HHS Public Access

Author manuscript

Am J Public Health. Author manuscript; available in PMC 2022 June 01.

Published in final edited form as:

Am J Public Health. 2022 June ; 112(6): 834–838. doi:10.2105/AJPH.2022.306793.

Associated Costs are a Barrier to HIV Pre-exposure Prophylaxis Access in the United States

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Abstract

There are disparities in PrEP uptake among groups at higher risk for HIV. The current gap in financial assistance for PrEP-associated medical visits and laboratory tests remains one of the most significant barriers to PrEP access. Less is known about interventions to reduce financial barriers for PrEP-associated medical visits and laboratory tests. We describe the current cost and insurance landscape and explore two potential policy approaches to improve access and reduce financial barriers to PrEP-associated medical visits and laboratory costs: (1) Public-Payer Models for PrEP Financing and (2) the Expansion of CDC Federal Funding Streams. More analysis is required to assess the most effective and equitable policy strategy to advocate for increased financial accessibility for PrEP-associated costs and services. The urgent call to end the HIV epidemic and address health equity must include innovative strategies that decrease current financial barriers for PrEP-associated ancillary services, so no one is left behind.

INTRODUCTION

HIV pre-exposure prophylaxis (PrEP), a biomedical HIV prevention intervention, reduces the risk of HIV acquisition by upwards of 90% for sexual encounters and 70% for injection drug use. If widely used, PrEP has the potential to help end the HIV epidemic in the U.S.[1] In 2015, the Centers for Disease Control and Prevention (CDC) estimated that approximately 1.2 million people were at high risk of acquiring HIV and had a clinical indication for PrEP.[2] One of the four pillars of the federal government's *Ending the HIV Epidemic* (EHE) Initiative is increasing access to and use of PrEP – in fiscal year 2021, $386 million was appropriated for the EHE initiative, of which $102 million was allocated to provide "HIV testing, linkage to care, and prescription of PrEP".[1] Additionally, the National HIV/AIDS

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Contributors – All authors contributed to the conceptualization, writing, editing, and revising of the editorial.

Human Participant Protection – This is a non-human subject research study.

Strategy for the United States 2022–2025 has an objective to increase PrEP coverage to 50% from a 2017 baseline of 13.2%.[3] Despite the first PrEP antiretroviral being approved by the United States Food and Drug Administration in 2012, less than 20% of those at high risk of HIV received a PrEP prescription in 2019.[4]

There are inequities in PrEP uptake across communities at higher risk for HIV – Black and Hispanic communities, cisgender women, transgender women, and people living in the South – due, in part, to high brand-name medication costs and limited access to financial resources to cover costs of PrEP-associated medical visits and laboratory tests, among other factors.[5] Counterintuitively, the most updated available PrEP-utilization data demonstrates health systems and public health efforts have been less effective at reaching those most at-risk for HIV. Black and Hispanic individuals are estimated to have higher rates of clinical indications for PrEP at 43.7% and 24.7% respectively.[6] Despite this, in 2016, almost 70% of PrEP users were White, while only 11% were Black and 13% were Hispanic.[6] There are also disparities across gender, age, and geography. PrEP uptake amongst men was 14 times higher than uptake amongst women in 2016, and people who are 25–44 years old were more likely to be PrEP users than people of other ages.[6] The US-South accounted for over half of new HIV diagnoses in 2016 but represents only 30% of all PrEP users.[7] Overall, Southern states had the lowest levels of PrEP utilization relative to HIV diagnoses.[7]

While many programs provide access to PrEP medication, there are few programs that address the PrEP-associated services, which includes laboratory tests and medical visits that are integral components of the PrEP intervention as outlined by CDC guidelines.[8] The high cost of the initial PrEP medications has necessitated reliance on a fragmented PrEP access system that is not able to provide integrated PrEP-associated services. Manufacturer assistance and donation programs were necessary to provide access for uninsured individuals, but these programs could not cover other PrEP services. Entities that are able to secure 340B discounts for the purchase of drugs (and generate revenue when they are reimbursed at a higher price for those drugs) have also been at the center of PrEP access and financing, creating another set of access points and program. This variety of federal, state, and local programs provide piecemeal access to PrEP services [Table 1]. These fragmented systems and services create consumer complexity and confusion, not to mention multiple burdensome eligibility and application processes.

According to data from National Average Drug Acquisition Cost (NADAC), the undiscounted cost of a 30-day bottle of branded TDF/FTC is $1,790.91 and branded TAF/FTC is $1,875.93, while generic TDF/FTC is $35.37.[9] FAIR Health estimates that the cash cost of PrEP care for the initiation of PrEP is $2,666.90 for uninsured patients, of which approximately $1,000 is encompassed in laboratory tests and medical visits [Supplemental Table 1].[10] These cost projections include the cost of the daily medication, quarterly primary care physician visits, and recommended laboratory tests. Importantly, this does not factor in additional testing that would be recommended based on risk, such as Hepatitis C screenings or HIV RNA tests for patients with symptoms of acute HIV. The prices charged to uninsured consumers may vary depending on the practice of individual providers and pharmacies; however, these monthly costs offer an objective estimate of the total cash cost of PrEP services.

The gaps in financial assistance for PrEP-associated services remain a significant anticipated barrier to PrEP access among poor or underinsured persons. Due to the actual and perceived cost barrier, there may be lower uptake of PrEP in at-risk communities, increasing the likelihood of transmission and prevalence of HIV.[4] Not addressing the low uptake of PrEP in the U.S. could lead to an outcome that is not cost-effective nor preventive at the population level. This paper will focus on the consequences of financial inaccessibility of PrEP, recent policy efforts to address gaps in assistance by reducing cost-sharing, and explore two potential policy strategies to improve financing for PrEP-associated services.

COSTS/CONSEQUENCES OF PrEP FINANCIAL INACCESSIBILITY

The federal government spends approximately $20 billion in annual direct health expenditures for HIV prevention and care.[11] Direct costs include outpatient visits to HIV specialists, medication costs, laboratory costs, hospitalizations, and other healthcare expenses. The cost averted by avoiding one new HIV transmission amounts to over $400,000 in lifetime costs.[12] Quantifying externality costs for social and economic loss that a person with a new HIV diagnosis incurs is more nuanced.

In a simulated model, PrEP was shown to reduce lifetime HIV risk in populations at high-risk for infection. With an assumed PrEP efficacy of 90%, the analysis modeled a significant reduction of lifetime infection risk among a high-risk, MSM population, from 43.5% to 5.8%.[13] While this simulation does not account for the varying PrEP uptake among racial subpopulations, which is particularly important considering the current inequities in uptake among Black and Hispanic communities, it demonstrates the relative cost-effectiveness of PrEP as an intervention is strongly dependent on drug cost.[13] For example, increasing generic TDF/FTC uptake may prove to be more cost-effective than branded PrEP products – one study comparing the cost-effectiveness of branded TAF/FTC to generic TDF/FTC found the generic was far more cost-effective at current prices in the US than the branded TAF/FTC, even for those at high-risk of adverse TDF/FTC effects.[14]

Regarding social costs, lack of access to PrEP can increase the risk of HIV transmission in communities with high HIV incidence. Most new U.S. HIV diagnoses are concentrated in socially marginalized communities, where social determinants of health and stigma are often a deterrent to PrEP utilization.[4,15,16] Clinicians in areas with social stigma surrounding PrEP may be less likely to prescribe PrEP. Social stigma, the need to change one's routine, administrative barriers, and patient-level stress also act as barriers to PrEP adherence.[4]

IMPACT OF USPSTF GRADE A FOR PrEP ON COVERAGE AND COST SHARING

Studies indicate that reducing cost-sharing for PrEP medication may help promote access to the drug.[17] The US Preventive Services Task Force (USPSTF) provides recommendations for a range of evidence-based, preventive services. The ACA requires insurance plans to cover USPSTF Grade A and B rated services without cost-sharing.[4] In June of 2019, the USPSTF finalized a Grade A recommendation for PrEP, meaning PrEP must be covered by most private insurance plans and Medicaid expansion programs without cost-sharing

beginning in January 2021.[16,18] In July, 2021, the federal government released additional guidance clarifying that PrEP is a comprehensive intervention comprised of the medication and essential support services (e.g. laboratory services, provider visits, etc.) and that plans must cover the medication and the essential support services without cost sharing.[19]

Despite this recent development, there are still gaps in coverage for public insurance programs and private plans. Following the USPSTF recommendation, Medicaid expansion states are required to cover, without copays, both the PrEP medication and associated services, while coverage for associated services is more limited in traditional Medicaid states. In addition, Medicare Part D is not subject to the ACA coverage and cost sharing requirements for USPSTF Grade A and B rated services, meaning PrEP medications and associated services may still have cost sharing.[16] While the USPSTF rating enabled PrEP and the associated services to be covered by the vast majority of health plans without cost-sharing, those with grandfathered commercial coverage and those with non-ACA compliant plans may still face steep cost-sharing barriers for PrEP-associated costs.[17]

While the USPSTF Grade A rating for PrEP expands financial access to clinical and laboratory services, it is contingent on cost-sharing protections being enforced. Despite most health plans being required by law to cover PrEP without cost-sharing, research has shown that many insurers are failing to adhere to guidelines due to a lack of enforcement.[20] Further research is necessary to ascertain state-level policy enforcement of the federal law and guidance.

POTENTIAL POLICY/FINANCING STRATEGIES

A growing body of literature seeks to identify policies and programs that can increase the financial accessibility of PrEP, but less is known about financial barriers for PrEP-associated medical visits and laboratory tests.[16] We explore two potential policy approaches to improve access and reduce financial barriers to PrEP-associated medical visits and laboratory costs: (1) Public-Payer Models and (2) Changes to CDC Funding Restrictions. We will identify the strengths and limitations of existing evidence and what remains unknown.

POLICY STRATEGY #1: PUBLIC PAYER PROGRAMS FOR PREP-ASSOCIATED COSTS

A study indicated that while the high cost of PrEP was a perceived barrier to access, this concern was alleviated by medication assistance programs.[15] These programs are supported by various healthcare sectors including industry-sponsors (Gilead Sciences, Inc.), nonprofit foundations (Patient Advocate Foundation), and federal (Ready, Set, PrEP) and state agencies. These programs provide PrEP to those without insurance and assist with medication copayments related to drug cost-sharing for those who are insured. While the literature highlights medication assistance programs as mechanisms to make PrEP more accessible to people with lower incomes and underinsured individuals, the failure of these programs to cover PrEP-associated services may make them less effective.[13] Because Medicaid provides far more comprehensive access to the full gamut of PrEP services, the

gap in access to PrEP-associated services is even more pronounced in states that have not expanded Medicaid under the Affordable Care Act, most notably in the South.[17]

This strategy suggests developing a state or federally-funded PrEP-assistance program that covers PrEP-associated services and leverages a payer of last resort provision to maximize public health funds. Some states already use a public payer of last resort model for PrEP financing, developing comprehensive programs for PrEP access using non-federal and local funding.[21] States where this model is in place include California, Colorado, District of Columbia, Illinois, Indiana, Massachusetts, New York, Ohio, Virginia, Washington.[21] In California, eligibility criteria for the program includes having an income less than 500% of the federal poverty level, California residency, and not having other PrEP coverage. If a patient is uninsured, the program will pay for all medical costs including medical visits and laboratory tests. If a patient is insured, the program will pay for all PrEP-associated medical out-of-pocket costs and cover any medication costs not covered by the drug manufacturer's copay assistance program.[22] Currently, these programs are limited in their dependency on state investment because non-EHE HIV surveillance and prevention CDC funds cannot fund medical visits and laboratory tests associated with PrEP, nor can they be used to purchase PrEP medications.[22]

A federally-funded PrEP assistance program model could be incorporated in the EHE "Ready, Set, PrEP " initiative at the federal level. To receive PrEP through this initiative, an individual must (1) test negative for HIV, (2) have a valid prescription from a healthcare provider for the medication, and (3) not have health insurance for outpatient prescription drugs.[24] Expanding the program to cover the medical visits and lab tests would increase the program's effectiveness by addressing persistent gaps in access. Despite extensive literature about mechanisms of public payer models,[23] there is not yet sufficient evidence suggesting a causal relationship between these models and PrEP accessibility.

POLICY STRATEGY #2: ALLOWING CDC/EHE FEDERAL FUNDING TO COVER PrEP-ASSOCIATED COSTS

While much progress has been made for insured individuals through the UPSTF Grade A recommendation and the federal guidance released in July 2021, there are still significant gaps in access for uninsured individuals. Until the implementation of EHE, CDC had a longstanding policy that these federal funds cannot pay for medications, most laboratory tests, and medical visits associated with PrEP. This policy was meant to preserve limited federal funding and focus HIV prevention funding on services for which there are no other payers. However, in 2019, the CDC EHE implementation awards authorized the use of $4.5 million in federal funds to cover PrEP lab services in three "Jumpstart Sites" with EHE jurisdictions – East Baton Rouge Parish, Louisiana; DeKalb County, Georgia; and Baltimore City, Maryland.[25] Through the expansion of CDC federal funding, The Open Health Care Clinic in East Baton Rouge Parish acquired a new lab site and increased PrEP laboratory testing capacities. DeKalb County's STD clinic implemented a PrEP awareness campaign and expedited their testing capabilities.[25] The CDC EHE funding released in 2020 included a similar relaxation of the previous policy surrounding paying for PrEP

related services for uninsured or underinsured people receiving PrEP in not-for-profit or governmental clinics.[1] Similarly, in 2020, HRSA's Bureau of Primary Health Care funded 195 community health centers to support access to and use of PrEP in EHE jurisdictions; expanding access to nearly 50,000 people. The program was expanded to a second cohort of community health centers beginning in August/September 2021.[26] Most recently, CDC has further reinforced this shift and encouraged health departments' Integrated HIV Surveillance and Prevention Programs funded by PS18–1802 to allocate HIV prevention funding to support PrEP ancillary services when needed.

This expansion of federal funding to include PrEP laboratory tests could be applied across all HIV prevention CDC funds, instead of solely EHE jurisdictions, and could include PrEP-associated clinical visits and allowances to purchase low-cost PrEP for uninsured individuals. Given that these awards were recent and localized in scope, there are limited empirical analyses regarding the impact of federal funding expansion on PrEP financial access. Further analysis is required to assess efficacy of federal funding streams on decreasing financial barriers to PrEP as well as schemes for PrEP prioritization.

CONCLUSIONS

While there is a growing body of literature on financing strategies for PrEP-associated medical visits and laboratory costs, there is limited evidence assessing the options within public health and healthcare systems at large. First, with increased clarity about cost-sharing protections for insured individuals through the USPSTF recommendation, enforcement will be key to alleviate the burden of high out-of-pocket costs for patients across health insurance groups. Second, the implementation of a national PrEP-assistance program covering all PrEP-associated costs could alleviate out-of-pocket costs for insured patients increase access for uninsured individuals and promote equity of access to preventive services across healthcare coverage. Comprehensive federal funding is imperative given states' varying political and social investment in HIV prevention. Last, the expansion of federal funding streams to cover the generic drug and PrEP-associated medical visits and laboratory costs through existing categorical funding could reduce financial barriers facing high-priority PrEP candidates.

Further economic modeling to predict the impact of these potential policy solutions is needed. These analyses should account for the impact of social determinants on access and include national and state-level political considerations. The urgent call to end the HIV epidemic and address health equity must include innovative strategies that decrease current financial barriers for PrEP-associated services, so no one is left behind.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments –

This work was supported by the National Institute of Allergy and Infectious Diseases at the National Institutes of Health (NIH) (grant number K08AI136644 to K.A.M.). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Conflicts of Interest –

Karishma Srikanth has no disclosures; this work was completed before her employment at the United States Agency for International Development. Amy Killelea reports that when she worked at NASTAD, the organization received grant funding from Gilead Sciences Inc. to support the programmatic work; all payments were to the institution and were separate from this work. Andrew Strumpf has no disclosures. Edwin Corbin-Gutierrez reports that NASTAD receives grant funding from Gilead Sciences Inc for organizational support; all funding to the institution was separate from this project. Tim Horn reports that NASTAD receives grant funding from Gilead Sciences Inc for organizational support; all funding to the institution was separate from this project. Kathleen McManus reports the above mentioned NIH grant to her institution for this work, an investigator-initiated research grant from Gilead Sciences, Inc for a project separate from this work and stock ownership in Gilead Sciences, Inc. Kathleen McManus also reports unpaid leadership positions: Co-chair of the Ryan White Medical Providers Coalition Steering Committee and Chair of the Advisory Committee to Virginia Medication Assistance Program.

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Table 1.

Fragmented PrEP Financial Assistance Programs

Gilead manufacturer assistance programs	Ready, Set, PrEP	State PrEP assistance programs	340B entities
Medication			
Provides medication (Truvada and Descovy) for uninsured individuals with income up to 500% FPL	Provides medication (Truvada and Descovy) for uninsured individuals	Refers individuals to manufacturer assistance programs and Ready, Set, PrEP	Provides medication to uninsured by purchasing at discounted price
Laboratory Tests			
Laboratory tests not covered	Laboratory tests not covered	Laboratory tests are covered through free schedule or public/grant funding	Laboratory tests are covered (sliding scale) or 340B revenue
Medical Services			
PrEP medical and ancillary services not covered	PrEP medical and ancillary services not covered	PrEP medical and ancillary services are covered through fee schedule or grant funding	PrEP medical and ancillary services are covered (sliding scale)