

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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ABSTRACT

Objective To explore the association of clinical guideline-related variables, demographics and Medicaid expansion on pre-exposure prophylaxis (PrEP) uptake in one of the largest US sample of men who have sex with men (MSM) and transgender and gender non-binary (TGNB) people ever analysed.

Methods We cross-sectionally analysed predictors of current PrEP use using demographic and HIV risk-related variables (level-1), as well as state-level variables (level-2) (ie, Medicaid expansion status). We further explored the role state of residence plays in PrEP uptake disparities across the USA.

Results We found that the odds of PrEP use were significantly greater in older age, white, cisgender men. Moreover, individuals who reported recent post-exposure prophylaxis use, a recent sexually transmitted infection diagnosis and recent drug use were significantly more likely to report PrEP use. Finally, 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 with 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 colour. 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.

INTRODUCTION

In 2012, the US Food and Drug Administration (FDA) approved the first daily HIV pre-exposure prophylactic (PrEP) medication in the form of tenofovir disoproxil fumarate and emtricitabine.¹ Following its approval, the Centers for Disease Control and Prevention (CDC) estimated that as many as 1.2 million Americans would benefit from taking the regimen.² By 2017, only approximately 80 000

Strengths and limitations of this study

- This study reports on patient-level risk factors of pre-exposure prophylactic (PrEP) use in a sample of over 6000 cisgender men and transgender people who have sex with men across the USA, representing all states.
- This study uses multi-level modelling analysis to understand the role of state-level Medicaid-expansion alongside individual-level predictors on current PrEP use.
- 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.
- This study was conducted in 2017 and 2018, and the implementation of PrEP across the USA is ever growing and changing.
- The study uses self-reported cross-sectional data, and causal inference cannot be drawn from the analysis.

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 USA have reported PrEP discontinuation rates of up to 60% following 6 months of initiation.^{5–8} An analysis of persistence (ie, continuous use) data using prescription drug records in the USA from 2012 to 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 men who have sex with men (MSM) communities.¹⁰ A limitation of current PrEP use reports in the USA 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 USA 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 programmes and drug assistance programmes, 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 programmes 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 screening/enrolment data from two similar-in-scope US 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 analysed predictors of current PrEP use using demographic and HIV risk-related variables (level-1), as well as state-level variables (level-2) (ie, Medicaid expansion status).

METHODS

About the studies

The *Together 5000* and *UNITE* studies are both US national cohorts longitudinally following sexual and gender minorities at-risk for HIV. Both cohorts are similar in scope, exploring sexual behaviour 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 USA to enrol in longitudinal assessments. During each study's enrolment phase, app-users were presented with an ad for the study. Those interested were directed to a brief screening (ie, eligibility) survey on their devices browser. The present analysis uses the reconciled screening data from each study dataset (ie, 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 5000 study and the remainder from UNITE*. Our current analysis, exploring individual-level 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, Latino, 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 3 months (ie, cannabis, cocaine, stimulants, methamphetamine, inhalants, sedatives, Gamma Hydroxybutyrate (GHB), ecstasy/MDMA, hallucinogen), and whether they received a sexually transmitted infection (STI) diagnosis (ie, syphilis, chlamydia or gonorrhoea) 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 categorised as fully expanded, not expanded, or conditionally expanded. Conditional expansion includes any alternative Medicaid expansion model differing from the ACA format and one state that started expansion in 2020 (ie, Nebraska).²¹

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 OR and 95% CI of our fixed-effect variables, as well as the random effect intraclass correlation coefficients (ICC), the median ORs (MORs) of each of our models and the interval OR (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 V.9.4. We used Satterthwaite df. Random effects components were calculated manually.^{22 23} Given our large sample size, we analysed 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, Latino 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 years old (68% vs 51%), white participants (59% vs 53%), people who recently used PEP (23% vs 5%), who recently used drugs (74% vs 58%) and those who reported a recent STI diagnosis (29% vs 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 online supplemental file 1).

Our regression model results are presented in **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 with people 24 years old and younger, with individuals 25–29 having 2.2 greater odds (adjusted odds ratio (aOR) =2.21, 95% CI 2.15 to 2.28), 30–39 having 3.2 greater odds (aOR=3.20, 95% CI 3.12 to 3.29) and those 50 years old and older having 2.9 greater odds (aOR=2.91, 95% CI 2.82 to 3.01) of current PrEP use. All races had significantly lower odds current PrEP use when compared with white participants, with Black participants having 27% lower odds (aOR=0.73, 95% CI 0.71 to 0.76), 26% lower for Latino (aOR=0.74, 95% CI 0.73 to 0.76), and 21% lower for multiracial individuals (aOR=0.79, 95% CI 0.76 to 0.81). Those who identified as female (aOR=0.44, 95% CI 0.35 to 0.56) or as a transgender person (aOR=0.71, 95% CI 0.66 to 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 to 4.04), drug use in the past 3 months (aOR=1.73, 95% CI 1.70 to 1.76) or were diagnosed with an STI in the previous 12 months (aOR=3.34, 95% CI 3.27 to 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 to 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 to 0.95). For the states with no expansion (aOR=0.69) the IOR-80 was between 0.37 and 1.30, and for those conditional expansions (aOR=0.73) it was between 0.39 and 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 with 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.

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 epidemiological surveillance reports exploring PrEP uptake in the USA 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

**Table 1** Demographics and clinical guideline-related characteristics of national sample of cisgender men and transgender people who have sex with men (level-1)

Variables	n	%	Not currently on PrEP		Current PrEP user			
	123 905		104 330	84%	18 126	15%		
Age group							2711	<0.0001
24 and under	32 852	26.5	30 694	29	2 158	12		
25–29	26 347	21.3	22 471	22	3 876	21		
30–49	48 904	39.5	39 370	38	9 534	53		
50+	15 802	12.8	13 042	13	2 760	15		
Gender identity (n=123 453)							69.81	<0.0001
Male	120 861	97.9	102 827	99	18 034	99		
Female (trans woman)	388	0.3	367	0.4	21	0.1		
Transgender person	1 959	1.6	1 759	2	200	1.1		
Something else	245	0.2	225	0.2	20	0.1		
Race							280.9	<0.0001
Black	14 237	11.5	12 524	12	1 713	9		
Latinx	23 999	19.4	20 894	20	3 105	17		
White	65 941	53.2	55 210	53	10 731	59		
Multiracial	11 845	9.6	10 240	10	1 605	9		
Other	7 883	6.4	6 709	6	1 174	6		
PEP in past 12 months (n=123 552)							6616	<0.0001
Yes	9 713	7.8	5 542	5	4 171	23		
No	113 839	91.9	99 717	96	14 122	78		
Drug use in past 3 months (n=122 456)							1615	<0.0001
Yes	73 837	59.6	60 464	58	13 373	74		
No	48 619	39.2	43 866	42	4 753	26		
STI diagnosis in past 12 months (n=122 734)							5296	<0.0001
Yes	15 605	12.6	10 280	10	5 325	29		
No	107 129	86.5	94 292	90	12 837	71		

PEP, post-exposure prophylaxis; PrEP, pre-exposure prophylactic; STI, sexually transmitted infection.

of the largest US 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 USA. 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 USA 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 USA.²⁵ The guidelines, set forth by the CDC, have a strong focus on objective risk (ie, 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 three 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 USA 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

Table 2 Multilevel mixed-effects regression models predicting current pre-exposure prophylactic use

Fixed-effects variables	Model 1 (null)	Model 2	95% CI	Model 3	95% CI
Demographics					
Age group (24 and under)					
25–29		2.21	(2.09 to 2.35)	2.21	(2.15 to 2.28)
30–49		3.20	(3.04 to 3.37)	3.19	(3.04 to 3.37)
50+		2.91	(2.73 to 3.1)	2.9	(2.82 to 3.01)
Race/ethnicity (white)					
Black		0.73	(0.69 to 0.78)	0.73	(0.71 to 0.76)
Latino		0.75	(0.71 to 0.78)	0.74	(0.73 to 0.76)
Multiracial		0.79	(0.74 to 0.84)	0.79	(0.76 to 0.81)
Other		0.82	(0.76 to 0.88)	0.82	(0.79 to 0.85)
Gender identity (male)					
Female (trans woman)		0.44	(0.28 to 0.7)	0.44	(0.35 to 0.56)
Something else		0.44	(0.26 to 0.73)	0.42	(0.33 to 0.56)
Transgender person		0.71	(0.61 to 0.84)	0.71	(0.66 to 0.77)
Risk variables					
PEP use in past 12 months (ref: no)		3.94	(3.76 to 4.14)	3.94	(3.85 to 4.04)
STI diagnosis in past 12 months (ref: no)		3.34	(3.21 to 3.48)	3.34	(3.27 to 3.42)
Drug use in past 3 months (ref: no)		1.73	(1.67 to 1.8)	1.73	(1.7 to 1.76)
State-level variable					
Medicaid expansion status					
No expansion				0.69	(0.54 to 0.88)
Conditional expansion				0.73	(0.56 to 0.95)
Random effect components					
Interval OR (IOR-80)					
Medicaid expansion status					
No expansion				(0.37 to 1.30)	
Conditional expansion				(0.39 to 1.38)	
Intercept variance	0.21	0.15		0.12	
Interclass correlation coefficient (ICC)	0.06	0.04		0.04	
Median OR (MOR)	1.54	1.45		1.40	

PEP, post-exposure prophylaxis; STI, sexually transmitted infection.

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 ‘when 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 Thirty more inclusive set of clinical recommendations may have a much greater impact on PrEP uptake than traditional community outreach strategies; agencies and organisations 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. Online supplemental 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 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 (ie, OR) 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 (eg, state size),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 colour often live in smaller enclaves, and using the entire state 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 USA—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.

Finally, 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 used 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 colour. 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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Contributors PBC wrote and was the primary lead on all aspects of the paper. PBC and CG conceptualised the paper, with PBC performing the main analysis—both reviewed multiple 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, conceptualised 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.

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Ethics approval This study involves human participants and was approved by 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). Participants gave informed consent to participate in the study before taking part.

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