claim, for example, rather than one individual. Though an objective clinical guidance is in place to assess PrEP eligibility, the units of analysis used thus far have been unable to be used to explore the association of these and PrEP uptake. Using the combined the screening/enrollment data from two similar-in-scope U.S. national cohorts, we created one of the largest national samples of MSM and transgender and gender non-binary (TGNB) individuals who have sex with men. Using a mixed-effect multilevel logistic analysis (MLA) approach, we analyzed predictors of current PrEP use using demographic and HIV risk-related variables (level-1), as well as state-level variables (level-2) (i.e, Medicaid Expansion status).

## Methods

### About the studies

The *Together 5,000* and *UNITE* studies are both U.S. national cohorts longitudinally following sexual and gender minorities at-risk for HIV. Both cohorts are similar in scope, exploring sexual behavior and PrEP uptake. Details on both studies have been described elsewhere.[26, 27] Briefly, each used advertisements on geospatial sexual networking apps to recruit MSM and TGNB people who have sex with men across the U.S. to enroll in longitudinal assessments. During each study's enrollment phase, app-users were presented with an ad for the study. Those interested were directed to a brief screening (i.e., eligibility) survey on their devices

browser. The present analysis utilizes the reconciled screening data from each study dataset (i.e., all variables that were identical across both screening surveys). Both studies enrolled samples in 2017 and 2018.

The sample's composition, which was not designed to be nationally representative, is nonetheless one of the largest national surveys of sexual minorities, consisting of 157,035 responses, with 27% of the responses being from the *Together 5,000* study and the remainder from *UNITE*. Our current analysis, exploring individual- and state-level predictors of current PrEP use, was limited to individuals not living with HIV, and those residing in one of the 50 states, Washington, DC, or Puerto Rico – hereby referred to as "states." Our decision to limit the analytical sample to these states was based on state-level data availability. Our final sample was inclusive of 123,905 (79%) cisgender men and TGNB people who have sex with men.

**Individual-level variables (level-1)**

**Demographics**. Participants were grouped according to their age (under 18 years old, 18-24 years old, 25-29 years old, 30-49 years old, 50+ years old), gender identity (male, female (assigned male at birth), transgender person, something else), and race/ethnicity (Black, Latinx, white, multiracial, other).

**Current PrEP use.** Participants were asked about their PrEP status and current users were identified based on their self-reported status (current use/not).

**Clinical criteria guideline variables.** In both studies, participants were asked about post-exposure prophylaxis (PEP) use in the prior 12 months, drug use in the past three months (i.e., cannabis, cocaine, stimulants, methamphetamine, inhalants, sedatives, GHB, MDMA, hallucinogen), and whether they received a sexually transmitted infection (STI) diagnosis (i.e., syphilis, chlamydia or gonorrhea) in the past 12 months. Based on their answers, we developed

three dichotomous (yes/no) variables indicating their PEP, drug use, and STI experiences within the timeframes noted.

**State-level variables (level-2)**

**Medicaid expansion status.** We created a three-level variable to indicate the state's Medicaid expansion status as of 2020. We categorized as fully expanded, not expanded, or conditionally expanded. Conditional expansion includes any alternative Medicaid expansion model differing from the Affordable Care Act (ACA) format and one state that started expansion in 2020 (i.e., Nebraska).[28]

**Patient and Public Involvement**

Patients were not involved in the development of this study

**Ethics Approval Statement**

Procedures for each of the cohort studies, as well as those to merge de-identified datasets were reviewed and approved by the CUNY Internal Review Board (Protocol number: 2019-0334).

**Analysis**

Our analysis included a descriptive assessment of our sample's demographics and HIV-clinical guideline-related variables, as well as a description of state-level variables. Next, we built a multilevel logistic multivariable mixed-effects regression model predicting current PrEP use (yes/no), using individual- (level-1) and state-level (level-2) predictors. We calculated the fixed effects odds ratio and 95% confidence interval of our fixed-effect variables, as well as the random effect intraclass correlation coefficients (ICC), the median odds ratios (MOR) of each of our models, and the interval odds ratio (IOR-80) of our fixed-effect level-2 variables – random

effect components were calculated via previously reported equations and methods.[29, 30] Our model-building approach was the following, first, we constructed a null model (model 1) in order to calculate the ICC and determine the variance in PrEP use accounted by an individual's state of residency. After, we built a model with level-1 variables (model 2) to explore the fixed effects of individual-level factors on current PrEP use. Finally, we built a full mixed effect multilevel logistic model (model 3) with all variables in both levels. Our analysis was conducted using the PROC GLIMMIX procedure with one random effect at the intercept, a binary distribution and a logit link on SAS 9.4. We used Satterthwaite degrees of freedom. Random effects components were calculated manually.[29, 30] Given our large sample size, we analyzed our intervals of confidence and effect sizes when discussing statistical significance.

**Results**

Our US sample varied demographically with over a quarter being under 24 years old, 13% were over 50 years of age, about 1.7% were transgender people, and 40% were either Black, Latinx or Multiracial. About 8% used PEP in the past 12 months, 60% used drugs in the past 3 months, and 13% had a positive STI results in the past 12 months. In total, 15% of the sample were current PrEP users, and the proportion of PrEP use was significantly greater in older adults (68% v. 51%), white participants (59% v. 53%), people who recently used PEP (23% v 5%), who recently used drugs (74% v. 58%), and those who reported a recent STI diagnosis (29% v. 10%). Table 1 provides further details about our sample individual-level (level-1) variables. States-level characteristics (level-2) also varied greatly with about 54% having fully expanded Medicaid, and 22% having conditionally expanded. We provided this list as an appendix.

**Table 1. Demographics and Clinical Guideline-related Characteristics of Sample (level-1)**

| | *n* | % | *Not currently on PrEP* | | *Current PrEP user* | | | |
|---|---|---|---|---|---|---|---|---|
| **Variables** | 123905 | | 104330 | 84% | 18126 | 15% | | |
| **Age group** | | | | | | | 2711 | <0.0001 |
| 24 & under | 32852 | 26.5% | 30694 | 29% | 2158 | 12% | | |
| 25-29 | 26347 | 21.3% | 22471 | 22% | 3876 | 21% | | |
| 30-49 | 48904 | 39.5% | 39370 | 38% | 9534 | 53% | | |
| 50+ | 15802 | 12.8% | 13042 | 13% | 2760 | 15% | | |
| **Gender identity (*n*= 123453)** | | | | | | | 69.81 | <0.0001 |
| Male | 105514 | 85.2% | 102827 | 99% | 18034 | 99% | | |
| Female (Trans woman) | 348 | 0.3% | 367 | 0.4% | 21 | 0.1% | | |
| Transgender Person | 1706 | 1.4% | 1759 | 2% | 200 | 1.1% | | |
| Something else | 215 | 0.2% | 225 | 0.2% | 20 | 0.1% | | |
| **Race** | | | | | | | 280.9 | <0.0001 |
| Black | 14237 | 11.5% | 12524 | 12% | 1713 | 9% | | |
| Latinx | 23999 | 19.4% | 20894 | 20% | 3105 | 17% | | |
| White | 65941 | 53.2% | 55210 | 53% | 10731 | 59% | | |
| Multiracial | 11845 | 9.6% | 10240 | 10% | 1605 | 9% | | |
| Other | 7883 | 6.4% | 6709 | 6% | 1174 | 6% | | |
| **PEP in past 12 months (*n*= 123552)** | | | | | | | 6616 | <0.0001 |
| Yes | 9713 | 7.8% | 5542 | 5% | 4171 | 23% | | |
| No | 113839 | 91.9% | 99717 | 96% | 14122 | 78% | | |
| **Drug use in past 3 months (*n*= 122456)** | | | | | | | 1615 | <0.0001 |
| Yes | 73837 | 59.6% | 60464 | 58% | 13373 | 74% | | |
| No | 48619 | 39.2% | 43866 | 42% | 4753 | 26% | | |
| **STI diagnosis in past 12 months (*n* = 122734)** | | | | | | | 5296 | <0.0001 |
| Yes | 15605 | 12.6% | 10280 | 10% | 5325 | 29% | | |
| No | 107129 | 86.5% | 94292 | 90% | 12837 | 71% | | |

Our regression model results are presented on Table 2, we report here the findings of our model 3. The odds of current PrEP use for all age groups were significantly higher when compared to people 24 years old and younger, with individuals 25-29 having 2.2 greater odds (aOR = 2.21, 95% CI: 2.15 - 2.28), 30-39 having 3.2 greater odds (aOR = 3.20, 95% CI: 3.12 - 3.29) and those 50 years old and older having 2.9 greater odds (aOR = 2.91, 95% CI: 2.82 - 3.01) of current PrEP use. All races had significantly lower odds current PrEP use when compared to white participants, with Black participants having 27% lower odds (aOR = 0.73, 95% CI: 0.71 – 0.76), 26% lower for Latinx (aOR = 0.74, 95% CI: 0.73 – 0.76), and 21% lower for multiracial individuals (aOR = 0.79, 95% CI: 0.76 – 0.81). Those who identified as female (aOR = 0.44, 95% CI: 0.35 – 0.56) or as a transgender person (aOR = 0.71, 95% CI: 0.66 – 0.77) had 66% and 29% significantly lower odds of being current PrEP users than those identifying as male. Individuals who reported PEP use in the past 12 months (aOR = 3.94, 95% CI: 3.85 – 4.04), drug use in the past 3 months (aOR = 1.73, 95% CI: 1.70 – 1.76) or were diagnosed with an STI in the previous 12 months (aOR = 3.34, 95% CI: 3.27 – 3.42) had significantly greater odds of being current PrEP users. On the state level, individuals living in states with no Medicaid expansion had 31% lower odds of being current PrEP users (aOR = 0.69, 95% CI: 0.54 – 0.88), and those living in conditional Medicaid expansion state had 27% lower odds of being current PrEP users than individuals living in states with full expansion (aOR = 0.73, 95% CI: 0.56 – 0.95). For the states with no expansion (aOR= 0.69) the IOR-80 was between 0.37 – 1.30, and for those conditional expansion (aOR=0.73) it was between 0.39 – 1.38. The median odds of PrEP use between individuals with identical individual characteristics but from different states were 1.40 for the ones living in the Medicaid expansion states, compared to those not living in Medicaid expansion states. Overall, the state of residency accounted for about 6% in the variance of PrEP

use overall, and after accounting for fixed-effects of individuals and Medicaid expansion, it accounts for only 4% of the remaining variance.

Table 2. Multilevel mixed-effects regression predicting current PrEP use

| Fixed-Effects Variables | Model 1 (Null) | Model 2 | 95% CI | Model 3 | 95% CI |
|---|---|---|---|---|---|
| **Demographics** | | | | | |
| Age group (24 & Under) | | | | | |
| 25-29 | | 2.21 | (2.09, 2.35) | 2.21 | (2.15, 2.28) |
| 30-49 | | 3.20 | (3.04, 3.37) | 3.19 | (3.04, 3.37) |
| 50+ | | 2.91 | (2.73, 3.1) | 2.9 | (2.82, 3.01) |
| Race/Ethnicity (White) | | | | | |
| Black | | 0.73 | (0.69, 0.78) | 0.73 | (0.71, 0.76) |
| Latinx | | 0.75 | (0.71, 0.78) | 0.74 | (0.73, 0.76) |
| Multiracial | | 0.79 | (0.74, 0.84) | 0.79 | (0.76, 0.81) |
| Other | | 0.82 | (0.76, 0.88) | 0.82 | (0.79, 0.85) |
| Gender Identity (Male) | | | | | |
| Female (Trans woman) | | 0.44 | (0.28, 0.7) | 0.44 | (0.35, 0.56) |
| Something else | | 0.44 | (0.26, 0.73) | 0.42 | (0.33, 0.56) |
| Transgender person | | 0.71 | (0.61, 0.84) | 0.71 | (0.66, 0.77) |
| **Risk Variables** | | | | | |
| PEP use in past 12 months (ref: No) | | 3.94 | (3.76, 4.14) | 3.94 | (3.85, 4.04) |
| STI diagnosis in past 12 months (ref: No) | | 3.34 | (3.21, 3.48) | 3.34 | (3.27, 3.42) |
| Drug use in past 3 months (ref: No) | | 1.73 | (1.67, 1.8) | 1.73 | (1.7, 1.76) |
| **State-level Variable** | | | | | |
| Medicaid Expansion status | | | | | |
| No Expansion | | | | 0.69 | (0.54, 0.88) |
| Conditional Expansion | | | | 0.73 | (0.56, 0.95) |
| | | | | | |
| **Random Effect Components** | | | | | |
| Interval Odds Ratio (IOR-80) | | | | | |
| Medicaid Expansion status | | | | | |
| No Expansion | | | | (0.37 - 1.30) | |
| Conditional Expansion | | | | (0.39 - 1.38) | |
| Intercept Variance | 0.21 | 0.15 | | 0.12 | |
| Interclass Correlation Coefficient (ICC) | 0.06 | 0.04 | | 0.04 | |
| Median Odds Ratio (MOR) | 1.54 | 1.45 | | 1.40 | |

## Discussion

In this US national survey with over 120,000 responses, we found that older age, white race, cisgender male identity, and meeting objective criteria per current guidelines were positive predictors of current PrEP use. Previous epidemiologic surveillance reports exploring PrEP uptake in the US using prescription drug data have found similar demographic outcomes.[7] Furthermore, though a state's Medicaid expansion status significantly predicted the likelihood an individual is currently taking PrEP, these effects were weak across states and did not explain variation in PrEP use in our analysis. Our study represents one of the largest U.S. national samples to explore multilevel predictors of current PrEP use, using individual and risk-related variables, and state-level variables.

Our findings affirmed the demographic disconnect between HIV and PrEP epidemiology in the US. While HIV incidence is disproportionally distributed in Black and Brown MSM and TGNB youth communities,[15] PrEP was most commonly used by older white cisgender men.[7] These effects persisted without change in effect size after controlling for Medicaid expansion. This contrast cannot be overlooked for the racial inequities in HIV outcomes in the US are historic and enduring. Aside from denying protection to communities who stand to benefit the most from PrEP, demographic inequities in access to HIV prevention interventions can significantly increase the magnitude of this racial inequity. Nevertheless, PrEP use was much more common among those who would have otherwise benefited from its protection most, such as those who had taken PEP, been recently treated for an STI, or reported drug use. This scenario presents a critical consideration to the successes, and possible limitations, of current PrEP guidelines in the US.[31] The guidelines, set forth by the CDC, have a strong focus on objective risk (i.e., recent bacterial STI, history of inconsistent or no condom use, sharing injection

equipment).[32] To that extent, our results demonstrated that guidelines can be successful in translating theory to practice: participants who reported any recent guideline criteria had as much as 3 times the odds of PrEP use than otherwise. However, the persistent demographic disconnect between *who gets HIV* and *who takes PrEP* requires discussing the limitations of recommending PrEP solely based on objective risk. Researchers in the US have previously speculated about the role an extension of guidelines would have in impacting PrEP uptake.[33] Using the premise of determining "good fit" of PrEP for a given patient's goals, instead of "eligibility" for PrEP they suggest PrEP may be used to reduce HIV-related anxiety during sex and increase inter-partner intimacy.[33] The CDC and other agencies overseeing clinical guidelines should immediately consider heeding such advice. Australia, for example, is considered a model-jurisdiction for PrEP implementation, with several reports associating community PrEP uptake to substantial declines in HIV incidence.[34, 35] The guidelines for offering PrEP in Australia are much broader and comprehensive than those of the CDC, including reasons for offering PrEP such as "w*hen a person plans to travel during which time they anticipate that they will be having condomless sex with casual partners,"* and *"when a person reports being so anxious about HIV infection that it may prevent them from having regular HIV testing, or engaging in any form of anal sex."*[36] A more inclusive set of clinical recommendations may have a much greater impact on PrEP uptake than traditional community outreach strategies; agencies and organizations with jurisdiction over these guidelines should consider doing so.

In exploring the role of a state's Medicaid expansion in predicting current PrEP use, we found mixed results. The median OR (MOR = 1.40) suggests that at least 50% of the odds of PrEP use between multiple pairs of identical individuals living in different states are 40% greater or higher, on average, for individuals living in states with Medicaid expansion. This finding is in

line with previously reported effect estimates of PrEP use in relation to Medicaid expansion.[23-25] However, our final model ICC indicated that the state of residency of a given participant accounted for only 4% of the variance of PrEP use in our analysis, and the IOR-80 for our Medicaid expansion variables measure of association (i.e., odds ratio) included the null value - 1. In MLA, the inclusion of the null value on the IOR-80 indicates that the variable was not relevant to understanding the state-level variation in an individual predisposition to use PrEP.[30] Furthermore, the positive MOR observed in our analysis must be understood in light of the small ICC presented in our model, though there may have been strong differences between two individuals from different states tendency to use PrEP, there was not enough variation between states for Medicaid expansion to impact PrEP use. In MLA, the estimate of the ICC is highly dependent on the area-level variable variance (e.g, state-level),[29] which suggests that perhaps a smaller area-level analysis, like zip code or county-level, may be better suited to understand the impact of Medicaid expansion on PrEP uptake. Previously reported regional disparities in PrEP use seems to suggest this as well. For example, though Medicaid expansion has been associated with increased PrEP use, a majority of states have been found to have less than one PrEP-providing clinic per 100,000 people.[37] A narrower area of analysis, using MLA, may be advisable to explore how much geographic region explains disparities in PrEP use, and to explore the question about Medicaid expansion more effectively.

**Limitations:**

Our findings must be understood in light of several limitations. First, our data were collected via self-report and may be subjected to social desirability bias. Several demographic variables that could further influence PrEP use were not measured such as health insurance status, income, and other social determinants of health. In our analysis we did not control from

insurance type, for example, rather we explored the population-level effect of living in a Medicaid expansion state. It may be relevant to oversample patients receiving Medicaid and control for insurance information in future analysis.

Lastly, the parent studies of our dataset recruited participants using similar strategies that may have resulted in the same participants responding to both surveys. We note that we treated each individual response as independent. Although we cannot ascertain precisely the amount of overlap of participants across surveys, the studies' recruitment strategies utilized multiple applications platforms, each of which has millions of daily users. Therefore, the relative pool of available participants is several times the magnitude of those who actually took our surveys.

**Conclusion:**

Our analysis showed that PrEP use is less common in communities standing to benefit the most from it – young MSM and TGNB of color. However, individuals meeting federal guidelines for PrEP were significantly more likely to use PrEP. Updating guidelines may provide a strong avenue to improve uptake and reduce racial disparities. Additionally, individuals living in states where Medicaid was expanded were similarly more likely to use PrEP, however we did not find that this variable was significant to explain state-level differences in PrEP use.

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**Authorship contribution statement**

PC, and CG conceptualized the paper, with PC performing the main analysis - both reviewed multiples drafts and contributed to each section of the paper. CM performed the initial bivariate analysis, extracted the data, and provided valuable data analysis and variable development feedback. SJ Developed the dataset, conceptualized the variables, and reviewed multiple drafts of the manuscript. JR provided key methodology feedback, and analytical guidance. Additionally, JR helped with the interpretation of results.

**Data Sharing Statement**

No additional data available

**Author(s') disclosure statement(s)**

All authors report no conflict of interest.

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**Appendix. State-level (level-2) Medicaid Expansion Status**

| State | Sample population | Medicaid Expansion Status 2020 |
|---|---|---|
| Alabama | 1,461 | Not expanded |
| Alaska | 204 | Fully expanded |
| Arizona | 2,791 | Conditionally Expanded |
| Arkansas | 830 | Conditionally Expanded |
| California | 16,723 | Fully expanded |
| Colorado | 2,413 | Fully expanded |
| Connecticut | 1,137 | Fully expanded |
| Delaware | 340 | Fully expanded |
| District of Columbia | 1,072 | Fully expanded |
| Florida | 9,654 | Not expanded |
| Georgia | 4,311 | Not expanded |
| Hawaii | 511 | Fully expanded |
| Idaho | 497 | Fully expanded |
| Illinois | 5,079 | Fully expanded |
| Indiana | 2,098 | Conditionally Expanded |
| Iowa | 912 | Conditionally Expanded |
| Kansas | 776 | Not expanded |
| Kentucky | 1,432 | Conditionally Expanded |
| Louisiana | 1,600 | Fully expanded |
| Maine | 371 | Fully expanded |
| Maryland | 1,944 | Fully expanded |
| Massachusetts | 2,816 | Fully expanded |
| Michigan | 2,745 | Conditionally Expanded |
| Minnesota | 1,739 | Fully expanded |
| Mississippi | 744 | Not expanded |
| Missouri | 1,807 | Not expanded |
| Montana | 308 | Fully expanded |
| Nebraska | 594 | Conditionally Expanded |
| Nevada | 1,412 | Fully expanded |
| New Hampshire | 413 | Conditionally Expanded |
| New Jersey | 2,741 | Fully expanded |
| New Mexico | 822 | Conditionally Expanded |
| New York | 11,010 | Fully expanded |
| North Carolina | 3,367 | Not expanded |
| North Dakota | 199 | Fully expanded |
| Ohio | 3,652 | Conditionally Expanded |
| Oklahoma | 1,163 | Not expanded |
| Oregon | 1,659 | Fully expanded |
| Pennsylvania | 4,192 | Fully expanded |
| Puerto Rico | 1,119 | Fully expanded |
| Rhode Island | 432 | Fully expanded |
| South Carolina | 1,504 | Not expanded |

| | | |
|---|---|---|
| South Dakota | 192 | Not expanded |
| Tennessee | 2,005 | Not expanded |
| Texas | 11,750 | Not expanded |
| Utah | 1,285 | Conditionally Expanded |
| Vermont | 193 | Fully expanded |
| Virginia | 2,757 | Fully expanded |
| Washington | 2,812 | Fully expanded |
| West Virginia | 511 | Fully expanded |
| Wisconsin | 1,641 | Not expanded |
| Wyoming | 165 | Not expanded |

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# Demographic, Clinical Guideline Criteria, Medicaid Expansion and State of Residency: A Multilevel Analysis of PrEP use on a Large US Sample

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**Demographic, Clinical Guideline Criteria, Medicaid Expansion and State of Residency: A Multilevel Analysis of PrEP use on a Large US Sample**

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## Abstract

**Objective:** To explore the association of clinical guideline-related variables, demographics and Medicaid expansion on PrEP uptake in one of the largest US sample of MSM and TGNB people ever analyzed.

**Methods:** We analyzed predictors of current PrEP use using demographic and HIV risk-related variables (level-1), as well as state-level variables (level-2) (i.e, Medicaid Expansion status). We further explored the role state of residence plays in PrEP uptake disparities across the US.

**Results:** We found that the odds of PrEP use were significantly greater in older age, white, cisgender men. Moreover, individuals who reported recent PEP use, a recent sexually transmitted infection diagnosis and recent drug use were significantly more likely to report PrEP use. Lastly, we found **that** the median odds of PrEP use between similar individuals from different states were 1.40 for the ones living in the Medicaid expansion states, compared to those not living in Medicaid expansion states. State of residence did not play a significant role in explaining PrEP disparities overall.

**Conclusion:** Our analysis showed that PrEP use is less common in communities standing to benefit the most from it – young MSM and TGNB of color. However, individuals meeting federal guidelines for PrEP were significantly more likely to use PrEP. Though we found a positive association between living in Medicaid expansion states and PrEP use; that variable, as well as one's state of residency, were not suitable to explain variations in PrEP use in the US.

## Article summary

### Strengths and limitations of this study

1. This study reports on patient-level risk factors of PrEP use in a sample of over 6,000 cisgender men and transgender people who have sex with men across the United States, representing all states.
2. This study uses multi-level modelling analysis to understand the role of state-level predictors alongside individual-level predictors of PrEP use.
3. This study includes the magnitude of clinical guidelines criteria predictors of PrEP use in a US national sample, and the role of Medicaid Expansion on PrEP use.
4. This study was conducted in 2017 and 2018, and the implementation of PrEP across the United States is ever growing and changing.
5. The study uses self-reported cross-sectional data, and causal inference cannot be drawn from the analysis

## Introduction

In 2012, the US Food and Drug Administration (FDA) approved the first daily HIV preexposure prophylactic (PrEP) medication in the form of tenofovir disoproxil fumarate and emtricitabine (TDF/FTC).[1] Following its approval, the CDC estimated that as many as 1.2 million Americans would benefit from taking the regimen.[2] By 2017, only approximately 80,000 prescriptions were filled by unique HIV-negative users.[3]

Recent estimations of PrEP use in the general population suggest that as many as 200,000 individuals have initiated or persisted in PrEP year-over-year since the 2012 FDA approval through 2020,[4] a number still lower than expected.[2] Researchers in the US have reported PrEP discontinuation rates of up to 60% following six-months of initiation.[5-8] An analysis of persistence (i.e., continous use) data using prescription drug records in the US from 2012-2017 found that PrEP persistence was only 14-months on average, and significantly differed by race, age group and insurance status.[9] Understanding this issue is critical for communities at-risk for HIV, especially Black and Latinx MSM communities. [10] A limitation of current PrEP use reports in the US is their reliance on pharmacy claims data,[3] or multiple different sources to obtain estimates,[4] limiting one's ability to account for confounding variables, like HIV-related risk factors. They also limit a deeper exploration of complex questions by limiting the study unit to a prescription claim, for example, rather than one individual. There is an immediate need to develop solutions to mitigate both issues - the overall uptake and persistence in PrEP, and the observed racial disparity in communities standing to benefit the most from it.

A prominent issue impacting PrEP uptake in the US is coverage, both financial coverage in the form of health insurance, and geographic coverage in the form of access to a provider who is competent and accepts your medical coverage. Issues related to having health insurance

coverage or being able to afford costs associated with medical care are widely reported throughout the PrEP literature,[11-14] and they relate to an individual inability to pay for costs associated with taking PrEP. However, financial coverage is also managed at the state-level, through state-run Medicaid programs and drug assistance programs (DAP), which grant some access and affordability to PrEP. Patients enrolled in Medicaid have mixed levels of PrEP access, with enrollees with incomes under 150% of the federal poverty level (FPL) receiving PrEP for nearly free due to federal laws limiting costs.[15] In 2010, the affordable care act (ACA) provided states with the ability to expand Medicaid programs to adults aged 65 and younger with incomes 138% of the FPL (about $17,000 a year) and below.[15] Several states have chosen to expand Medicaid, and reports have linked increases in PrEP use to these expansions,[16-18] suggesting that state variation in PrEP use may explain some of the disparities observed in the population at-large. Thus far, the issue of Medicaid expansion has only been explored on the aggregate level, limiting studies to measures of association which only informs on effect size but not on the impact of the variable on the distribution of PrEP across communities. Understanding the impact of Medicaid expansion on a population-level can support a better understanding of the complexities in regional disparities in PrEP use, for example, by exploring the association of Medicaid expansion and racial disparities in PrEP uptake. Furthermore, it seems imperative to understand whether the state of residency of a particular individual is significant to explain PrEP uptake.

Using the combined the screening/enrollment data from two similar-in-scope U.S. national cohorts, we created one of the largest national samples of MSM and transgender and gender non-binary (TGNB) individuals who have sex with men. Using a mixed-effect multilevel logistic analysis (MLA) approach, we analyzed predictors of current PrEP use using

demographic and HIV risk-related variables (level-1), as well as state-level variables (level-2) (i.e, Medicaid Expansion status).

## Methods

### About the studies

The *Together 5,000* and *UNITE* studies are both U.S. national cohorts longitudinally following sexual and gender minorities at-risk for HIV. Both cohorts are similar in scope, exploring sexual behavior and PrEP uptake. Details on both studies have been described elsewhere.[19,20] Briefly, each used advertisements on geospatial sexual networking apps to recruit MSM and TGNB people who have sex with men across the U.S. to enroll in longitudinal assessments. During each study's enrollment phase, app-users were presented with an ad for the study. Those interested were directed to a brief screening (i.e., eligibility) survey on their devices browser. The present analysis utilizes the reconciled screening data from each study dataset (i.e., all variables that were identical across both screening surveys). Both studies enrolled samples in 2017 and 2018.

The sample's composition, which was not designed to be nationally representative, is nonetheless one of the largest national surveys of sexual minorities, consisting of 157,035 responses, with 27% of the responses being from the *Together 5,000* study and the remainder from *UNITE*. Our current analysis, exploring individual- and state-level predictors of current PrEP use, was limited to individuals not living with HIV, and those residing in one of the 50 states, Washington, DC, or Puerto Rico – hereby referred to as "states." Our decision to limit the analytical sample to these states was based on state-level data availability. Our final sample was inclusive of 123,905 (79%) cisgender men and TGNB people who have sex with men.

### Individual-level variables (level-1)

**Demographics**. Participants were grouped according to their age (under 24 years old, 25-29 years old, 30-49 years old, 50+ years old), gender identity (male, female (assigned male at birth), transgender person, something else), and race/ethnicity (Black, Latinx, white, multiracial, other).

**Current PrEP use.** Participants were asked about their PrEP status and current users were identified based on their self-reported status (current use/not).

**Clinical criteria guideline variables.** In both studies, participants were asked about post-exposure prophylaxis (PEP) use in the prior 12 months, drug use in the past three months (i.e., cannabis, cocaine, stimulants, methamphetamine, inhalants, sedatives, GHB, MDMA, hallucinogen), and whether they received a sexually transmitted infection (STI) diagnosis (i.e., syphilis, chlamydia or gonorrhea) in the past 12 months. Based on their answers, we developed three dichotomous (yes/no) variables indicating their PEP, drug use, and STI experiences within the timeframes noted.

**State-level variables (level-2)**

**Medicaid expansion status.** We created a three-level variable to indicate the state's Medicaid expansion status as of 2020. We categorized as fully expanded, not expanded, or conditionally expanded. Conditional expansion includes any alternative Medicaid expansion model differing from the Affordable Care Act (ACA) format and one state that started expansion in 2020 (i.e., Nebraska).[21]

**Patient and Public Involvement**

Patients were not involved in the development of this study

**Ethics Approval Statement**

Procedures for each of the cohort studies, as well as those to merge de-identified datasets were reviewed and approved by the CUNY Internal Review Board (Protocol number: 2019-0334).

**Analysis**

Our analysis included a descriptive assessment of our sample's demographics and HIV-clinical guideline-related variables, as well as a description of state-level variables. Next, we built a multilevel logistic multivariable mixed-effects regression model predicting current PrEP use (yes/no), using individual- (level-1) and state-level (level-2) predictors. We calculated the fixed effects odds ratio and 95% confidence interval of our fixed-effect variables, as well as the random effect intraclass correlation coefficients (ICC), the median odds ratios (MOR) of each of our models, and the interval odds ratio (IOR-80) of our fixed-effect level-2 variables – random effect components were calculated via previously reported equations and methods.[22,23] Our model-building approach was the following, first, we constructed a null model (model 1) in order to calculate the ICC and determine the variance in PrEP use accounted by an individual's state of residency. After, we built a model with level-1 variables (model 2) to explore the fixed effects of individual-level factors on current PrEP use. Finally, we built a full mixed effect multilevel logistic model (model 3) with all variables in both levels. Our analysis was conducted using the PROC GLIMMIX procedure with one random effect at the intercept, a binary distribution and a logit link on SAS 9.4. We used Satterthwaite degrees of freedom. Random effects components were calculated manually.[22,23] Given our large sample size, we analyzed our intervals of confidence and effect sizes when discussing statistical significance.

**Results**

Our US sample varied demographically with over a quarter being under 24 years old, 13% were over 50 years of age, about 1.7% were transgender people, and 40% were either Black, Latinx or Multiracial. About 8% used PEP in the past 12 months, 60% used drugs in the past 3 months, and 13% had a positive STI results in the past 12 months. In total, 15% of the sample were current PrEP users, and the proportion of PrEP use was significantly greater in adults older than 29 y.o. (68% v. 51%), white participants (59% v. 53%), people who recently used PEP (23% v 5%), who recently used drugs (74% v. 58%), and those who reported a recent STI diagnosis (29% v. 10%). Table 1 provides further details about our sample individual-level (level-1) variables. States-level characteristics (level-2) also varied greatly with about 54% having fully expanded Medicaid, and 22% having conditionally expanded. We provided this list as an appendix.

**Table 1. Demographics and Clinical Guideline-related Characteristics of National Sample of Cisgender Men and Transgender People who have Sex with Men (level-1)**

| | *n* | % | *Not currently on PrEP* | | *Current PrEP user* | | | |
|---|---|---|---|---|---|---|---|---|
| **Variables** | 123905 | | 104330 | 84% | 18126 | 15% | | |
| **Age group** | | | | | | | 2711 | <0.0001 |
| 24 & under | 32852 | 26.5% | 30694 | 29% | 2158 | 12% | | |
| 25-29 | 26347 | 21.3% | 22471 | 22% | 3876 | 21% | | |
| 30-49 | 48904 | 39.5% | 39370 | 38% | 9534 | 53% | | |
| 50+ | 15802 | 12.8% | 13042 | 13% | 2760 | 15% | | |
| **Gender identity (*n*= 123453)** | | | | | | | 69.81 | <0.0001 |
| Male | 120861 | 97.9% | 102827 | 99% | 18034 | 99% | | |
| Female (Trans woman) | 388 | 0.3% | 367 | 0.4% | 21 | 0.1% | | |
| Transgender Person | 1959 | 1.6% | 1759 | 2% | 200 | 1.1% | | |
| Something else | 245 | 0.2% | 225 | 0.2% | 20 | 0.1% | | |
| **Race** | | | | | | | 280.9 | <0.0001 |
| Black | 14237 | 11.5% | 12524 | 12% | 1713 | 9% | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Latinx | 23999 | 19.4% | 20894 | 20% | 3105 | 17% | | |
| White | 65941 | 53.2% | 55210 | 53% | 10731 | 59% | | |
| Multiracial | 11845 | 9.6% | 10240 | 10% | 1605 | 9% | | |
| Other | 7883 | 6.4% | 6709 | 6% | 1174 | 6% | | |
| **PEP in past 12 months (*n*= 123552)** | | | | | | | 6616 | <0.0001 |
| Yes | 9713 | 7.8% | 5542 | 5% | 4171 | 23% | | |
| No | 113839 | 91.9% | 99717 | 96% | 14122 | 78% | | |
| **Drug use in past 3 months (*n*= 122456)** | | | | | | | 1615 | <0.0001 |
| Yes | 73837 | 59.6% | 60464 | 58% | 13373 | 74% | | |
| No | 48619 | 39.2% | 43866 | 42% | 4753 | 26% | | |
| **STI diagnosis in past 12 months (*n* = 122734)** | | | | | | | 5296 | <0.0001 |
| Yes | 15605 | 12.6% | 10280 | 10% | 5325 | 29% | | |
| No | 107129 | 86.5% | 94292 | 90% | 12837 | 71% | | |

Our regression model results are presented on Table 2, we report here the findings of our model 3. The odds of current PrEP use for all age groups were significantly higher when compared to people 24 years old and younger, with individuals 25-29 having 2.2 greater odds (aOR = 2.21, 95% CI: 2.15 - 2.28), 30-39 having 3.2 greater odds (aOR = 3.20, 95% CI: 3.12 - 3.29) and those 50 years old and older having 2.9 greater odds (aOR = 2.91, 95% CI: 2.82 - 3.01) of current PrEP use. All races had significantly lower odds current PrEP use when compared to white participants, with Black participants having 27% lower odds (aOR = 0.73, 95% CI: 0.71 – 0.76), 26% lower for Latinx (aOR = 0.74, 95% CI: 0.73 – 0.76), and 21% lower for multiracial individuals (aOR = 0.79, 95% CI: 0.76 – 0.81). Those who identified as female (aOR = 0.44, 95% CI: 0.35 – 0.56) or as a transgender person (aOR = 0.71, 95% CI: 0.66 – 0.77) had 66% and 29% significantly lower odds of being current PrEP users than those identifying as male. Individuals who reported PEP use in the past 12 months (aOR = 3.94, 95% CI: 3.85 – 4.04), drug use in the past 3 months (aOR = 1.73, 95% CI: 1.70 – 1.76) or were diagnosed with an STI in the previous 12 months (aOR = 3.34, 95% CI: 3.27 – 3.42) had significantly greater odds of being current PrEP users. On the state level, individuals living in states with no Medicaid expansion had 31% lower odds of being current PrEP users (aOR = 0.69, 95% CI: 0.54 – 0.88), and those living in conditional Medicaid expansion state had 27% lower odds of being current PrEP users than individuals living in states with full expansion (aOR = 0.73, 95% CI: 0.56 – 0.95). For the states with no expansion (aOR= 0.69) the IOR-80 was between 0.37 – 1.30, and for those conditional expansion (aOR=0.73) it was between 0.39 – 1.38. The median odds of PrEP use between individuals with identical individual characteristics but from different states were 1.40 for the ones living in the Medicaid expansion states, compared to those not living in Medicaid expansion states. Overall, the state of residency accounted for about 6% in the variance of PrEP

use overall, and after accounting for fixed-effects of individuals and Medicaid expansion, it accounts for only 4% of the remaining variance.

**Table 2. Multilevel Mixed-Effects Regression Models Predicting Current PrEP Use**

| Fixed-Effects Variables | Model 1 (Null) | Model 2 | 95% CI | Model 3 | 95% CI |
|---|---|---|---|---|---|
| **Demographics** | | | | | |
| Age group (24 & Under) | | | | | |
| 25-29 | | 2.21 | (2.09, 2.35) | 2.21 | (2.15, 2.28) |
| 30-49 | | 3.20 | (3.04, 3.37) | 3.19 | (3.04, 3.37) |
| 50+ | | 2.91 | (2.73, 3.1) | 2.9 | (2.82, 3.01) |
| Race/Ethnicity (White) | | | | | |
| Black | | 0.73 | (0.69, 0.78) | 0.73 | (0.71, 0.76) |
| Latinx | | 0.75 | (0.71, 0.78) | 0.74 | (0.73, 0.76) |
| Multiracial | | 0.79 | (0.74, 0.84) | 0.79 | (0.76, 0.81) |
| Other | | 0.82 | (0.76, 0.88) | 0.82 | (0.79, 0.85) |
| Gender Identity (Male) | | | | | |
| Female (Trans woman) | | 0.44 | (0.28, 0.7) | 0.44 | (0.35, 0.56) |
| Something else | | 0.44 | (0.26, 0.73) | 0.42 | (0.33, 0.56) |
| Transgender person | | 0.71 | (0.61, 0.84) | 0.71 | (0.66, 0.77) |
| **Risk Variables** | | | | | |
| PEP use in past 12 months (ref: No) | | 3.94 | (3.76, 4.14) | 3.94 | (3.85, 4.04) |
| STI diagnosis in past 12 months (ref: No) | | 3.34 | (3.21, 3.48) | 3.34 | (3.27, 3.42) |
| Drug use in past 3 months (ref: No) | | 1.73 | (1.67, 1.8) | 1.73 | (1.7, 1.76) |
| **State-level Variable** | | | | | |
| Medicaid Expansion status | | | | | |
| No Expansion | | | | 0.69 | (0.54, 0.88) |
| Conditional Expansion | | | | 0.73 | (0.56, 0.95) |
| | | | | | |
| **Random Effect Components** | | | | | |
| Interval Odds Ratio (IOR-80) | | | | | |
| Medicaid Expansion status | | | | | |
| No Expansion | | | | (0.37 - 1.30) | |
| Conditional Expansion | | | | (0.39 - 1.38) | |
| Intercept Variance | 0.21 | 0.15 | | 0.12 | |
| Interclass Correlation Coefficient (ICC) | 0.06 | 0.04 | | 0.04 | |
| Median Odds Ratio (MOR) | 1.54 | 1.45 | | 1.40 | |

## Discussion

In this US national survey with over 120,000 responses, we found that older age, white race, cisgender male identity, and meeting objective criteria per current guidelines were positive predictors of current PrEP use. Previous epidemiologic surveillance reports exploring PrEP uptake in the US using prescription drug data have found similar demographic outcomes.[3] Furthermore, though a state's Medicaid expansion status significantly predicted the likelihood an individual is currently taking PrEP, these effects were weak across states and did not explain variation in PrEP use in our analysis. Our study represents one of the largest U.S. national samples to explore multilevel predictors of current PrEP use, using individual and risk-related variables, and state-level variables.

Our findings affirmed the demographic disconnect between HIV and PrEP epidemiology in the US. While HIV incidence is disproportionally distributed in Black and Brown MSM and TGNB youth communities,[24] PrEP was most commonly used by older white cisgender men.[3] These effects persisted without change in effect size after controlling for Medicaid expansion. This contrast cannot be overlooked for the racial inequities in HIV outcomes in the US are historic and enduring. Aside from denying protection to communities who stand to benefit the most from PrEP, demographic inequities in access to HIV prevention interventions can significantly increase the magnitude of this racial inequity. Nevertheless, PrEP use was much more common among those who would have otherwise benefited from its protection most, such as those who had taken PEP, been recently treated for an STI, or reported drug use. This scenario presents a critical consideration to the successes, and possible limitations, of current PrEP guidelines in the US.[25] The guidelines, set forth by the CDC, have a strong focus on objective risk (i.e., recent bacterial STI, history of inconsistent or no condom use, sharing injection

equipment).[26] To that extent, our results demonstrated that guidelines can be successful in translating theory to practice: participants who reported any recent guideline criteria had as much as 3 times the odds of PrEP use than otherwise. However, the persistent demographic disconnect between *who gets HIV* and *who takes PrEP* requires discussing the limitations of recommending PrEP solely based on objective risk. Researchers in the US have previously speculated about the role an extension of guidelines would have in impacting PrEP uptake.[27] Using the premise of determining "good fit" of PrEP for a given patient's goals, instead of "eligibility" for PrEP they suggest PrEP may be used to reduce HIV-related anxiety during sex and increase inter-partner intimacy.[27] The CDC and other agencies overseeing clinical guidelines should immediately consider heeding such advice. Australia, for example, is considered a model-jurisdiction for PrEP implementation, with several reports associating community PrEP uptake to substantial declines in HIV incidence.[28,29] The guidelines for offering PrEP in Australia are much broader and comprehensive than those of the CDC, including reasons for offering PrEP such as "w*hen a person plans to travel during which time they anticipate that they will be having condomless sex with casual partners,"* and *"when a person reports being so anxious about HIV infection that it may prevent them from having regular HIV testing, or engaging in any form of anal sex."*[30] A more inclusive set of clinical recommendations may have a much greater impact on PrEP uptake than traditional community outreach strategies; agencies and organizations with jurisdiction over these guidelines should consider doing so.

In exploring the role of a state's Medicaid expansion in predicting current PrEP use, we found mixed results. The median OR (MOR = 1.40) suggests that at least 50% of the odds of PrEP use between multiple pairs of identical individuals living in different states are 40% greater or higher, on average, for individuals living in states with Medicaid expansion. This finding is in

line with previously reported effect estimates of PrEP use in relation to Medicaid expansion.[16-18] However, our final model ICC indicated that the state of residency of a given participant accounted for only 4% of the variance of PrEP use in our analysis, and the IOR-80 for our Medicaid expansion variables measure of association (i.e., odds ratio) included the null value - 1. In MLA, the inclusion of the null value on the IOR-80 indicates that the variable was not relevant to understanding the state-level variation in an individual predisposition to use PrEP.[23] Furthermore, the positive MOR observed in our analysis must be understood in light of the small ICC presented in our model, though there may have been strong differences between two individuals from different states tendency to use PrEP, there was not enough variation between states for Medicaid expansion to impact PrEP use. In MLA, the estimate of the ICC is highly dependent on the area-level variable variance (e.g, state-level),[22] which suggests that perhaps a smaller area-level analysis, like zip code or county-level, may be better suited to understand the impact of Medicaid expansion on PrEP uptake. Previously reported regional disparities in PrEP use seems to suggest this as well. For example, though Medicaid expansion has been associated with increased PrEP use, a majority of states have been found to have less than one PrEP-providing clinic per 100,000 people.[31] A narrower area of analysis, using MLA, may be advisable to explore how much geographic region explains disparities in PrEP use, and to explore the question about Medicaid expansion more effectively.

**Limitations:**

Our findings must be understood in light of several limitations. First, our data were collected via self-report and may be subjected to social desirability bias. Several demographic variables that could further influence PrEP use were not measured such as health insurance status, income, and other social determinants of health. Further, our outcome variable (current

PrEP use) In our analysis we did not control from insurance type, for example, rather we explored the population-level effect of living in a Medicaid expansion state. It may be relevant to oversample patients receiving Medicaid and control for insurance information in future analysis.

The time our data was collected (2017-2018) is an additional limitation, and the relevance of the findings to the field of PrEP uptake might seem none. We call the reader's attention to the wholesome numbers of PrEP users reported in the United States – approximately 200,000 – a stagnant number since then until now.[8] We believe our findings provide some value to the question as to whether Medicaid expansion, as a variable, has an impact on an individual decision to start PrEP.

Lastly, the parent studies of our dataset recruited participants using similar strategies that may have resulted in the same participants responding to both surveys. We note that we treated each individual response as independent. Although we cannot ascertain precisely the amount of overlap of participants across surveys, the studies' recruitment strategies utilized multiple applications platforms, each of which has millions of daily users. Therefore, the relative pool of available participants is several times the magnitude of those who actually took our surveys.

**Conclusion:**

Our analysis showed that PrEP use is less common in communities standing to benefit the most from it – young MSM and TGNB of color. However, individuals meeting federal guidelines for PrEP were significantly more likely to use PrEP. Updating guidelines may provide a strong avenue to improve uptake and reduce racial disparities. Additionally, individuals living in states where Medicaid was expanded were similarly more likely to use PrEP, however we did not find that this variable was significant to explain state-level differences in PrEP use.

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**Authorship contribution statement**

PC, and CG conceptualized the paper, with PC performing the main analysis - both reviewed multiples drafts and contributed to each section of the paper. CM performed the initial bivariate analysis, extracted the data, and provided valuable data analysis and variable development feedback. SJ Developed the dataset, conceptualized the variables, and reviewed multiple drafts of the manuscript. JR provided key methodology feedback, and analytical guidance. Additionally, JR helped with the interpretation of results.

**Data Sharing Statement**

No additional data available

**Author(s') disclosure statement(s)**

All authors report no conflict of interest.

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**Appendix. State-level (level-2) Medicaid Expansion Status**

| State | Sample population | Medicaid Expansion Status 2020 |
|---|---|---|
| Alabama | 1,461 | Not expanded |
| Alaska | 204 | Fully expanded |
| Arizona | 2,791 | Conditionally Expanded |
| Arkansas | 830 | Conditionally Expanded |
| California | 16,723 | Fully expanded |
| Colorado | 2,413 | Fully expanded |
| Connecticut | 1,137 | Fully expanded |
| Delaware | 340 | Fully expanded |
| District of Columbia | 1,072 | Fully expanded |
| Florida | 9,654 | Not expanded |
| Georgia | 4,311 | Not expanded |
| Hawaii | 511 | Fully expanded |
| Idaho | 497 | Fully expanded |
| Illinois | 5,079 | Fully expanded |
| Indiana | 2,098 | Conditionally Expanded |
| Iowa | 912 | Conditionally Expanded |
| Kansas | 776 | Not expanded |
| Kentucky | 1,432 | Conditionally Expanded |
| Louisiana | 1,600 | Fully expanded |
| Maine | 371 | Fully expanded |
| Maryland | 1,944 | Fully expanded |
| Massachusetts | 2,816 | Fully expanded |
| Michigan | 2,745 | Conditionally Expanded |
| Minnesota | 1,739 | Fully expanded |
| Mississippi | 744 | Not expanded |
| Missouri | 1,807 | Not expanded |
| Montana | 308 | Fully expanded |
| Nebraska | 594 | Conditionally Expanded |
| Nevada | 1,412 | Fully expanded |
| New Hampshire | 413 | Conditionally Expanded |
| New Jersey | 2,741 | Fully expanded |
| New Mexico | 822 | Conditionally Expanded |
| New York | 11,010 | Fully expanded |
| North Carolina | 3,367 | Not expanded |
| North Dakota | 199 | Fully expanded |
| Ohio | 3,652 | Conditionally Expanded |
| Oklahoma | 1,163 | Not expanded |
| Oregon | 1,659 | Fully expanded |
| Pennsylvania | 4,192 | Fully expanded |
| Puerto Rico | 1,119 | Fully expanded |
| Rhode Island | 432 | Fully expanded |
| South Carolina | 1,504 | Not expanded |

| | | |
|---|---|---|
| South Dakota | 192 | Not expanded |
| Tennessee | 2,005 | Not expanded |
| Texas | 11,750 | Not expanded |
| Utah | 1,285 | Conditionally Expanded |
| Vermont | 193 | Fully expanded |
| Virginia | 2,757 | Fully expanded |
| Washington | 2,812 | Fully expanded |
| West Virginia | 511 | Fully expanded |
| Wisconsin | 1,641 | Not expanded |
| Wyoming | 165 | Not expanded |

BMJ Open

# Demographic, Clinical Guideline Criteria, Medicaid Expansion and State of Residency: A Multilevel Analysis of PrEP use on a Large US Sample

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# Demographic, Clinical Guideline Criteria, Medicaid Expansion and State of Residency: A Multilevel Analysis of PrEP use on a Large US Sample

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## Abstract

**Objective:** To explore the association of clinical guideline-related variables, demographics and Medicaid expansion on PrEP uptake in one of the largest US sample of MSM and TGNB people ever analyzed.

**Methods:** We cross-sectionally analyzed predictors of current PrEP use using demographic and HIV risk-related variables (level-1), as well as state-level variables (level-2) (i.e, Medicaid Expansion status). We further explored the role state of residence plays in PrEP uptake disparities across the US.

**Results:** We found that the odds of PrEP use were significantly greater in older age, white, cisgender men. Moreover, individuals who reported recent PEP use, a recent sexually transmitted infection diagnosis and recent drug use were significantly more likely to report PrEP use. Lastly, we found **that** the median odds of PrEP use between similar individuals from different states were 1.40 for the ones living in the Medicaid expansion states, compared to those not living in Medicaid expansion states. State of residence did not play a significant role in explaining PrEP disparities overall.

**Conclusion:** Our analysis showed that PrEP use is less common in communities standing to benefit the most from it – young MSM and TGNB of color. However, individuals meeting federal guidelines for PrEP were significantly more likely to use PrEP. Though we found a positive association between living in Medicaid expansion states and PrEP use; that variable, as well as one's state of residency, were not suitable to explain variations in PrEP use in the US.

## Article summary

### Strengths and limitations of this study

1. This study reports on patient-level risk factors of PrEP use in a sample of over 6,000 cisgender men and transgender people who have sex with men across the United States, representing all states.
2. This study uses multi-level modelling analysis to understand the role of state-level medicaid-expansion alongside individual-level predictors of PrEP use.
3. This study includes the magnitude of clinical guidelines criteria predictors of PrEP use in a US national sample, and the role of Medicaid expansion on PrEP use.
4. This study was conducted in 2017 and 2018, and the implementation of PrEP across the United States is ever growing and changing.
5. The study uses self-reported cross-sectional data, and causal inference cannot be drawn from the analysis

## Introduction

In 2012, the US Food and Drug Administration (FDA) approved the first daily HIV preexposure prophylactic (PrEP) medication in the form of tenofovir disoproxil fumarate and emtricitabine (TDF/FTC).[1] Following its approval, the CDC estimated that as many as 1.2 million Americans would benefit from taking the regimen.[2] By 2017, only approximately 80,000 prescriptions were filled by unique HIV-negative users.[3]

Recent estimations of PrEP use in the general population suggest that as many as 200,000 individuals have initiated or persisted in PrEP year-over-year since the 2012 FDA approval through 2020,[4] a number still lower than expected.[2] Researchers in the US have reported PrEP discontinuation rates of up to 60% following six-months of initiation.[5-8] An analysis of persistence (i.e., continous use) data using prescription drug records in the US from 2012-2017 found that PrEP persistence was only 14-months on average, and significantly differed by race, age group and insurance status.[9] Understanding this issue is critical for communities at-risk for HIV, especially Black and Latinx MSM communities.[10] A limitation of current PrEP use reports in the US is their reliance on pharmacy claims data,[3] or multiple different sources to obtain estimates,[4] limiting one's ability to account for confounding variables, like HIV-related risk factors. They also limit a deeper exploration of complex questions by limiting the study unit to a prescription claim, for example, rather than one individual. There is an immediate need to develop solutions to mitigate both issues - the overall uptake and persistence in PrEP, and the observed racial disparity in communities standing to benefit the most from it.

A prominent issue impacting PrEP uptake in the US is coverage, both financial coverage in the form of health insurance, and geographic coverage in the form of access to a provider who is competent and accepts your medical coverage. Issues related to having health insurance

coverage or being able to afford costs associated with medical care are widely reported throughout the PrEP literature,[11-14] and they relate to an individual inability to pay for costs associated with taking PrEP. However, financial coverage is also managed at the state-level, through state-run Medicaid programs and drug assistance programs (DAP), which grant some access and affordability to PrEP. Patients enrolled in Medicaid have mixed levels of PrEP access, with enrollees with incomes under 150% of the federal poverty level (FPL) receiving PrEP for nearly free due to federal laws limiting costs.[15] In 2010, the affordable care act (ACA) provided states with the ability to expand Medicaid programs to adults aged 65 and younger with incomes 138% of the FPL (about $17,000 a year) and below.[15] Several states have chosen to expand Medicaid, and reports have linked increases in PrEP use to these expansions,[16-18] suggesting that state variation in PrEP use may explain some of the disparities observed in the population at-large. Thus far, the issue of Medicaid expansion has only been explored on the aggregate level, limiting studies to measures of association which only informs on effect size but not on the impact of the variable on the distribution of PrEP across communities. Understanding the impact of Medicaid expansion on a population-level can support a better understanding of the complexities in regional disparities in PrEP use, for example, by exploring the association of Medicaid expansion and racial disparities in PrEP uptake. Furthermore, it seems imperative to understand whether the state of residency of a particular individual is significant to explain PrEP uptake.

Using the combined the screening/enrollment data from two similar-in-scope U.S. national cohorts, we created one of the largest national samples of MSM and transgender and gender non-binary (TGNB) individuals who have sex with men. Using a mixed-effect multilevel logistic analysis (MLA) approach, we analyzed predictors of current PrEP use using

demographic and HIV risk-related variables (level-1), as well as state-level variables (level-2) (i.e, Medicaid Expansion status).

## Methods

### About the studies

The *Together 5,000* and *UNITE* studies are both U.S. national cohorts longitudinally following sexual and gender minorities at-risk for HIV. Both cohorts are similar in scope, exploring sexual behavior and PrEP uptake. Details on both studies have been described elsewhere.[19,20] Briefly, each used advertisements on geospatial sexual networking apps to recruit MSM and TGNB people who have sex with men across the U.S. to enroll in longitudinal assessments. During each study's enrollment phase, app-users were presented with an ad for the study. Those interested were directed to a brief screening (i.e., eligibility) survey on their devices browser. The present analysis utilizes the reconciled screening data from each study dataset (i.e., all variables that were identical across both screening surveys). Both studies enrolled samples in 2017 and 2018.

The sample's composition, which was not designed to be nationally representative, is nonetheless one of the largest national surveys of sexual minorities, consisting of 157,035 responses, with 27% of the responses being from the *Together 5,000* study and the remainder from *UNITE*. Our current analysis, exploring individual- and state-level predictors of current PrEP use, was limited to individuals not living with HIV, and those residing in one of the 50 states, Washington, DC, or Puerto Rico – hereby referred to as "states." Our decision to limit the analytical sample to these states was based on state-level data availability. Our final sample was inclusive of 123,905 (79%) cisgender men and TGNB people who have sex with men.

### Individual-level variables (level-1)

7

**Demographics**. Participants were grouped according to their age (under 24 years old, 25-29 years old, 30-49 years old, 50+ years old), gender identity (male, female (assigned male at birth), transgender person, something else), and race/ethnicity (Black, Latinx, white, multiracial, other).

**Current PrEP use.** Participants were asked about their PrEP status and current users were identified based on their self-reported status (current use/not).

**Clinical criteria guideline variables.** In both studies, participants were asked about post-exposure prophylaxis (PEP) use in the prior 12 months, drug use in the past three months (i.e., cannabis, cocaine, stimulants, methamphetamine, inhalants, sedatives, GHB, MDMA, hallucinogen), and whether they received a sexually transmitted infection (STI) diagnosis (i.e., syphilis, chlamydia or gonorrhea) in the past 12 months. Based on their answers, we developed three dichotomous (yes/no) variables indicating their PEP, drug use, and STI experiences within the timeframes noted.

**State-level variables (level-2)**

**Medicaid expansion status.** We created a three-level variable to indicate the state's Medicaid expansion status as of 2020. We categorized as fully expanded, not expanded, or conditionally expanded. Conditional expansion includes any alternative Medicaid expansion model differing from the Affordable Care Act (ACA) format and one state that started expansion in 2020 (i.e., Nebraska).[21]

**Patient and Public Involvement**

Patients were not involved in the development of this study

**Ethics Approval Statement**

Procedures for each of the cohort studies, as well as those to merge de-identified datasets were reviewed and approved by the CUNY Internal Review Board (Protocol number: 2019-0334).

**Analysis**

Our analysis included a descriptive assessment of our sample's demographics and HIV-clinical guideline-related variables, as well as a description of state-level variables. Next, we built a multilevel logistic multivariable mixed-effects regression model predicting current PrEP use (yes/no), using individual- (level-1) and state-level (level-2) predictors. We calculated the fixed effects odds ratio and 95% confidence interval of our fixed-effect variables, as well as the random effect intraclass correlation coefficients (ICC), the median odds ratios (MOR) of each of our models, and the interval odds ratio (IOR-80) of our fixed-effect level-2 variables – random effect components were calculated via previously reported equations and methods.[22,23] Our model-building approach was the following, first, we constructed a null model (model 1) in order to calculate the ICC and determine the variance in PrEP use accounted by an individual's state of residency. After, we built a model with level-1 variables (model 2) to explore the fixed effects of individual-level factors on current PrEP use. Finally, we built a full mixed effect multilevel logistic model (model 3) with all variables in both levels. Our analysis was conducted using the PROC GLIMMIX procedure with one random effect at the intercept, a binary distribution and a logit link on SAS 9.4. We used Satterthwaite degrees of freedom. Random effects components were calculated manually.[22,23] Given our large sample size, we analyzed our intervals of confidence and effect sizes when discussing statistical significance.

**Results**

Our US sample varied demographically with over a quarter being under 24 years old, 13% were over 50 years of age, about 1.7% were transgender people, and 40% were either Black, Latinx or Multiracial. About 8% used PEP in the past 12 months, 60% used drugs in the past 3 months, and 13% had a positive STI results in the past 12 months. In total, 15% of the sample were current PrEP users, and the proportion of PrEP use was significantly greater in adults older than 29 y.o. (68% v. 51%), white participants (59% v. 53%), people who recently used PEP (23% v 5%), who recently used drugs (74% v. 58%), and those who reported a recent STI diagnosis (29% v. 10%). Table 1 provides further details about our sample individual-level (level-1) variables. States-level characteristics (level-2) also varied greatly with about 54% having fully expanded Medicaid, and 22% having conditionally expanded. We provided this list as an appendix (See Supplement 1).

**Table 1. Demographics and Clinical Guideline-related Characteristics of National Sample of Cisgender Men and Transgender People who have Sex with Men (level-1)**

| | *n* | % | *Not currently on PrEP* | | *Current PrEP user* | | | |
|---|---|---|---|---|---|---|---|---|
| **Variables** | 123905 | | 104330 | 84% | 18126 | 15% | | |
| **Age group** | | | | | | | 2711 | <0.0001 |
| 24 & under | 32852 | 26.5% | 30694 | 29% | 2158 | 12% | | |
| 25-29 | 26347 | 21.3% | 22471 | 22% | 3876 | 21% | | |
| 30-49 | 48904 | 39.5% | 39370 | 38% | 9534 | 53% | | |
| 50+ | 15802 | 12.8% | 13042 | 13% | 2760 | 15% | | |
| **Gender identity (*n*= 123453)** | | | | | | | 69.81 | <0.0001 |
| Male | 120861 | 97.9% | 102827 | 99% | 18034 | 99% | | |
| Female (Trans woman) | 388 | 0.3% | 367 | 0.4% | 21 | 0.1% | | |
| Transgender Person | 1959 | 1.6% | 1759 | 2% | 200 | 1.1% | | |
| Something else | 245 | 0.2% | 225 | 0.2% | 20 | 0.1% | | |
| **Race** | | | | | | | 280.9 | <0.0001 |
| Black | 14237 | 11.5% | 12524 | 12% | 1713 | 9% | | |

10

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Latinx | 23999 | 19.4% | 20894 | 20% | 3105 | 17% | | |
| White | 65941 | 53.2% | 55210 | 53% | 10731 | 59% | | |
| Multiracial | 11845 | 9.6% | 10240 | 10% | 1605 | 9% | | |
| Other | 7883 | 6.4% | 6709 | 6% | 1174 | 6% | | |
| **PEP in past 12 months (*n*= 123552)** | | | | | | | 6616 | <0.0001 |
| Yes | 9713 | 7.8% | 5542 | 5% | 4171 | 23% | | |
| No | 113839 | 91.9% | 99717 | 96% | 14122 | 78% | | |
| **Drug use in past 3 months (*n*= 122456)** | | | | | | | 1615 | <0.0001 |
| Yes | 73837 | 59.6% | 60464 | 58% | 13373 | 74% | | |
| No | 48619 | 39.2% | 43866 | 42% | 4753 | 26% | | |
| **STI diagnosis in past 12 months (*n* = 122734)** | | | | | | | 5296 | <0.0001 |
| Yes | 15605 | 12.6% | 10280 | 10% | 5325 | 29% | | |
| No | 107129 | 86.5% | 94292 | 90% | 12837 | 71% | | |

184

Our regression model results are presented on Table 2, we report here the findings of our model 3. The odds of current PrEP use for all age groups were significantly higher when compared to people 24 years old and younger, with individuals 25-29 having 2.2 greater odds (aOR = 2.21, 95% CI: 2.15 - 2.28), 30-39 having 3.2 greater odds (aOR = 3.20, 95% CI: 3.12 - 3.29) and those 50 years old and older having 2.9 greater odds (aOR = 2.91, 95% CI: 2.82 - 3.01) of current PrEP use. All races had significantly lower odds current PrEP use when compared to white participants, with Black participants having 27% lower odds (aOR = 0.73, 95% CI: 0.71 – 0.76), 26% lower for Latinx (aOR = 0.74, 95% CI: 0.73 – 0.76), and 21% lower for multiracial individuals (aOR = 0.79, 95% CI: 0.76 – 0.81). Those who identified as female (aOR = 0.44, 95% CI: 0.35 – 0.56) or as a transgender person (aOR = 0.71, 95% CI: 0.66 – 0.77) had 66% and 29% significantly lower odds of being current PrEP users than those identifying as male. Individuals who reported PEP use in the past 12 months (aOR = 3.94, 95% CI: 3.85 – 4.04), drug use in the past 3 months (aOR = 1.73, 95% CI: 1.70 – 1.76) or were diagnosed with an STI in the previous 12 months (aOR = 3.34, 95% CI: 3.27 – 3.42) had significantly greater odds of being current PrEP users. On the state level, individuals living in states with no Medicaid expansion had 31% lower odds of being current PrEP users (aOR = 0.69, 95% CI: 0.54 – 0.88), and those living in conditional Medicaid expansion state had 27% lower odds of being current PrEP users than individuals living in states with full expansion (aOR = 0.73, 95% CI: 0.56 – 0.95). For the states with no expansion (aOR= 0.69) the IOR-80 was between 0.37 – 1.30, and for those conditional expansion (aOR=0.73) it was between 0.39 – 1.38. The median odds of PrEP use between individuals with identical individual characteristics but from different states were 1.40 for the ones living in the Medicaid expansion states, compared to those not living in Medicaid expansion states. Overall, the state of residency accounted for about 6% in the variance of PrEP

use overall, and after accounting for fixed-effects of individuals and Medicaid expansion, it accounts for only 4% of the remaining variance.

**Table 2. Multilevel Mixed-Effects Regression Models Predicting Current PrEP Use**

| Fixed-Effects Variables | Model 1 (Null) | Model 2 | 95% CI | Model 3 | 95% CI |
|---|---|---|---|---|---|
| **Demographics** | | | | | |
| Age group (24 & Under) | | | | | |
| 25-29 | | 2.21 | (2.09, 2.35) | 2.21 | (2.15, 2.28) |
| 30-49 | | 3.20 | (3.04, 3.37) | 3.19 | (3.04, 3.37) |
| 50+ | | 2.91 | (2.73, 3.1) | 2.9 | (2.82, 3.01) |
| Race/Ethnicity (White) | | | | | |
| Black | | 0.73 | (0.69, 0.78) | 0.73 | (0.71, 0.76) |
| Latinx | | 0.75 | (0.71, 0.78) | 0.74 | (0.73, 0.76) |
| Multiracial | | 0.79 | (0.74, 0.84) | 0.79 | (0.76, 0.81) |
| Other | | 0.82 | (0.76, 0.88) | 0.82 | (0.79, 0.85) |
| Gender Identity (Male) | | | | | |
| Female (Trans woman) | | 0.44 | (0.28, 0.7) | 0.44 | (0.35, 0.56) |
| Something else | | 0.44 | (0.26, 0.73) | 0.42 | (0.33, 0.56) |
| Transgender person | | 0.71 | (0.61, 0.84) | 0.71 | (0.66, 0.77) |
| **Risk Variables** | | | | | |
| PEP use in past 12 months (ref: No) | | 3.94 | (3.76, 4.14) | 3.94 | (3.85, 4.04) |
| STI diagnosis in past 12 months (ref: No) | | 3.34 | (3.21, 3.48) | 3.34 | (3.27, 3.42) |
| Drug use in past 3 months (ref: No) | | 1.73 | (1.67, 1.8) | 1.73 | (1.7, 1.76) |
| **State-level Variable** | | | | | |
| Medicaid Expansion status | | | | | |
| No Expansion | | | | 0.69 | (0.54, 0.88) |
| Conditional Expansion | | | | 0.73 | (0.56, 0.95) |
| | | | | | |
| **Random Effect Components** | | | | | |
| Interval Odds Ratio (IOR-80) | | | | | |
| Medicaid Expansion status | | | | | |
| No Expansion | | | | (0.37 - 1.30) | |
| Conditional Expansion | | | | (0.39 - 1.38) | |
| Intercept Variance | 0.21 | 0.15 | | 0.12 | |
| Interclass Correlation Coefficient (ICC) | 0.06 | 0.04 | | 0.04 | |
| Median Odds Ratio (MOR) | 1.54 | 1.45 | | 1.40 | |

13

## Discussion

In this US national survey with over 120,000 responses, we found that older age, white race, cisgender male identity, and meeting objective criteria per current guidelines were positive predictors of current PrEP use. Previous epidemiologic surveillance reports exploring PrEP uptake in the US using prescription drug data have found similar demographic outcomes.[3] Furthermore, though a state's Medicaid expansion status significantly predicted the likelihood an individual is currently taking PrEP, these effects were weak across states and did not explain variation in PrEP use in our analysis. Our study represents one of the largest U.S. national samples to explore multilevel predictors of current PrEP use, using individual and risk-related variables, and state-level variables.

Our findings affirmed the demographic disconnect between HIV and PrEP epidemiology in the US. While HIV incidence is disproportionally distributed in Black and Brown MSM and TGNB youth communities,[24] PrEP was most commonly used by older white cisgender men.[3] These effects persisted without change in effect size after controlling for Medicaid expansion. This contrast cannot be overlooked for the racial inequities in HIV outcomes in the US are historic and enduring. Aside from denying protection to communities who stand to benefit the most from PrEP, demographic inequities in access to HIV prevention interventions can significantly increase the magnitude of this racial inequity. Nevertheless, PrEP use was much more common among those who would have otherwise benefited from its protection most, such as those who had taken PEP, been recently treated for an STI, or reported drug use. This scenario presents a critical consideration to the successes, and possible limitations, of current PrEP guidelines in the US.[25] The guidelines, set forth by the CDC, have a strong focus on objective risk (i.e., recent bacterial STI, history of inconsistent or no condom use, sharing injection

equipment).[26] To that extent, our results demonstrated that guidelines can be successful in translating theory to practice: participants who reported any recent guideline criteria had as much as 3 times the odds of PrEP use than otherwise. However, the persistent demographic disconnect between *who gets HIV* and *who takes PrEP* requires discussing the limitations of recommending PrEP solely based on objective risk. Researchers in the US have previously speculated about the role an extension of guidelines would have in impacting PrEP uptake.[27] Using the premise of determining "good fit" of PrEP for a given patient's goals, instead of "eligibility" for PrEP they suggest PrEP may be used to reduce HIV-related anxiety during sex and increase inter-partner intimacy.[27] The CDC and other agencies overseeing clinical guidelines should immediately consider heeding such advice. Australia, for example, is considered a model-jurisdiction for PrEP implementation, with several reports associating community PrEP uptake to substantial declines in HIV incidence.[28,29] The guidelines for offering PrEP in Australia are much broader and comprehensive than those of the CDC, including reasons for offering PrEP such as "w*hen a person plans to travel during which time they anticipate that they will be having condomless sex with casual partners,"* and *"when a person reports being so anxious about HIV infection that it may prevent them from having regular HIV testing, or engaging in any form of anal sex."*[30] A more inclusive set of clinical recommendations may have a much greater impact on PrEP uptake than traditional community outreach strategies; agencies and organizations with jurisdiction over these guidelines should consider doing so.

In exploring the role of a state's Medicaid expansion in predicting current PrEP use, we found mixed results. Appendix 1 provides a detailed description of the state-level sample and some important demographic breakdown, as well as each state's Medicaid expansion status at the time of the study. The median OR (MOR = 1.40) suggests that at least 50% of the odds of PrEP

use between multiple pairs of identical individuals living in different states are 40% greater or higher, on average, for individuals living in states with Medicaid expansion. This finding is in line with previously reported effect estimates of PrEP use in relation to Medicaid expansion.[16-18] However, our final model ICC indicated that the state of residency of a given participant accounted for only 4% of the variance of PrEP use in our analysis, and the IOR-80 for our Medicaid expansion variables measure of association (i.e., odds ratio) included the null value - 1. In MLA, the inclusion of the null value on the IOR-80 indicates that the variable was not relevant to understanding the state-level variation in an individual predisposition to use PrEP.[23] Furthermore, the positive MOR observed in our analysis must be understood in light of the small ICC presented in our model, though there may have been strong differences between two individuals from different states tendency to use PrEP, there was not enough variation between states for Medicaid expansion to impact PrEP use. In MLA, the estimate of the ICC is highly dependent on the area-level variable variance (e.g, state-level),[22] which suggests that perhaps a smaller area-level analysis, like zip code or county-level, may be better suited to understand the impact of Medicaid expansion on PrEP uptake. Previously reported regional disparities in PrEP use seems to suggest this as well. For example, though Medicaid expansion has been associated with increased PrEP use, a majority of states have been found to have less than one PrEP-providing clinic per 100,000 people.[31] A narrower area of analysis, using MLA, may be advisable to explore how much geographic region explains disparities in PrEP use, and to explore the question about Medicaid expansion more effectively. The latter analysis, in fact, provides a better health equity framing to our question, because communities of color often live in smaller enclaves, and using the entire of a sate area may dissolve the true impact of the state's policy in these communities.

**Limitations:**

Our findings must be understood in light of several limitations. First, our data were collected via self-report and may be subjected to social desirability bias. Several demographic variables that could further influence PrEP use were not measured such as health insurance status, income, and other social determinants of health. Further, our outcome variable (current PrEP use) In our analysis we did not control from insurance type, for example, rather we explored the population-level effect of living in a Medicaid expansion state. It may be relevant to oversample patients receiving Medicaid and control for insurance information in future analysis.

The time our data was collected (2017-2018) is an additional limitation, and the relevance of the findings to the field of PrEP uptake might seem none. We call the reader's attention to the wholesome numbers of PrEP users reported in the United States – approximately 200,000 – a stagnant number since then until now.[8] We believe our findings provide some value to the question as to whether Medicaid expansion, as a variable, has an impact on an individual decision to start PrEP.

Lastly, the parent studies of our dataset recruited participants using similar strategies that may have resulted in the same participants responding to both surveys. We note that we treated each individual response as independent. Although we cannot ascertain precisely the amount of overlap of participants across surveys, the studies' recruitment strategies utilized multiple applications platforms, each of which has millions of daily users. Therefore, the relative pool of available participants is several times the magnitude of those who actually took our surveys.

**Conclusion:**

Our analysis showed that PrEP use is less common in communities standing to benefit the most from it – young MSM and TGNB of color. However, individuals meeting federal

guidelines for PrEP were significantly more likely to use PrEP. Updating guidelines may provide a strong avenue to improve uptake and reduce racial disparities. Additionally, individuals living in states where Medicaid was expanded were similarly more likely to use PrEP, however we did not find that this variable was significant to explain state-level differences in PrEP use.

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**Authorship contribution statement**

PC, and CG conceptualized the paper, with PC performing the main analysis - both reviewed multiples drafts and contributed to each section of the paper. CM performed the initial bivariate analysis, extracted the data, and provided valuable data analysis and variable development feedback. SJ Developed the dataset, conceptualized the variables, and reviewed multiple drafts of the manuscript. JR provided key methodology feedback, and analytical guidance. Additionally, JR helped with the interpretation of results.

**Data Sharing Statement**

No additional data available

**Author(s') disclosure statement(s)**

All authors report no conflict of interest.

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19

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**Appendix. State-level (level-2) Medicaid Expansion Status**

| State | Sample population | Medicaid Expansion Status 2020 |
|---|---|---|
| Alabama | 1,461 | Not expanded |
| Alaska | 204 | Fully expanded |
| Arizona | 2,791 | Conditionally Expanded |
| Arkansas | 830 | Conditionally Expanded |
| California | 16,723 | Fully expanded |
| Colorado | 2,413 | Fully expanded |
| Connecticut | 1,137 | Fully expanded |
| Delaware | 340 | Fully expanded |
| District of Columbia | 1,072 | Fully expanded |
| Florida | 9,654 | Not expanded |
| Georgia | 4,311 | Not expanded |
| Hawaii | 511 | Fully expanded |
| Idaho | 497 | Fully expanded |
| Illinois | 5,079 | Fully expanded |
| Indiana | 2,098 | Conditionally Expanded |
| Iowa | 912 | Conditionally Expanded |
| Kansas | 776 | Not expanded |
| Kentucky | 1,432 | Conditionally Expanded |
| Louisiana | 1,600 | Fully expanded |
| Maine | 371 | Fully expanded |
| Maryland | 1,944 | Fully expanded |
| Massachusetts | 2,816 | Fully expanded |
| Michigan | 2,745 | Conditionally Expanded |
| Minnesota | 1,739 | Fully expanded |
| Mississippi | 744 | Not expanded |
| Missouri | 1,807 | Not expanded |
| Montana | 308 | Fully expanded |
| Nebraska | 594 | Conditionally Expanded |
| Nevada | 1,412 | Fully expanded |
| New Hampshire | 413 | Conditionally Expanded |
| New Jersey | 2,741 | Fully expanded |
| New Mexico | 822 | Conditionally Expanded |
| New York | 11,010 | Fully expanded |
| North Carolina | 3,367 | Not expanded |
| North Dakota | 199 | Fully expanded |
| Ohio | 3,652 | Conditionally Expanded |
| Oklahoma | 1,163 | Not expanded |
| Oregon | 1,659 | Fully expanded |
| Pennsylvania | 4,192 | Fully expanded |
| Puerto Rico | 1,119 | Fully expanded |
| Rhode Island | 432 | Fully expanded |
| South Carolina | 1,504 | Not expanded |
| South Dakota | 192 | Not expanded |

| | | |
|---|---|---|
| Tennessee | 2,005 | Not expanded |
| Texas | 11,750 | Not expanded |
| Utah | 1,285 | Conditionally Expanded |
| Vermont | 193 | Fully expanded |
| Virginia | 2,757 | Fully expanded |
| Washington | 2,812 | Fully expanded |
| West Virginia | 511 | Fully expanded |
| Wisconsin | 1,641 | Not expanded |
| Wyoming | 165 | Not expanded |

| Age group | | | | Race/Ethnicity | | |
|---|---|---|---|---|---|---|
| 24 and under | 25-29 | 30-49 | 50+ | Black | Latino | White |
| 446 | 301 | 561 | 153 | 389 | 70 | 884 |
| 41 | 47 | 90 | 26 | 11 | 13 | 101 |
| 785 | 602 | 1,048 | 356 | 144 | 773 | 1,352 |
| 225 | 172 | 318 | 115 | 107 | 52 | 571 |
| 4,454 | 3,662 | 6,605 | 2,002 | 1,181 | 5,435 | 5,912 |
| 575 | 566 | 995 | 277 | 140 | 468 | 1,407 |
| 309 | 230 | 403 | 195 | 120 | 184 | 675 |
| 83 | 57 | 138 | 62 | 64 | 34 | 208 |
| 201 | 262 | 484 | 125 | 208 | 129 | 563 |
| 2,439 | 1,867 | 3,746 | 1,602 | 1,089 | 2,658 | 4,746 |
| 1,116 | 956 | 1,713 | 526 | 1,233 | 380 | 2,193 |
| 92 | 91 | 230 | 98 | 12 | 45 | 140 |
| 151 | 110 | 180 | 56 | 1 | 89 | 352 |
| 1,263 | 1,108 | 2,060 | 648 | 669 | 978 | 2,735 |
| 632 | 401 | 759 | 306 | 215 | 154 | 1,520 |
| 247 | 66 | 367 | 132 | 46 | 65 | 707 |
| 242 | 173 | 276 | 85 | 59 | 87 | 519 |
| 399 | 303 | 562 | 168 | 132 | 62 | 1,129 |
| 435 | 352 | 667 | 173 | 357 | 132 | 954 |
| 78 | 82 | 141 | 70 | 9 | 16 | 319 |
| 521 | 423 | 762 | 238 | 448 | 233 | 939 |
| 724 | 612 | 1,052 | 428 | 214 | 407 | 1,671 |
| 745 | 531 | 1,095 | 374 | 325 | 179 | 1,920 |
| 450 | 349 | 717 | 223 | 91 | 140 | 1,206 |
| 203 | 168 | 267 | 106 | 222 | 15 | 461 |
| 509 | 340 | 703 | 255 | 183 | 90 | 1,367 |
| 85 | 62 | 134 | 27 | 11 | 17 | 236 |
| 192 | 121 | 194 | 87 | 38 | 72 | 428 |
| 362 | 287 | 586 | 177 | 136 | 355 | 647 |
| 88 | 62 | 172 | 91 | 15 | 25 | 339 |
| 730 | 496 | 1,044 | 471 | 330 | 521 | 1,423 |
| 221 | 173 | 345 | 83 | 17 | 381 | 223 |
| 2,608 | 2,554 | 4,591 | 1,257 | 1,337 | 2,042 | 5,521 |
| 965 | 732 | 1,279 | 391 | 702 | 331 | 1,940 |
| 57 | 36 | 83 | 23 | 10 | 10 | 145 |
| 901 | 780 | 1,455 | 516 | 435 | 168 | 2,670 |
| 314 | 205 | 505 | 139 | 91 | 98 | 697 |
| 356 | 345 | 750 | 208 | 60 | 226 | 108 |
| 1,153 | 899 | 1,574 | 566 | 437 | 355 | 2,909 |
| 285 | 219 | 492 | 123 | 26 | 49 | 292 |
| 106 | 94 | 160 | 72 | 8 | 807 | 28 |
| 427 | 287 | 566 | 224 | 365 | 95 | 907 |
| 51 | 43 | 74 | 24 | 7 | 11 | 135 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 514 | 465 | 788 | 238 | 267 | 120 | 1,434 |
| 3,600 | 2,567 | 4,438 | 1,145 | 1,464 | 4,383 | 4,291 |
| 363 | 280 | 532 | 110 | 27 | 182 | 888 |
| 57 | 29 | 77 | 30 | 6 | 16 | 153 |
| 814 | 601 | 1,005 | 337 | 483 | 308 | 1,539 |
| 644 | 623 | 1,203 | 342 | 122 | 354 | 170 |
| 127 | 99 | 211 | 74 | 28 | 11 | 441 |
| 421 | 349 | 643 | 228 | 145 | 1,453 | 1,179 |
| 46 | 36 | 64 | 20 | 1 | 21 | 121 |

| y | |
|---|---|
| **Multiracial** | **Other** |
| 69 | 49 |
| 40 | 39 |
| 366 | 156 |
| 61 | 39 |
| 2,343 | 1,852 |
| 289 | 109 |
| 98 | 60 |
| 19 | 15 |
| 80 | 92 |
| 817 | 344 |
| 295 | 210 |
| 123 | 191 |
| 44 | 11 |
| 396 | 301 |
| 140 | 69 |
| 51 | 43 |
| 71 | 40 |
| 77 | 32 |
| 107 | 50 |
| 12 | 15 |
| 194 | 130 |
| 277 | 247 |
| 199 | 122 |
| 147 | 155 |
| 27 | 19 |
| 104 | 63 |
| 19 | 25 |
| 43 | 13 |
| 167 | 107 |
| 26 | 8 |
| 241 | 223 |
| 118 | 83 |
| 1,192 | 918 |
| 232 | 162 |
| 14 | 20 |
| 266 | 113 |
| 124 | 153 |
| 196 | 96 |
| 294 | 197 |
| 40 | 25 |
| 262 | 14 |
| 90 | 47 |
| 21 | 18 |

| | |
|---|---|
| 127 | 57 |
| 1,064 | 548 |
| 122 | 66 |
| 8 | 10 |
| 248 | 179 |
| 355 | 261 |
| 18 | 13 |
| 99 | 65 |
| 13 | 9 |

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

| | Item No | Recommendation | Page and line number |
|---|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract | Page 2 Line 25 |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | Page 2 Line 21-40 |
| **Introduction** | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | Page 4-5 Lines 59-99 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | Page 5 Lines 100 - 105 |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design early in the paper | Page 6 Lines 108-117 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | Page 6 Lines 118-125 |
| Participants | 6 | (*a*) Give the eligibility criteria, and the sources and methods of selection of participants | Page 6 Lines 121-124 |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | Page 7 Lines 127 - 145 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | Page 7 Lines 127 - 145 |
| Bias | 9 | Describe any efforts to address potential sources of bias | Page 8 Lines 161-165 |
| Study size | 10 | Explain how the study size was arrived at | Page 6 Lines 119 -125 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | Page 8 Lines 154 - 170 |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | Page 8 Lines 154 - 170 |
| | | (*b*) Describe any methods used to examine subgroups and interactions | N/A |
| | | (*c*) Explain how missing data were addressed | N/A |
| | | (*d*) If applicable, describe analytical methods taking account of sampling strategy | N/A |
| | | (*e*) Describe any sensitivity analyses | N/A |
| **Results** | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow- | Page 6 Lines 121-124 + Table 1 |

| | | | |
|---|---|---|---|
| | | up, and analysed | |
| | | (b) Give reasons for non-participation at each stage | N/A |
| | | (c) Consider use of a flow diagram | N/A |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | Table 1 Page 9 Lines 172 - 182 |
| | | (b) Indicate number of participants with missing data for each variable of interest | Table 1 |
| Outcome data | 15* | Report numbers of outcome events or summary measures | Table2 |
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | Page 11 Lines 185- 209 |
| | | (*b*) Report category boundaries when continuous variables were categorized | N/A |
| | | (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | N/A |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | N/A |
| **Discussion** | | | |
| Key results | 18 | Summarise key results with reference to study objectives | Page 13 Lines 212 -220 |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | Pae 16 Lines 279 - 297 |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | Page 13,14,15 Lines 221 - 277 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | Page 16 Lines 279 – 285 |
| **Other information** | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | Page 18 Line 329 - 332 |

*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.