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RESEARCH ARTICLE

# Impact of insurance coverage on utilization of pre-exposure prophylaxis for HIV prevention

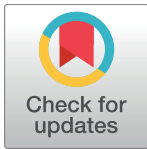
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**Data Availability Statement:** A minimum data set has been uploaded in order to protect the identity of the participants in this study. We are happy to make other data available, but request that interested individuals email the corresponding author (Rupa Patel, [rupapatel@wustl.edu](mailto:rupapatel@wustl.edu)) to ensure appropriate use since these are patient-level data.

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## Abstract

Pre-exposure prophylaxis (PrEP) can reduce U.S. HIV incidence. We assessed insurance coverage and its association with PrEP utilization. We reviewed patient data at three PrEP clinics (Jackson, Mississippi; St. Louis, Missouri; Providence, Rhode Island) from 2014–2015. The outcome, PrEP utilization, was defined as patient PrEP use at three months. Multivariable logistic regression was performed to determine the association between insurance coverage and PrEP utilization. Of 201 patients (Jackson: 34%; St. Louis: 28%; Providence: 28%), 91% were male, 51% were White, median age was 29 years, and 21% were uninsured; 82% of patients reported taking PrEP at three months. Insurance coverage was significantly associated with PrEP utilization. After adjusting for Medicaid-expansion and individual socio-demographics, insured patients were four times as likely to use PrEP services compared to the uninsured (OR: 4.49, 95% CI: 1.68–12.01;  $p = 0.003$ ). Disparities in insurance coverage are important considerations in implementation programs and may impede PrEP utilization.

## Introduction

In 2014, over 40,000 individuals were diagnosed with human immunodeficiency virus (HIV) infection in the United States (US) with the majority among men who have sex with men (MSM) [1]. There are large disparities in HIV incidence, with African Americans facing a disproportionate burden of new infections [1]. Pre-exposure prophylaxis (PrEP) refers to the use of antiretrovirals to prevent HIV infection prior to exposure. It is estimated that over 1.2 million

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adults in the US are at risk for HIV and would benefit from PrEP [2]. Taken as a daily single oral tablet, PrEP has been proven to prevent HIV infection in MSM and other populations [3,4]. PrEP implementation has become a national priority to reduce new HIV infections [5,6].

One potential barrier to wider PrEP use in the US is insurance coverage. Insurance coverage usually leads to increased access to healthcare and use of healthcare services [7]. However, 17.9% of adults ages 25–34 years were uninsured in 2015, despite the passage of the Affordable Care Act [8]. Few studies have evaluated whether insurance coverage impacts PrEP care [5]. We previously evaluated retention-in-care outcomes among patients enrolled in PrEP programs in three US cities; insurance was not found to affect PrEP care and retention among a subanalysis of MSM at these sites [9]. Recent data from participants in the US PrEP Demonstration Project showed that individuals who were non-white, uninsured, and of lower socioeconomic status reported barriers to accessing PrEP after the Demonstration Project ended [10]. White participants, in addition to those with health insurance, higher education, older age, and reported willingness to pay more for PrEP, were more likely to have continued PrEP after study completion [10]. These differences in PrEP use by race and socioeconomic status could potentially exacerbate existing disparities in HIV incidence.

To further explore the impact of insurance coverage on PrEP utilization in the US, we evaluated whether insurance status was associated with PrEP utilization among patients prescribed PrEP at clinics in three states with varied Medicaid expansion [11].

## Methods

We reviewed patients in clinical PrEP programs in Providence, Rhode Island, Jackson, Mississippi and St. Louis, Missouri from January 2014 to December 2015. In Rhode Island, PrEP patients were seen at a sexually transmitted diseases and HIV prevention clinic that was academically affiliated; patients were referred to the clinic from an onsite HIV clinic and other providers [9]. In Mississippi, PrEP patients were seen at a lesbian/gay/bisexual/transgender outpatient clinic; patients were referred from other providers and the state sexually transmitted diseases clinic [9]. In Missouri, PrEP patients were seen at an academic infectious diseases specialty clinic; referrals to this clinic were from community-based organizations, local outpatient providers, and an onsite HIV clinic [9]. All three sites were the major outpatient PrEP providers in their respective states. This analysis was a sub-study of an ongoing prospective observational cohort [9]. Inclusion criteria were patients who were prescribed PrEP for at least three months. Demographic and insurance-related information was collected during clinical visits as part of routine patient care procedures and data was extracted from the electronic medical records. Demographic data included age, gender, race, ethnicity, education, income, and insurance type. Insurance type included having no insurance or having private or public insurance (i.e. government-funded) [9].

As a part of the Affordable Care Act, state governments could choose to expand Medicaid eligibility to those with annual incomes below 138% of the federal poverty level [12]. Nineteen U.S. states have not yet expanded Medicaid. At the time of this study, Rhode Island was the only Medicaid-expansion state among our three sites. We created an indicator variable for state Medicaid expansion and grouped study states according to this status. Insurance status was further categorized by whether patients who had either private or public insurance. Private insurance included individual or group commercial insurance. Public insurance was defined as Medicaid, Medicare, or another public insurance program.

This study was approved by the Institutional Review Boards at Washington University in St. Louis, University of Mississippi, and The Miriam Hospital for human subject's research. All participants provided written informed consent.

## Statistical analysis

The primary outcome was PrEP utilization, defined as patient report of taking PrEP at their three-month follow-up evaluation. Evaluations were performed in person as part of a routine clinical care visit or over the phone, when a physical appointment was not possible; routine clinical care was administered as per national guidelines [9]. Independent variables included age, race, education, income, insurance status, state Medicaid expansion, and study site. We created a Medicaid state expansion variable to account for the fact that in states with Medicaid expansion, it may be easier to acquire insurance, which may affect care utilization [13,14]. The association between independent variables and the outcome was assessed using chi-square or Fisher's exact tests. To investigate factors predicting the primary outcome, univariate and multivariate logistic regression models were used. Odds ratios (OR) and 95% confidence intervals (CI) were calculated. We assessed the impact of insurance on PrEP utilization using a multivariable logistic regression Model 1 and adjusted for age, race, education, income, and individual insurance coverage. In subsequent models, we also assessed how insurance was affected by the addition of state Medicaid expansion (Model 2) and study site (Model 3). We accounted for Medicaid expansion since this affects the ability to obtain insurance for people within specific states. To control for the study site within the analysis, we looked at study site in two ways: 1) with Mississippi as a referent (versus Missouri and Rhode Island) and 2) with each state separately with Rhode Island as a referent. All statistical tests were two-sided and the significance level was set at 0.05.

## Results

Overall, 201 PrEP patients were included into the analysis (33.8% from Mississippi, 27.9% from Missouri, and 38.3% from Rhode Island). Eighty-two percent of patients reported taking PrEP at three months.

Patient characteristics included median age of 29 years (Interquartile Range [IQR] 24–37), 91.0% were male, 51.2% were white, 34.3% were African American, 6.0% were Latino, 64.7% were college graduates, 79.1% had either public or private insurance, and median income was \$25,000 (IQR \$7,200–\$50,000) (Table 1). Almost all patients (95%) were insured in Providence, 49% in Jackson and 95% in St. Louis ( $P < 0.01$ ).

Univariate and multivariate logistic regression analyses are shown in Table 2. In the initial multivariate logistic regression analysis model (Model 1), which included age, race, education, income and individual insurance coverage, having insurance was significantly and positively associated with PrEP utilization (OR = 3.48, 95% CI: 1.39–8.69). Insurance remained significant when adjusting for state Medicaid expansion (Model 2) as well as for study site (Model 3) (OR = 4.49, 95% CI: 1.68–12.01 and OR = 3.98, 95% CI: 1.36–11.63, respectively). None of the other independent variables were found to be significant predictors. When looking at the effect of the study site using Jackson, Mississippi as a referent on the outcome, there were no significant findings in univariate or multivariate analysis (i.e. adjusting for demographics, insurance, and study site) (unadjusted OR = 1.74, 95% CI: 0.83–3.63 and adjusted OR = 0.79, 95% CI: 0.29–2.18). The significance of insurance was not affected by this re-categorization of study site using Jackson, Mississippi as the referent (OR = 4.15, 95% CI: 1.49–11.59).

## Discussion

We found that having insurance coverage may significantly impact PrEP utilization. Insured patients in our sample were four times as likely to use PrEP services compared to the uninsured. Our results should be taken into the context that nearly one out of five young adults are uninsured and that national HIV burden is highest in the southern US, where non-Medicaid

**Table 1. Study population characteristics (N = 201).**

Characteristic	Missed 3-month Appointment N = 36	Attended 3-month Appointment N = 165	P value
Gender			0.34 <sup>†</sup>
Male	31 (86.1)	152 (92.1)	
Female	5 (13.9)	12 (7.3)	
Transgender	0 (0.0)	1 (0.6)	
Age (Years)			<b>0.02</b>
18–24	15 (41.7)	36 (31.8)	
25–34	9 (25.0)	75 (45.5)	
>34	12 (33.3)	54 (32.7)	
Race			0.09 <sup>†</sup>
White	15 (41.7)	88 (53.3)	
African American	18 (50.0)	51 (30.9)	
Latino	0 (0.0)	12 (7.3)	
Mixed/Other	3 (8.3)	14 (8.5)	
Education			0.91
< College	13 (36.1)	58 (35.2)	
≥ College	23 (63.9)	107 (64.8)	
Income			0.13
< \$25000	22 (61.1)	78 (47.3)	
≥ \$25000	14 (38.9)	87 (52.7)	
Insurance			<b>0.003</b>
None	15 (41.7)	27 (16.4)	
Public	4 (11.1)	24 (14.5)	
Private	17 (47.2)	114 (69.1)	
State Medicaid Expansion*			0.65
No	21 (58.3)	103 (62.4)	
Yes	15 (41.7)	62 (37.6)	
Site			0.10
Providence	15 (41.7)	62 (37.6)	
St. Louis	5 (13.9)	51 (30.9)	
Jackson	16 (44.4)	52 (31.5)	

<sup>†</sup>Fisher’s Exact Test

\*Medicaid Expansion State: Rhode Island

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expansion limits insurance coverage eligibility [1,8]. Furthermore, in the context of upcoming proposed changes to the healthcare system, our findings indicate that there could be potential setbacks in PrEP implementation if reforms make accessing insurance more difficult [14,15]. The proposed American Health Care Act would cause 14 million people to lose their insurance in 2018 and 24 million over the next decade [15,16]. Specific reforms include changing the federal match for Medicaid to a block grant policy where the government caps the amount of money allotted per Medicaid enrollee and would match only 50% of costs per enrollee versus the 90% under the Affordable Care Act [14,15]. This change in Medicaid policy would cause 17 million Americans to lose their insurance within 10 years. Other reforms that have the potential to change insurance access or quality of coverage to pay for PrEP-related care and costs for young adults, a group with high HIV incidence, include changing a mandate for employers to provide insurance as well as a \$7 billion reduction in federal subsidies to reduce deductible and copayment costs for care for enrollees. Inadequate insurance coverage for at-

**Table 2. Univariate and multivariate logistic regression analysis for HIV pre-exposure prophylaxis utilization among 201 patients in three US cities (Jackson, Mississippi; St. Louis, Missouri; Providence, Rhode Island) from January 2014 to December 2015.**

Characteristic	Unadjusted OR (95% CI)	Model 1 * aOR (95% CI)	Model 2 ** aOR (95% CI)	Model 3 *** aOR (95% CI)
Age Group				
< 30 years	1.0	1.0	1.0	1.0
≥ 30 years	1.21 (0.58–2.49)	0.92 (0.41–2.10)	0.95 (0.41–2.18)	0.95 (0.41–2.19)
Race				
White	1.0	1.0	1.0	1.0
Not White	0.63 (0.30–1.30)	0.99 (0.40–2.47)	0.86 (0.34–2.19)	0.90 (0.35–2.35)
Education				
< College	1.0	1.0	1.0	1.0
≥ College	1.04 (0.49–2.21)	0.87 (0.38–1.98)	0.81 (0.36–1.85)	0.82 (0.36–1.88)
Income				
< \$25000	1.0	1.0	1.0	1.0
≥ \$25000	1.75 (0.84–3.66)	1.19 (0.49–2.90)	1.23 (0.50–3.00)	1.21 (0.50–2.97)
Insurance				
No	1.0	1.0	1.0	1.0
Yes (public or private)	<b>3.65 (1.67–7.97)</b>	<b>3.48 (1.39–8.69)</b>	<b>4.49 (1.68–12.01)</b>	<b>3.98 (1.36–11.63)</b>
State Medicaid Expansion <sup>†</sup>				
No	1.0	-	1.0	-
Yes	0.84 (0.41–1.76)	-	0.46 (0.19–1.10)	-
Site				
Providence	1.0	-	-	1.0
St. Louis	2.47 (0.84–7.25)	-	-	2.58 (0.86–7.70)
Jackson	0.79 (0.36–1.74)	-	-	1.82 (0.62–5.38)

Abbreviations: OR, odds ratio; aOR, adjusted OR

\*Adjusted for age, race, education, income, and individual insurance coverage

\*\*Adjusted for age, race, education, income, individual insurance coverage, and state Medicaid expansion

\*\*\*Adjusted for age, race, education, income, individual insurance coverage, and study site

<sup>†</sup>Medicaid Expansion State: Rhode Island

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risk individuals undermines the goal of reducing HIV incidence through PrEP and other preventative care.

Since Medicaid eligibility expansion increases the ability to obtain insurance despite variations in patient backgrounds (i.e. race, income, age, etc.), we evaluated this concept within our analysis. In this sample, adjusting for Medicaid expansion using multiple logistic regression did not diminish insurance coverage’s association with PrEP utilization. This study is limited by the inclusion of only one Medicaid expansion state; however our analyses highlighted private insurance’s effect on PrEP utilization given the effect of insurance remained significant after controlling separately for Medicaid expansion status in the model. Further larger studies should explore Medicaid expansion’s impact on PrEP use. Such findings could help influence retaining stronger preventive care policies within the context of today’s health care policy reforms.

Prior studies have demonstrated that insurance coverage influences PrEP care [5,10]. Among patients in The Demo Project in San Francisco, 11.8% discontinued PrEP due to leaving their health plan. Prior work has demonstrated that a significant facilitator to PrEP uptake is free access [17]. A modeling study conducted in Georgia, a Medicaid non-expansion state, among 562 MSM predicted that only 15% of MSM would achieve protection from HIV by

using PrEP largely due to significant barriers to health care access, which was defined as receiving a prescription and paying provider visits and laboratory-related costs [18]. Although the manufacturer of PrEP, Gilead Sciences, has a patient drug assistance program, the current study demonstrates that ongoing structural gaps may impede PrEP use by those who might benefit most [19]. The findings are particularly notable, given that the patients in this study received care in specialized clinics, with staff available to help them navigate the paperwork needed to access insurance and/or medication.

Limitations of the study include a small sample size, a large portion of uninsured patients came from one site (MS), and that insurance coverage was examined at one time point (i.e. initial evaluation). Future studies should include other clinical settings, rural populations, more states with varying Medicaid expansion, a method to capture insurance mobility, and evaluate insurance coverage's effects on other aspects of PrEP care. Examining these factors will provide important insights for PrEP program planners, policy makers, and others on how to effectively improve PrEP implementation, especially for individuals with financial barriers and who lack insurance.

Insurance coverage had a significant and positive impact on PrEP utilization. Disparities in insurance coverage may impede PrEP implementation in non-trial clinical settings and may exacerbate disparities in PrEP access. These findings from three diverse areas suggest state- and local-level PrEP implementation efforts should address barriers to insurance coverage as a critical component to successful programmatic efforts.

## Supporting information

**S1 File. Insurance and retention in PrEP care dataset.**  
(XLSX)

## Author Contributions

**Conceptualization:** RRP LM AN TM CEO PAC.

**Data curation:** RRP LM LCH CEO PAC.

**Formal analysis:** LCH CEO JL.

**Funding acquisition:** RRP PAC LM.

**Investigation:** RRP PAC LM LCH.

**Methodology:** RRP LM AN TM LCH CEO JL KHM PAC.

**Project administration:** RRP PAC LM CEO.

**Validation:** RRP LM TM LCH CEO JL PAC.

**Visualization:** LCH CEO JL.

**Writing – original draft:** RRP PAC.

**Writing – review & editing:** RRP LM AN TM LCH CEO JL KHM PAC.

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