


Costs of Providing Preexposure Prophylaxis for HIV Prevention at Community Health Centers in the United States

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Ram K. Shrestha, PhD¹ ; Nicholas Davis, MS²;
Megan Coleman, DNP, MSN³; Laura K. Rusie, ScM²;
and Dawn K. Smith, MD, MS, MPH¹

Abstract

Objective: Preexposure prophylaxis (PrEP) is recommended for people at risk of acquiring HIV. We assessed billable costs associated with PrEP delivery at community health centers.

Methods: The Sustainable Health Center Implementation PrEP Pilot (SHIPP) study is an observational cohort of people receiving daily oral PrEP at participating federally qualified health centers and other community health centers. We assessed health care utilization and billable costs of providing PrEP at 2 health centers, 1 in Chicago, Illinois, and 1 in Washington, DC, from 2014 to 2018. The health centers followed the clinical practice guidelines for PrEP provision, including regular visits with health care providers and ongoing laboratory monitoring. Using clinic billing records and Current Procedural Terminology (CPT) coding, we retrospectively extracted data on the frequency and costs (in 2017 US dollars) of PrEP clinic visits and laboratory screening, for each patient, for 12 months since first PrEP prescription.

Results: The average annual number of PrEP clinic visits and associated laboratory screens per patient was 5.1 visits and 25.2 screens in Chicago (n = 482 patients) and 5.4 visits and 24.8 screens in Washington, DC (n = 56 patients). The average annual PrEP billable cost per patient was \$583 for clinic visits and \$1070 for laboratory screens in Chicago and \$923 for clinic visits and \$1018 for laboratory screens in Washington, DC. The average annual total cost per patient was \$1653 (95% CI, \$1639-\$1668) in Chicago and \$1941 (95% CI, \$1811-\$2071) in Washington, DC.

Conclusions: Our analysis, which provides PrEP billable cost estimates based on empirical data, may help inform health care providers who are considering implementing this HIV prevention strategy.

Keywords

HIV prevention, preexposure prophylaxis, PrEP implementation, economic evaluation, cost-effectiveness

An estimated 35 924 new HIV infections occurred in 2019 in the United States,¹ despite the availability of effective HIV treatment and prevention measures, including preexposure prophylaxis (PrEP).² PrEP with daily tenofovir disoproxil fumarate co-formulated with emtricitabine (F/TDF [Truvada]) is shown to be highly effective in preventing HIV acquisition in all populations at risk for HIV, including men, women, and people who inject drugs. More recently, tenofovir alafenamide co-formulated with emtricitabine (F/TAF [Descovy]) has also been shown to be effective for men and transgender women who have sex with men.³⁻⁶ Furthermore, PrEP is a major component of the new federal initiative, Ending the HIV Epidemic in the United States, which seeks to reduce the number of new HIV infections by 75% in 5

years and at least 90% in 10 years.⁷ A wide implementation and coverage of PrEP in the populations at greatest risk of

¹ Division of HIV Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, Atlanta, GA, USA

² Howard Brown Health, Chicago, IL, USA

³ Whitman-Walker Health, Washington, DC, USA

Corresponding Author:

Ram K. Shrestha, PhD, Centers for Disease Control and Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Division of HIV Prevention, 1600 Clifton Rd NE, MS E-48, Atlanta, GA 30329, USA.

Email: rshrestha@cdc.gov

HIV acquisition can be critical in achieving these prevention goals.

Awareness and use of PrEP have increased substantially since the US Food and Drug Administration approved F/TDF for PrEP in 2012.⁸⁻¹⁰ An increasing number of state and local health departments is interested in supporting PrEP implementation. A survey of local health departments in 2015 showed that 29% were already engaged in at least 1 PrEP implementation activity, and others were expecting to do so.¹¹ Federally qualified health centers (FQHCs) are potential sites to deliver PrEP because they serve racial and ethnic minority populations with higher risk for HIV acquisition, but a national survey of FQHCs indicated that only 19% of them offered PrEP.¹² Nationally, PrEP coverage among people with indications for PrEP has remained low, particularly among racial and ethnic minority and female populations.¹³ While an estimated 1.2 million people had indications for PrEP, only 22.9% overall, 8.0% of African American people, and 9.6% of women with indications for PrEP were prescribed PrEP in 2019.¹⁴

In 2019, the US Preventive Services Task Force recommended (grade A)¹⁵ that health care providers offer PrEP to those with indications for PrEP, based on sexual and drug use behaviors that suggest a substantial risk of HIV acquisition.¹⁶ The 2017 US Public Health Service clinical practice guidelines provide details on screening for indications, prescribing, and adherence support for people receiving PrEP.¹⁶ Although a wide range of health care providers and clinics could provide PrEP, the delivery, laboratory testing, adherence support, and concerns about anticipated cost to programs and out-of-pocket costs to patients are major barriers that potentially limit wider coverage of PrEP nationwide.^{16,17} In 2014, the Centers for Disease Control and Prevention (CDC) launched the Sustainable Health Center Implementation PrEP Pilot (SHIPP) study¹⁸ to evaluate health service implementation challenges, including delivery, health outcomes, and sustainability of PrEP provision in community health centers. We assessed health care utilization and billable costs of PrEP use at 2 FQHCs that provide sexual health and primary care services in communities with high HIV incidence and prevalence.

Methods

SHIPP Study Design

The SHIPP study, conducted from 2014 to 2019, was an observational study of a cohort of people receiving daily oral PrEP at 5 participating community health centers.¹⁷ The delivery of PrEP care involved several phases.^{16,17} First, clinicians assessed patients for PrEP indications, including taking their sexual and drug use history; documenting patients' HIV, sexually transmitted infections (STIs), and hepatitis B status and renal function; ruling out potential acute HIV infection; and assessing pregnancy status for patients with childbearing potential. Second, the patients choosing to initiate PrEP were prescribed a ≤ 90 -day supply of F/TDF daily

for PrEP for their first prescription. At the time of the SHIPP study, F/TAF was not yet approved for PrEP. In addition, the patients were provided with brief counseling on the importance of adherence to daily medication, the requirement for quarterly follow-up visits, and laboratory screens. Third, the patients were followed up at 1 month after PrEP initiation by a clinic visit, telephone call, or email to assess any early issues with side effects and medication adherence. Thereafter, they were followed with quarterly visits. At each 3-month follow-up visit, they were provided laboratory screening for HIV, STI, renal function (estimated creatinine clearance), and pregnancy, when indicated. Patients were reviewed for STI and acute HIV symptoms and medication adherence and were counseled on sexual risk reduction. Patients who remained HIV negative and wished to continue were prescribed PrEP for the next 3 months.

Study Participants and Project Sites

Patients who participated in the SHIPP study were aged ≥ 18 years, chose to initiate PrEP, and had no contraindications for PrEP. Patients who were sexually active or planned to become sexually active were enrolled along with people who inject drugs. Because cost analysis was an optional component of the SHIPP study, only 2 of the 5 SHIPP study clinics, both FQHCs—Howard Brown Health in Chicago, Illinois, and Whitman-Walker Health in Washington, DC—participated in the cost analysis.

Howard Brown Health is a large organization that provides health care services to medically underserved populations, including lesbian, gay, bisexual, transgender, and queer (LGBTQ) communities in Chicago. The organization is a multisite operation with 11 clinics serving people on the north, south, and west sides of the city. Howard Brown Health had been offering PrEP when the SHIPP study began. Patient screening and education for PrEP can occur quarterly or at multiple points in the Howard Brown Health model, including during primary care visits, walk-in sexual health visits, and outreach events.

Whitman-Walker Health is a multisite organization that serves racial and ethnic minority and medically underserved populations in Washington, DC, and specializes in LGBTQ and HIV care. The organization had been providing essential HIV and primary care services in Washington, DC, and it expanded its PrEP delivery efforts during the SHIPP study. PrEP clinical visits occurred at 1 of 2 Whitman-Walker Health medical centers. Clinic visits were conducted at least quarterly in person at either clinical site. All participants were seen either in person or spoken to by telephone after 2 weeks to 1 month to assess adherence and side effects.

Cost Data Collection and Analysis

We conducted a cost analysis of PrEP delivery based on patients' clinic visits, laboratory screening, and health care billing data collected retrospectively. We collected health

Table 1. Annual service utilization and program cost of providing preexposure prophylaxis to SHIPP study participants aged ≥ 18 years at Howard Brown Health, Chicago, Illinois, and Whitman-Walker Health, Washington, DC, 2014-2018^a

PrEP-related item	Services utilization		Program cost, \$ ^b	
	Total no.	Mean no. (95% CI) per patient	Total	Mean cost (95% CI) per patient
Howard Brown Health (n = 482 patients)				
Clinic visit	2476	5.1 (4.9-5.3)	281 231	583 (562-605)
Laboratory testing	12 134	25.2 (25.0-25.3)	515 633	1070 (1059-1080)
Total	14 610	30.3 (30.1-30.5)	796 863	1653 (1639-1668)
Whitman-Walker Health (n = 56 patients)				
Clinic visit ^c	300	5.4 (5.0-5.7)	51 677	923 (826-1020)
Laboratory testing	1391	24.8 (23.2-26.5)	57 026	1018 (946-1091)
Total	1691	30.2 (28.5-31.9)	108 703	1941 (1811-2071)

Abbreviations: PrEP, preexposure prophylaxis; SHIPP, Sustainable Health Center Implementation PrEP Pilot.

^a The SHIPP study is an observational cohort of people receiving daily oral PrEP at participating federally qualified health centers and other community health centers.

^b Annual costs estimated following each patient for 12 months since first PrEP prescription (in 2017 US dollars).

^c Included some payments related to prescribing or administering laboratory screens during the clinic visit.

care utilization data, including the frequency and billable costs of clinic visits and laboratory screens, abstracted from clinic billing records and Current Procedural Terminology (CPT) coding. For clinic visit costs, we used the rates negotiated between health centers and payers for new and established patients. We applied the 2017 national payment rates of the Centers for Medicare & Medicaid Services to laboratory screens and estimated the costs of laboratory services (in 2017 US dollars).¹⁹ We obtained data on patient visits and laboratory screens from the date of first PrEP prescription written through 12 months of PrEP care. The analysis estimates the health care provider's billable costs associated with PrEP delivery in that the FQHC clinics provided PrEP prescription, adherence monitoring, and counseling services and the laboratories provided testing services.^{20,21} The billing data reflect the gross costs of an intervention.²²⁻²⁴ Gross costs are routinely used as a proxy for health care providers' costs of the intervention in cost and cost-effectiveness analyses,^{20,21,25-27} particularly when more ideal microcosting data are not available.²² We did not assess patients' time, productivity costs, and out-of-pocket costs (eg, copays, coinsurance, deductibles for services, laboratory fees). Our analysis did not include PrEP medication costs.

The 2 health centers differed in medical record keeping and database management. In Chicago, data for all patients with at least 1 PrEP prescription from January 2016 through July 2018 (considered to be part of the SHIPP observational cohort) were queried and extracted directly from the electronic medical record (EMR). The definitions used for PrEP-related visits and for associated costs were reviewed by Howard Brown Health's PrEP staff and billing manager, respectively. The unique numeric EMR patient identifier in each billing record was matched to SHIPP identification numbers, and all identifying information was stripped from the data before transmitting to CDC. Data cleaning and

transformation were performed using SAS version 9.4 (SAS Institute, Inc).

In Washington, DC, data were collected by manual abstraction of patients' clinic visits and laboratory screens from the paper-based medical records and EMRs, from March 2014 through September 2017. First, the CDC data manager identified SHIPP study patients based on their unique study code (SHIPP identification numbers) and provided the list of patients to the clinic for data collection. Second, the clinic data manager created an internal list of patients by merging the SHIPP identification number with the EMR identification number to locate patients' records in the clinic and manually abstracted the data, including CPT codes for PrEP-related clinic visits and laboratory screens. The clinic visits and laboratory screens that were not related to PrEP were excluded from the dataset. Third, the clinic data manager added the clinic visit and laboratory payments for each record. Then, the EMR identification number was deleted, and the final deidentified dataset was transmitted to CDC. The dataset was reviewed by Whitman-Walker Health medical professionals, the billing manager, and the senior director overseeing billing to ensure accuracy in reporting PrEP-related health care utilization and costs.

We calculated the annual total billable costs of the program and average cost per patient visit and laboratory screen.

The SHIPP study obtained ethical approval from the CDC Institutional Review Board, and the cost analysis was determined to be a nonresearch activity that used unlinked anonymized data.

Results

We counted 2476 PrEP clinic visits and 12 134 associated laboratory screens in Chicago (n = 482 patients) and 300 visits and 1391 screens in Washington, DC (n = 56 patients; Table 1). The annual total billable costs for PrEP patient care

were \$796 863 in Chicago and \$108 703 in Washington, DC. The annual program costs for clinic visits and laboratory screens (in 2017 US dollars) were \$281 231 and \$515 633 in Chicago and \$51 677 and \$57 026 in Washington, DC, respectively.

The average annual number of PrEP clinic visits and laboratory screens per patient was 5.1 (95% CI, 4.9-5.3) visits and 25.2 (95% CI, 25.0-25.3) screens in Chicago and 5.4 (95% CI, 5.0-5.7) visits and 24.8 (95% CI, 23.2-26.5) screens in Washington, DC (Table 1). The average billable cost per patient was \$1653 (95% CI, \$1639-\$1668) in Chicago and \$1941 (95% CI, \$1811-\$2071) in Washington, DC. The average billable cost per patient for clinic visit and laboratory screens was \$583 (95% CI, \$562-\$605) and \$1070 (95% CI, \$1059-\$1080) in Chicago and \$923 (95% CI, \$826-\$1020) and \$1018 (95% CI, \$946-\$1091) in Washington, DC, respectively.

The cost varied by type of service and laboratory screens. In Chicago, commonly used PrEP-related services were laboratory screens for HIV and STIs and clinic visits (level III and level IV, outpatient evaluation and management coding) by established patients (Table 2). In Washington, DC, the commonly used laboratory screens were comprehensive metabolic panel (which includes an estimated creatinine clearance) and HIV and STI testing (Table 3).

Discussion

We estimated the health care utilization and costs of providing PrEP care in 2 FQHCs in the United States. To our knowledge, this analysis provides the first comprehensive estimates of the billable costs of PrEP use at community health centers. Although we did not measure all costs of the health centers providing PrEP services, our estimate of billable costs might be useful to inform cost-effectiveness analyses of providing PrEP through community health centers and similar settings when they are considered along with other available data.

Data on PrEP delivery costs are limited, although PrEP awareness and use among people at risk for HIV infection are increasing.⁸⁻¹⁰ The literature on cost analysis and cost-effectiveness modeling of PrEP interventions often uses partial cost data and assumptions about PrEP-related service utilization. In the literature, the cost per patient varied widely, including clinic visits and laboratory screens ranging from \$475 to \$2347, primarily because of the differences in assumptions about inclusion and exclusion of the procedures and prices.^{20,21,27,29-32} Our estimates of the PrEP delivery costs are within the upper limit of the costs reported in the literature. Desai et al used a comprehensive list of costs, including initial screening for PrEP eligibility and ongoing medical monitoring and adherence, in their cost-effectiveness modeling. They reported the average annual cost of PrEP delivery per patient at \$1770 in 2008 (in 2017 US dollars).²⁷ The number of clinic visits and

laboratory screens were based on expert judgment, and the costs were based on Medicare payment rates. Following the required laboratory screens and clinic visits recommended by the 2017 clinical practice guidelines, Smith et al estimated annual per-patient costs of PrEP care ranging from \$1098 to \$2347 (in 2017 US dollars), which were influenced by the different laboratory tests recommended for men who have sex with men and heterosexual male and female patients.²⁰

Annual health care utilization and costs could vary by patient's sex or transmission risk groups, because some laboratory screening recommendations vary by risk group (eg, pregnancy test for patients with childbearing potential and additional STI screening for men who have sex with men). Based on the clinical practice guidelines, a patient could have up to 6 clinic visits a year—an initial screening, receipt of prescription, and 4 quarterly follow-up visits—and 12 to 28 laboratory screens, depending on the patient's sex and risk group.^{16,20} In our analysis, per-patient annual average clinic visits were 5.1 and 5.4, and annual average laboratory screens were 25.2 and 24.8 in Chicago and Washington, DC, respectively. These results are within the range recommended by the clinical practice guidelines.¹⁶

The 2 health centers differed in medical record keeping and database management. The center in Chicago abstracted data on health care utilization and cost from multiple databases and EMRs electronically, whereas the center in Washington, DC, abstracted the data manually, focusing directly on total PrEP-related clinic visits and laboratory screens only. Although the choice of methods could have influenced our results, our estimates show strikingly similar results on PrEP-related health care utilization and costs in both sites.

Because our analysis focused on estimating billable costs associated with PrEP delivery, we included the payments to both health centers and laboratories. Health centers and health care providers planning to initiate or scale up PrEP may use this information to assess their cost burden and reimbursement potentials.

Limitations

Our analysis had some limitations. First, we used medical claims and billing data to estimate PrEP delivery costs. The analysis excluded some of the costs not billed to the health insurance providers or the costs covered by other sources, including start-up costs, training, patient navigation, and donated items and services. Thus, we may have understated the overall cost of PrEP delivery. On the other hand, the medical claims and billing data reflected negotiated charges and payments, and charges in particular can be higher than actual costs incurred in delivering the program, suggesting that our estimates might have been overstated. Thus, the net effect of these factors on our cost estimate could be minimal. To minimize variation in our cost estimates, we used the Centers for

Table 2. Description of annual laboratory costs of preexposure prophylaxis use among SHIPP study participants at Howard Brown Health, Chicago, Illinois, 2016-2018^a

Type of visit	No. of patients	Mean no. of services per patient	Cost per patient, mean (95% CI), \$ ^b
Clinic visit for new patients, preventive, age 18-39 y	5	1.0	210.00 ^c
Clinic visit for new patients (level 3) ^d	43	1.0	165.00 ^c
Clinic visit for new patients (level 4) ^d	8	1.0	245.00 ^c
Clinic visit for established patients, preventive, aged 18-39 y	10	1.0	150.00 ^c
Clinic visit for established patients (level 2) ^d	79	1.4	103.48 (87.63-119.34)
Clinic visit for established patients (level 3) ^d	448	3.1	305.13 (286.90-323.37)
Clinic visit for established patients (level 4) ^d	182	1.6	239.13 (215.99-262.27)
Clinic visit for established patients (level 5) ^d	3	1.0	210.00 ^c
Clinic visit with medical practitioner	117	2.9	391.83 (343.80-439.86)
Clinic visit with medical provider	79	1.8	253.06 (210.89-295.24)
Clinic visit with nurse practitioner	8	9.0	469.85 (211.65-728.05)
Clinic visit with psychologist/social worker	4	3.3	182.61 (104.66-260.55)
Clinic visit with Medicare payment (prospective payment system), established patient	11	6.6	934.00 (252.50-1615.50)
Laboratory screens			
Uripobe (CT)	66	1.6	106.46 (88.41-124.51)
Uripobe (GC)	66	1.6	106.46 (88.41-124.51)
CT/GC NAAT, pharyngeal	468	3.6	236.89 (225.45-248.32)
CT/GC NAAT, rectal	457	3.4	217.67 (206.55-228.80)
CT/GC NAAT, urine	470	3.6	234.49 (223.52-245.46)
Comprehensive metabolic panel ^e	478	3.5	68.11 (65.60-70.63)
HIV Ag/Ab (fourth generation)	480	3.5	158.19 (151.99-164.39)
Syphilis Ab cascading reflex	453	3.0	23.85 (22.75-24.94)
HIV-1 RNA viral load	33	1.2	127.83 (110.94-144.71)
Insti rapid HIV Ab	70	1.2	20.00 (17.95-22.05)
SureCheck HIV 1/2	37	1.1	28.84 (26.04-31.64)
Hepatitis B core Ab	103	1.1	23.68 (22.64-24.72)
Hepatitis B surface Ag, with confirmation	103	1.1	20.45 (19.52-21.38)
Hepatitis B surface Ab quantitative	114	1.1	21.66 (20.51-22.80)
HIV rapid test (walk-in couples)	1	1.0	16.47 ^c
HIV rapid test (walk-in single)	27	1.4	23.79 (15.45-32.13)
Syphilis screen	33	1.2	9.36 (8.12-10.60)
Syphilis screen (walk-in)	35	1.4	10.86 (8.87-12.85)
HIV test (walk-in)	12	1.7	27.45 (18.66-36.24)
HIV-1 rapid test (walk-in patient)	4	1.0	16.47 ^c
HIV Clearview 1/2 test	75	1.1	23.41 (22.28-24.54)
Hepatitis B core IgM Ab	4	1.3	27.93 (18.44-37.41)
Hepatitis B Ab	5	1.2	26.81 (18.98-34.64)
Hepatitis B Ag	5	1.2	22.98 (16.27-29.69)
Hepatitis C Ab with reflex	472	3.3	93.22 (89.39-97.04)
Basic metabolic panel	18	1.2	23.94 (20.18-27.71)
GC culture	1	1.0	65.06 ^c
CT culture	1	1.0	65.06 ^c

Abbreviations: Ab, antibody; Ag, antigen; CT, Chlamydia trachomatis; GC, *Neisseria gonorrhoeae*; IgM, immunoglobulin M; NAAT, nucleic acid amplification test; PrEP, preexposure prophylaxis; SHIPP, Sustainable Health Center Implementation PrEP.

^a The SHIPP study is an observational cohort of people receiving daily oral PrEP at participating federally qualified health centers and other community health centers.

^b Annual costs estimated following each patient for 12 months since first PrEP prescription (in 2017 US dollars). The numbers may not add to totals in Table 1 because of rounding.

^c Results do not vary because the mean number of services per patient was 1. Multiple entries of clinic visits and laboratory screens are kept separate based on the way billing data were processed. The data did not include a claim for pregnancy test.

^d Clinic visit levels are based on outpatient evaluation and management coding implemented by the American Medical Association and Centers for Medicare & Medicaid Services, which reflects physician time spent with the patient and number and complexity of problems addressed during the encounter.²⁸

^e Comprehensive metabolic panel included an estimated creatinine clearance.

Table 3. Description of annual laboratory costs of preexposure prophylaxis use among SHIPP study^a participants at Whitman-Walker Health, Washington, DC, 2014-2017

Laboratory item	No. of patients	Mean no. of services per patient	Cost per patient, mean (95% CI), \$ ^b
Comprehensive metabolic panel	56	4.0	78.01 (57.58-98.44)
HIV-1 Ag, HIV-1/2 Ab	56	4.1	184.14 (135.91-232.37)
Blood serology, syphilis	55	3.5	27.79 (20.45-35.14)
Urine STI kit—NAAT CT/GC	55	3.5	224.75 (165.35-284.15)
Rectal STI kit—NAAT CT/GC	55	3.4	221.20 (162.74-279.67)
Pharyngeal STI kit—NAAT CT/GC	55	3.4	218.84 (161.00-276.67)
Hepatitis B surface Ab	42	1.1	22.75 (15.87-29.64)
Hepatitis B core Ab	24	1.0	22.34 ^c
Hepatitis B surface Ag	41	1.0	19.62 ^c
Hepatitis B quantitative DNA	3	1.0	79.40 ^c
Hepatitis C Ab	38	1.7	45.24 (30.86-59.63)

Abbreviations: Ab, antibody; Ag, antigen; CT, Chlamydia trachomatis; GC, *Neisseria gonorrhoeae*; NAAT, nucleic acid amplification test; PrEP, preexposure prophylaxis; SHIPP, Sustainable Health Center Implementation PrEP; STI, sexually transmitted infection.

^a The SHIPP study is an observational cohort of people receiving daily oral PrEP at participating federally qualified health centers and other community health centers.

^b Annual costs estimated following each patient for 12 months since first PrEP prescription (in 2017 US dollars). The numbers may not add to the totals in Table 1 because of rounding.

^c Results do not vary because the mean number of services per patient was 1. The data did not include a claim for pregnancy test.

Medicare & Medicaid Services national payment rates to estimate the cost of laboratory services in both health centers.

Second, our analysis was conducted based on billing data (gross costs) associated with service providers, and these costs do not account for the broader societal costs of PrEP, including patients' time and out-of-pocket costs. However, Furukawa et al estimated self-reported quarterly out-of-pocket cost of PrEP use at \$34 (median [IQR], \$5 [\$0-\$25]) per person, and the authors concluded that the out-of-pocket cost was low and did not affect persistence in PrEP use.¹⁷ Beginning in 2021, patient costs should be further reduced by the US Preventive Services Task Force grade A recommendation for PrEP leading to the requirement for no out-of-pocket costs for office visits of patients who are publicly or privately insured.³³

Lastly, our analysis included data from 2 health centers in large metropolitan areas only, because cost analysis was an optional component of the SHIPP study. Other SHIPP study sites were in different locations and served populations with different levels of health care utilization. Thus, generalization of our estimates to other health centers and health care settings might be limited.

Conclusions

PrEP is recommended for people at increased risk of HIV acquisition, and the expansion of PrEP delivery is a major component of the new federal initiative, Ending the HIV Epidemic in the United States.⁷ Our analysis provides PrEP delivery cost estimates based on clinical and laboratory billing data from 2 health centers that provide sexual health and primary care services to people in communities with a high HIV incidence and prevalence. Our results can inform health

care providers, program managers, and public health decision makers in planning and scaling up PrEP delivery.

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ORCID iD

Ram K. Shrestha, PhD  <https://orcid.org/0000-0002-2812-8933>

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