DOI: 10.1111/1475-6773.13285

RESEARCH BRIEF

HSR Health Services Research

Out-of-pocket costs and HIV pre-exposure prophylaxis persistence in a US multicity demonstration project

Nathan W. Furukawa MD, MPH[1,2] | John A. Schneider MD, MPH[3] | Megan E. Coleman FNP[4] | Jeffrey B. Wiener PhD[1] | Ram K. Shrestha PhD[1] | Dawn K. Smith MD, MS[1]

[1]Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, Georgia

[2]Epidemic Intelligence Service, Center for Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention, Atlanta, Georgia

[3]Departments of Medicine & Public Health Sciences, University of Chicago, Chicago, Illinois

[4]Whitman Walker Health, Washington, District of Columbia

Correspondence
Nathan W. Furukawa, MD, MPH, Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road NE Mailstop E45/US8-4, Atlanta, GA 30329.
Email: nmt6@cdc.gov

Funding information
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Abstract

Objective: To evaluate whether out-of-pocket (OOP) costs reduced HIV pre-exposure prophylaxis (PrEP) persistence.

Data Source: Participants from five urban community health centers (CHCs) in four US cities enrolled in a PrEP demonstration project from September 2014 to August 2017.

Study Design: Patients initiating PrEP were followed quarterly until they withdrew from PrEP care or the study ended. Self-reported OOP medication and clinic visit costs were assessed by semiannual questionnaires. Persistence was defined as the time from study enrollment to the last visit after which two subsequent 3-month visits were missed. Multivariable Cox proportional hazard regression was used to assess the effect of demographics, insurance, and OOP costs on PrEP persistence.

Principal Findings: Among 918 participants with OOP cost data, the average quarterly OOP cost was $34 (median: $5, IQR: $0-$25). Participants who were men, White, employed, completed college, and had commercial insurance had higher OOP costs. Higher OOP costs were not associated with lower PrEP persistence by Cox proportional hazards regression (adjusted hazard ratio = 1.00 per $50 increase, 95% CI = 0.97, 1.02).

Conclusion: Among patients receiving care from these urban CHCs, OOP costs were low and did not undermine PrEP persistence.

KEYWORDS
community health clinic, HIV prevention, out-of-pocket costs, persistence, pre-exposure prophylaxis

1 | BACKGROUND

HIV pre-exposure prophylaxis (PrEP) with daily oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) has been demonstrated to reduce the risk of acquiring HIV among persons whose sexual behaviors or injection drug use practices place them at ongoing risk of infection with HIV.[1-4] Recently, daily oral tenofovir alafenamide/emtricitabine has also been approved as PrEP for preventing male-male sexual transmission of HIV.[5] In order to be protected against HIV, persons on PrEP must both be adherent to taking daily PrEP and continue to engage in clinical care.[6,7] The relationship between low medication adherence and an increased risk of HIV infection has thoroughly described.[8] However, persistence, or the ability to retain patients longitudinally in PrEP care, has emerged as a key implementation challenge in increasing PrEP use: Approximately half of the patients prescribed PrEP drop out of PrEP care by 12 months.[9-14]

The out-of-pocket (OOP) cost of PrEP care has been proposed as one barrier to persisting in PrEP care. The cost of PrEP care including medication, laboratory, and clinic visit costs was estimated to be

$12,913 annually at federally qualified health centers (FQHCs) using 340B drug pricing.[15] However, patients usually obtain PrEP medication through commercial health insurance, public health insurance plans including Medicaid and Medicare, or assistance programs from the manufacturer that provides the drug for free for uninsured patients or pays the medication copayment for commercially insured patients. Insurance or assistance programs cover most of the cost of PrEP care, but any remaining OOP costs may still pose a barrier to PrEP persistence for some patients.[16,17] Past studies have demonstrated that lack of insurance was a barrier to PrEP persistence,[11,18] but other studies are mixed as to whether OOP costs negatively impact PrEP persistence.[9,13,19]

The goal of this study was to evaluate whether OOP costs affected PrEP persistence among persons receiving PrEP care at urban community health centers (CHCs).

What is Already Known on This Topic

- Pre-exposure prophylaxis (PrEP) is highly effective at preventing HIV infection, but only half of the patients who start PrEP continue it after 1 year.
- PrEP persistence, or the longitudinal retention in PrEP care, is necessary for the protection against HIV over time, and higher out-of-pocket (OOP) costs have been suggested to potentially associate with lower PrEP persistence.

What This Study Adds

- Among patients enrolled in a PrEP demonstration project at community health centers (CHCs), OOP costs were lower compared with other published studies and were not associated with reduced PrEP persistence.
- This study demonstrates that existing financial mechanisms can keep OOP costs low and CHCs may be ideal settings to scale up PrEP delivery to medically underserved populations.

2 | METHODS

2.1 | Study population

The Sustainable Health Center Implementation PrEP Pilot (SHIPP) study (ClinicalTrials.gov identifier: NCT02074891) was a 3-year observational cohort study across five CHCs in four cities designed to assess the demographic, behavioral, adherence, clinical outcomes, and cost elements of PrEP care. Three sites were FQHCs (Access Community and Howard Brown in Chicago, IL; and Whitman Walker in Washington, DC), one site was a public health clinic (Strawberry Mansion in Philadelphia, PA), and one site was a sexual health clinic (Open Arms in Jackson, MS). At the start of the study in September 2014, all persons aged 18 years or older who initiated PrEP at any of the five CHCs were offered enrollment into a medication adherence sub-study (MAS) until the recruitment goal was achieved. Persons enrolled in the MAS cohort completed self-report questionnaires at the time of their quarterly PrEP follow-up visits and had dried blood spot collection for tenofovir drug-level testing. MAS participants were followed every three months until they either were lost to follow-up or the study ending in March 2018 after the last enrolled participant had 12 months of follow-up. After full enrollment of the MAS cohort, all other persons on PrEP over the duration of the study were entered into an observation cohort where clinical, laboratory, and cost data were collected only from the electronic health record. The distribution of age, sex, gender, and race/ethnicity were similar in the MAS and observational cohorts.

Participants covered by commercial or public insurance had their PrEP medication, laboratory, and clinic visit fees billed to their insurance. Commercially insured participants were able to use the manufacturer copayment assistance program to cover medication copayments. Laboratory and clinic visit copayments were subject to a sliding scale based on income specific to each CHC. Uninsured participants accessed the medication through the manufacturer medication assistance program and paid laboratory and clinic visit fees using a sliding scale based on income specific to each CHC. Participants were prescribed TDF/FTC to either a commercial pharmacy of their choice or a co-located pharmacy for some participants seen at Whitman Walker or Howard Brown.

2.2 | Participant selection

Persons enrolled in the MAS cohort at any of the five study sites were included in this analysis. Reported OOP costs were first collected at the 6-month follow-up visit questionnaire. Participants who were lost to follow-up before they could complete the OOP cost question from the semiannual visit questionnaire were excluded from this analysis.

2.3 | Measurements

Self-reported medication and clinic visit OOP costs were captured during semiannual visit questionnaires: *"How much did you pay the last time you filled a prescription for PrEP medication?"* and *"How much was the co-pay for your last PrEP clinic visit?"* Three-month total OOP costs were calculated as the sum of 3-month medication and clinic visit OOP costs assuming each participant had 3 monthly fills of TDF/FTC and 1 follow-up visit per quarter. Medication and clinic visit OOP costs were averaged over multiple 6-month questionnaires to generate mean medication, clinic visit, and total OOP costs. Laboratory OOP costs were not asked and therefore unable to be included in total OOP costs.

PrEP persistence was defined as the difference between the date of enrollment in the MAS cohort and the date after which an enrolled

participant then missed two consecutive 3-month study visits and therefore stopped receiving prescriptions for PrEP. Completion of the quarterly visit questionnaire was required for the visit to be counted toward PrEP persistence. Two consecutive missed visits were used to define nonpersistence because a participant missing a single follow-up visit could reschedule but have that visit counted as their subsequent follow-up visit if it fell outside a window of expected follow-up. All enrolled participants in the MAS cohort who had not seroconverted or exited the study were censored at the time the study ended.

2.4 | Statistical analysis

The age, gender, race/ethnicity, education, employment, insurance status, and PrEP persistence of participants included in the cost analysis were reported for each incremental $50 increase in quarterly total OOP costs: $0, $1-49, $50-99, and ≥$100. Chi-square analysis and Wilcoxon rank-sum tests were used to compare categorical demographic categories and median PrEP persistence across the 4 categories of OOP costs. Three-month OOP medication, clinic visit, and total costs were reported in $50 increments and compared across insurance type using chi-square analysis. Mean 3-month OOP medication, clinic visit, and total costs were also compared across insurance type using analysis of variance.

A Cox proportional hazards regression model was used to assess the effect of study site, participant demographics, and OOP costs on PrEP persistence. OOP costs standardized to a 3-month period were time-varied in the Cox proportional hazards regression to account for variations in OOP costs over time. OOP costs were entered into the model as a continuous variable divided by $50 to represent the incremental change of $50 per quarter. Covariates with $P < .10$ in the bivariate analysis were then included in a multivariable Cox proportional hazards regression model to estimate the adjusted effect of OOP costs on PrEP persistence. A sensitivity analysis with a stricter definition of PrEP persistence that did not allow any missed visits was performed.

2.5 | Ethics

Written informed consent was obtained for individuals enrolled in the MAS cohort for extended interviews, dried blood spot drug-level testing, and antiretroviral resistance testing for participants who acquired HIV while taking PrEP. Receipt of PrEP care was not contingent on consenting to the sub-study. Ethical approval was obtained from the CDC Institutional Review Board (IRB) for all sites except the Philadelphia site which obtained separate IRB approval from the Philadelphia Department of Health.

3 | RESULTS

Over the course of the MAS enrollment from September 2014 to August 2017, 1,420 participants were enrolled in the MAS cohort and follow-up continued through March 2018. Of the 1420 participants enrolled in the sub-study, 918 (64.6 percent) had OOP cost data collected from one or more semiannual visit questionnaires and were included in the analysis. Excluded participants were more likely to be young, female, Black, unemployed, have a high school education or less, have public insurance, and have lower PrEP persistence than participants who were included (data not shown). Of the 918 participants included in the cost analysis, 429 (46.7 percent) were between 25-34 years old, 881 (88.3 percent) were male, 290 (31.6 percent) were non-Hispanic Black, 140 (15.3 percent) were Hispanic/Latino, 359 (39.1 percent) had an education of high school or less, 695 (75.7 percent) were employed, and 807 (87.9 percent) had insurance (Table 1). Further, 420 (45.8 percent) reported $0 in quarterly OOP costs, 399 (43.4 percent) reported $1-49, 41 (4.5 percent) reported $50-99, and 58 (6.3 percent) reported ≥$100.

Quarterly clinical and medication OOP costs were compared by study site, age, race/ethnicity, education, employment, insurance status, and PrEP persistence (Table 1). Participants enrolled at Open Arms in Jackson, MS, or Whitman Walker in Washington, DC, tended to have higher clinical and medication OOP costs than participants enrolled at Access Community or Howard Brown in Chicago, IL, or Strawberry Mansion in Philadelphia, PA ($P < .001$ for group difference). Participants who were men, non-Hispanic White, had a bachelor's degree or higher, were employed, and had commercial insurance had higher OOP costs compared with participants who were female, non-White, did not have a bachelor's degree, were unemployed, and had public or no insurance, respectively ($P < .001$ for group differences). Of the 290 non-Hispanic Black participants, 162 (55.9 percent) had $0 in quarterly OOP costs compared with 153/415 (36.9 percent) of non-Hispanic White participants and 71/140 (50.7 percent) of Hispanic/Latino participants. The median days of persistence was 378 (IQR: 204-566) for all participants. Paradoxically, participants who had $0 in OOP costs tended to have shorter persistence (median: 316 days, IQR: 190-496) than those with any (>$0) OOP costs (median: 423 days, IQR: 260-610; $P < .001$).The average quarterly OOP cost was $34 (median: $5, IQR: $0-$25) with $21 (63.4 percent) representing OOP medication costs and $12 (36.6 percent) representing OOP clinic visit costs. Participants with commercial insurance had an average quarterly OOP cost of $45 compared with $16 for public insurance and $10 for uninsured participants ($P = .002$; Table 2). Participants with commercial insurance were less likely to have $0 in total OOP costs (184/576, 31.9 percent) compared to participants with public insurance (177/231, 76.6 percent) or no insurance (59/111, 53.2 percent; $P < .001$).

A bivariate Cox proportional hazards regression model of PrEP persistence demonstrated that study site and age were both associated with differences in PrEP persistence (Table 3). Participants enrolled at Open Arms, Strawberry Mansion, and Whitman Walker had longer PrEP persistence than participants enrolled at Access Community and Howard Brown. Participants who were older had longer PrEP persistence (HR = 0.70 comparing participants ≥ 45 years to participants 18-24 years old, 95% CI = 0.53-0.91). Study site, age, employment, and OOP costs were included in the multivariable Cox proportional hazards regression model. In both the bivariate and

TABLE 1 Demographic characteristics and pre-exposure prophylaxis persistence by average quarterly medication and clinic visit out-of-pocket costs, Sustainable Health Center Implementation PrEP Pilot sub-study, 2014-2018 (N = 918)

	Total sample	$0	$1-49	$50-99	≥$100	*P*-value[a]
Total	918	420	399	41	58	
Study site, n (%)						
Access Community	52	34 (65.4)	12 (23.1)	2 (3.8)	4 (7.7)	<.001
Whitman Walker	356	112 (31.5)	193 (54.2)	18 (5.1)	33 (9.3)	
Strawberry Mansion	102	79 (77.5)	21 (20.6)	2 (2.0)	0	
Howard Brown	297	163 (54.9)	110 (37.0)	14 (4.7)	10 (3.4)	
Open Arms	111	32 (28.8)	63 (56.8)	5 (4.5)	11 (9.9)	
Age, n (%)						
8-24 y	176	90 (51.1)	69 (39.2)	6 (3.4)	11 (6.3)	.019
25-34 y	429	177 (41.3)	213 (49.7)	19 (4.4)	20 (4.7)	
35-44 y	162	72 (44.4)	68 (42.0)	7 (4.3)	15 (9.3)	
≥45 y	151	81 (53.6)	49 (32.5)	9 (6.0)	12 (7.9)	
Gender identity, n (%)						
Male	811	352 (43.4)	368 (45.4)	40 (4.9)	51 (6.3)	.001
Female	50	32 (64.0)	14 (28.0)	0	4 (8.0)	
Transgender male	12	10 (83.3)	2 (16.7)	0	0	
Transgender female	37	25 (67.6)	10 (27.0)	1 (2.7)	1 (2.7)	
Other/unknown	8	1 (12.5)	5 (62.5)	0	2 (25.0)	
Race/ethnicity, n (%)						
White, non-Hispanic/Latino	415	153 (36.9)	208 (50.1)	22 (5.3)	32 (7.7)	<.001
Black, non-Hispanic/Latino	290	162 (55.9)	102 (35.2)	9 (3.1)	17 (5.9)	
Hispanic/Latino	140	71 (50.7)	55 (39.3)	10 (7.1)	4 (2.9)	
Other	73	34 (46.6)	34 (46.6)	0	5 (6.8)	
Education, n (%)						
High school or less	359	217 (60.5)	111 (30.9)	16 (4.5)	15 (4.2)	<.001
Bachelors	313	117 (37.4)	164 (52.4)	16 (5.1)	16 (5.1)	
Postgraduate	243	84 (34.6)	123 (50.6)	9 (3.7)	27 (11.1)	
Unknown	3	2 (66.7)	1 (33.3)	0	0	
Employment, n (%)						
Employed	695	267 (38.4)	339 (48.8)	37 (5.3)	52 (7.5)	<.001
Student	48	22 (45.8)	21 (43.8)	2 (4.2)	3 (6.3)	
Unemployed	108	87 (80.6)	20 (18.5)	0	1 (0.9)	
Unknown	67	44 (65.7)	19 (28.4)	2 (3.0)	2 (3.0)	
Insurance status, n (%)						
Public	231	177 (76.6)	46 (19.9)	4 (1.7)	4 (1.7)	<.001
Private	576	184 (31.9)	305 (53.0)	34 (5.9)	53 (9.2)	
Uninsured	111	59 (53.2)	48 (43.2)	3 (2.7)	1 (0.9)	
Median persistence, days (IQR)	378 (204-566)	316 (190-496)	437 (258-606)	393 (201-702)	400 (307-658)	<.001

Abbreviations: IQR, interquartile range; OOP, out-of-pocket.

[a]*P*-values calculated from chi-square test except for Wilcoxon rank-sum test for median persistence.

multivariable models, OOP costs were not associated with a change in PrEP persistence (adjusted HR = 1.00 per increase of $50, 95% CI = 0.97, 1.02). Sensitivity analysis using a strict definition of PrEP persistence that did not allow for missed visits did not alter the lack of effect of OOP costs on PrEP persistence (adjusted HR = 0.99 per increase of $50, 95% CI = 0.97, 1.02).

TABLE 2 Medication, clinic visit, and total out-of-pocket costs by insurance type, Sustainable Health center Implementation PrEP Pilot sub-study, 2014-2018 (N = 918)

	Public n (%)	Commercial n (%)	Uninsured n (%)	*P*-value[a]
Total	231	576	111	
3-mo medication OOP costs				
$0	205 (88.7)	491 (85.2)	101 (91.0)	<.001
$1-49	22 (9.5)	24 (4.2)	6 (5.4)	
$50-99	1 (0.4)	24 (4.3)	3 (2.7)	
≥$100	3 (1.3)	36 (6.3)	1 (0.9)	
3-mo clinic visit OOP costs				
$0	196 (84.9)	201 (34.9)	65 (58.6)	<.001
$1-49	33 (14.3)	352 (61.1)	46 (41.4)	
$50-99	1 (0.4)	12 (2.1)	0	
≥$100	1 (0.4)	11 (1.9)	0	
Total 3-mo OOP costs				
$0	177 (76.6)	184 (31.9)	59 (53.2)	<.001
$1-49	46 (19.9)	305 (53.0)	48 (43.2)	
$50-99	4 (1.7)	34 (5.9)	3 (2.7)	
≥$100	4 (1.7)	53 (9.2)	1 (0.9)	
Mean medication OOP cost every 3 mo, $ (SD)	13 (121)	28 (134)	5 (31)	.092
Mean clinic visit OOP cost every 3 mo, $ (SD)	3 (13)	17 (32)	5 (9)	<.001
Mean total OOP costs every 3 mo, $ (SD)	16 (122)	45 (144)	10 (32)	.002

Abbreviations: OOP, out-of-pocket; SD, standard deviation.

[a]*P*-values calculated with chi-square analysis for categorical variables and analysis of variance for means

4 | CONCLUSIONS

Increasing the number of persons at risk of HIV infection who are taking PrEP is a key activity in the prevention pillar of the Ending the HIV Epidemic federal initiative.[20] Expanding delivery of PrEP in FQHCs and other CHCs is a key focus of the initiative since they care for medically underserved communities often with populations at higher risk of HIV. Therefore, understanding barriers to initiating and persisting in PrEP care in these settings is important in guiding its implementation and scale-up. Anticipated OOP costs could influence an individual's decision to seek out PrEP, complete the necessary testing, and initiate PrEP, while actual OOP costs, if substantial, could detrimentally affect PrEP adherence or persistence.11,16-18,21 This analysis attempted to answer whether OOP costs reduced PrEP persistence among individuals on PrEP in a CHC. Among this racially and socioeconomically diverse cohort, we found that medication and clinic visit OOP costs were $0 for nearly half of the patients and <$50 for nearly 90 percent of patients. Further, these OOP costs did not have an adverse effect on PrEP persistence, even after controlling for potential confounding factors. In fact, those with $0 in OOP costs had lower PrEP persistence, though this likely reflects the fact that OOP costs are lowest in CHC settings for the most medically underserved patients who may discontinue PrEP for other reasons. Overall, these findings suggest that delivering PrEP to communities at high risk of HIV is feasible and that there are existing ways to cover patients wanting PrEP so that they incur few OOP costs.

The low OOP cost of PrEP among patients attending urban CHCs and its lack of contribution to PrEP discontinuation in this setting is encouraging and adds to the growing literature on PrEP persistence. Chan and colleagues similarly found that OOP costs were not associated with PrEP discontinuation among patients attending sexual health and infectious disease clinics.[9] Further, Marcus and colleagues found that higher OOP costs were associated with lower adherence but not discontinuation in the Kaiser integrated managed care system.[19] Finally, Coy and colleagues demonstrated that medication copayments>$20 per month were associated with lower PrEP persistence among a national sample of persons using a single pharmacy chain whom 80 percent had commercial insurance.[13] Taken together, this suggests OOP costs can negatively impact PrEP persistence when high enough, but that OOP costs from PrEP care through CHCs may be low enough to not detrimentally impact persistence.

These findings should be interpreted with an understanding of the limitations inherent in this study. Firstly, cost data were

TABLE 3 Cox regression analysis of pre-exposure prophylaxis persistence, Sustainable Health center Implementation PrEP Pilot sub-study, 2014-2018 (N = 918)

	Bivariate		Multivariable	
	HR (95% CI)	*P*-value	HR (95% CI)	*P*-value
3-mo OOP costs (per $50 increment)	0.99 (0.96, 1.02)	.882	1.00 (0.97, 1.02)	.792
Study site		<.001		<.001
Access Community	Referent		Referent	
Whitman Walker	0.66 (0.48, 0.90)	.009	0.67 (0.48, 0.93)	.016
Strawberry Mansion	0.56 (0.38, 0.83)	.004	0.58 (0.39, 0.85)	.006
Howard Brown	1.03 (0.75, 1.43)	.839	1.05 (0.75, 1.46)	.775
Open Arms	0.33 (0.22, 0.51)	<.001	0.34 (0.22, 0.52)	<.001
Age		.037		.029
8-24 y	Referent		Referent	
25-34 y	0.86 (0.70, 1.06)	.153	0.88 (0.66, 1.02)	.072
35-44 y	0.75 (0.58, 0.97)	.028	0.72 (0.55, 0.94)	.014
≥45 y	0.70 (0.53, 0.91)	.009	0.68 (0.51, 0.91)	.008
Gender identity		.361		
Male	Referent			
Female	0.95 (0.67, 1.35)	.776		
Transgender male	1.32 (0.66, 2.65)	.439		
Transgender female	1.33 (0.90, 1.98)	.152		
Race/ethnicity		.296		
White, non-Hispanic/Latino	Referent			
Black, non-Hispanic/Latino	0.94 (0.78, 1.14)	.530		
Hispanic/Latino	1.18 (0.94, 1.48)	.159		
Other	1.11 (0.83, 1.49)	.482		
Education		.884		
High school or less	Referent			
Bachelors	0.96 (0.80, 1.16)	.665		
Postgraduate	0.96 (0.79, 1.17)	.677		
Employment		.070		.357
Employed	Referent		Referent	
Student	1.53 (1.09, 2.16)	.015	1.35 (0.95, 1.93)	.100
Unemployed	1.18 (0.92, 1.50)	.197	1.10 (0.85, 1.42)	.456
Insurance Status		.309		
Public	Referent			
Commercial	0.89 (0.74, 1.07)	.232		
Uninsured	0.82 (0.62, 1.09)	.162		

Abbreviations: CI, confidence interval; HR, hazard ratio; OOP, out-of-pocket.

missing for one third of sub-study participants because they were lost to follow-up before cost data could be assessed at the 6-month visit. These individuals differed demographically from the sample included in the analysis, and their early discontinuation may have been associated with higher OOP costs that they had less of an ability to pay. Secondly, OOP cost data were only collected for clinical and medication OOP costs and did not include OOP laboratory costs. A prior analysis suggested that billable laboratory costs might be up to $1721 per year for PrEP,[15] though most patients would likely pay significantly lower or no laboratory OOP costs if they receive care at a CHC. Third, our analysis was only able to take absolute OOP costs into account as household income was not reliably recorded at study enrollment. Cost relative to income may be a better predictor of PrEP persistence because it can reflect an individual's ability to pay. Finally, OOP costs were self-reported semiannually and subject to recall bias. The

likelihood of accurately reporting OOP costs may be confounded by the perceived level of benefit of PrEP.

Additional research designed to capture a more complete accounting of all OOP costs associated with PrEP care including medication, clinical, and laboratory costs is needed and should be collected shortly after starting PrEP to avoid selection bias. OOP costs should also be compared in relation to household income as education, employment status, and insurance status may not entirely capture an individual's means to pay even limited OOP costs. Finally, the effect of programs that reduce OOP costs on PrEP initiation and persistence is not known. Further research that assesses the impact of Medicaid expansion for low-income adults and manufacturer, state, and federal medication assistance programs on PrEP initiation and persistence is needed. A more complete understanding of the relationship between perceived and actual OOP costs and progression along the PrEP care continuum will help guide efforts to increase interest, uptake, adherence, and persistence in PrEP.

ACKNOWLEDGMENTS

Joint Acknowledgment/Disclosure Statement: The Sustainable Health Center Implementation PrEP Pilot Study was funded by the Centers for Disease Control and Prevention and donations provided to the CDC Foundation.

Disclosure: The findings and conclusions in this article are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

ORCID

Nathan W. Furukawa https://orcid.org/0000-0002-4268-0556

REFERENCES

1. Baeten JM, Donnell D, Ndase P, et al. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *N Engl J Med*. 2012;367(5):399-410.
2. Choopanya K, Martin M, Suntharasamai P, et al. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet*. 2013;381(9883):2083-2090.
3. Grant RM, Lama JR, Anderson PL, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med*. 2010;363(27):2587-2599.
4. Thigpen MC, Kebaabetswe PM, Paxton LA, et al. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *N Engl J Med*. 2012;367(5):423-434.
5. Hare CB, Coll J, Ruane P, et al. The Phase 3 DISCOVER Study: Daily F/TAF or F/TDF for HIV Pre-Exposure Prophylaxis. Presented at: Conference on Retroviruses and Opportunistic Infections; 2019; Seattle, Washington, U.S.A.
6. Marcus JL, Hurley LB, Nguyen DP, et al. Redefining human immunodeficiency virus (HIV) preexposure prophylaxis failures. *Clin Infect Dis*. 2017;65(10):1768-1769.
7. Serota DP, Rosenberg ES, Lockard AM, et al. Beyond the Biomedical: Preexposure prophylaxis failures in a cohort of young black men who have sex with men in Atlanta, Georgia. *Clin Infect Dis*. 2018;67(6):965-970.
8. Riddell J, Amico KR, Mayer KH. HIV preexposure prophylaxis: a review. *JAMA*. 2018;319(12):1261-1268.
9. Chan PA, Mena L, Patel R, et al. Retention in care outcomes for HIV pre-exposure prophylaxis implementation programmes among men who have sex with men in three US cities. *J Int AIDS Soc*. 2016;19(1):20903.
10. Rusie LK, Orengo C, Burrell D, et al. Preexposure prophylaxis initiation and retention in care over 5 years, 2012–2017: are quarterly visits too much? *Clin Infect Dis*. 2018;67(2):283-287.
11. Whitfield T, John S, Rendina H, et al. Why I Quit Pre-Exposure Prophylaxis (PrEP)? A mixed-method study exploring reasons for PrEP discontinuation and potential re-initiation among gay and bisexual men. *AIDS Behav*. 2018;22(11):3566-3575.
12. Lankowski AJ, Bien-Gund CH, Patel VV, et al. PrEP in the Real World: Predictors of 6-month retention in a diverse urban cohort. *AIDS Behav*. 2019;23(7):1797-1802.
13. Coy KC, Hazen RJ, Kirkham HS, et al. Persistence on HIV preexposure prophylaxis medication over a 2-year period among a national sample of 7148 PrEP users, United States, 2015 to 2017. *J Int AIDS Soc*. 2019;22(2):e25252.
14. Huang Y, Tao G, Smith D, et al. Persistence with HIV Preexposure prophylaxis in the United States, 2012-2016. Presented at: Conference on Retroviruses and Opportunistic Infections; 2019; Seattle, Washington.
15. Smith DK, Van Handel M, Huggins R. Estimated coverage to address financial barriers to HIV preexposure prophylaxis among persons with indications for its use, United States, 2015. *J Acquir Immune Defic Syndr*. 2017;76(5):465-472.
16. Patel R, Crane J, Farag C, et al. Out-of-pocket costs impact PrEP use among young adult MSM in the US healthcare system. Presented at: Conference on Retroviruses and Opportunistic Infections, 2018; Boston, MA.
17. Rolle CP, Rosenberg ES, Luisi N, et al. Willingness to use pre-exposure prophylaxis among Black and White men who have sex with men in Atlanta, Georgia. *Int J STD AIDS*. 2017;28(9):849-857.
18. Patel RR, Mena L, Nunn A, et al. Impact of insurance coverage on utilization of pre-exposure prophylaxis for HIV prevention. *PLoS ONE*. 2017;12(5):e0178737.
19. Marcus JL, Hurley LB, Hare CB, et al. Preexposure prophylaxis for HIV prevention in a large integrated health care system: adherence, renal safety, and discontinuation. *J Acquir Immune Defic Syndr*. 2016;73(5):540-546.
20. Fauci AS, Redfield RR, Sigounas G, et al. Ending the HIV epidemic: a plan for the United States ending the HIV epidemic editorial. *JAMA*. 2019;321(9):844-845.
21. Marks SJ, Merchant RC, Clark MA, et al. Potential healthcare insurance and provider barriers to pre-exposure prophylaxis utilization among young men who have sex with men. *AIDS Patient Care STDS*. 2017;31(11):470-478.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

How to cite this article: Furukawa NW, Schneider JA, Coleman ME, Wiener JB, Shrestha RK, Smith DK. Out-of-pocket costs and HIV pre-exposure prophylaxis persistence in a US multicity demonstration project. *Health Serv Res*. 2020;55:524–530. https://doi.org/10.1111/1475-6773.13285