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RESEARCH ARTICLE

Supporting Access to HIV Pre-Exposure Prophylaxis in a Shifting Financial and Insurance Landscape

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Introduction: Implementing HIV pre-exposure prophylaxis in the U.S. is critical to decreasing HIV transmission. However, regional disparities in pre-exposure prophylaxis use exist, with the southern U.S. having the lowest uptake relative to need. Community-based organizations in the South provide pre-exposure prophylaxis to many consumers, including those without health insurance.

Methods: The authors convened a community-building pre-exposure prophylaxis summit in April 2023 with representatives from diverse pre-exposure prophylaxis providers, including community-based organizations in Dallas, Texas, to evaluate the impact of recent changes in pre-exposure prophylaxis funding mechanisms on their capabilities to provide pre-exposure prophylaxis. Participants completed surveys (n=17) and focus groups (n=14 individuals in 2 groups).

Results: The authors found that reduced reimbursements from pre-exposure prophylaxis manufacturers have significantly altered the financial health of community-based organizations in Dallas, Texas, and jeopardized their capacity to provide pre-exposure prophylaxis. Community-based organizations reported difficulty in sustainably providing pre-exposure prophylaxis to uninsured clients because of fewer funds to cover unreimbursed costs for pre-exposure prophylaxis care. Many community-based organizations have diverted resources away from client outreach for pre-exposure prophylaxis and toward helping clients to enroll in commercial insurance plans that cover pre-exposure prophylaxis. These changes have further stressed community-based organizations by increasing the time spent by staff on managing prior authorizations for pre-exposure prophylaxis. Despite finding some success with workarounds, community-based organizations described continued financial fragility.

Conclusions: These findings suggest that fragmented funding streams jeopardize the ability of these vital organizations to continue providing pre-exposure prophylaxis services in a jurisdiction with high HIV incidence. Potential solutions include enhanced collaboration across community-based organizations and stable financial support from a national pre-exposure prophylaxis program.

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INTRODUCTION

HIV pre-exposure prophylaxis (PrEP) is highly effective at decreasing HIV transmission and could help curtail the HIV epidemic in the U.S.[1] PrEP is available in oral formulations, as tenofovir disoproxil fumarate with emtricitabine (TDF/FTC) or tenofovir alafenamide with emtricitabine (TAF/FTC) and as long-acting injectable cabotegravir.[2,3] Despite multiple formulations and generic medications available, only 36% of the 1.2 million people in the U.S. likely to benefit from PrEP received it in 2022,[4] with disproportionately low uptake among racial and ethnic minorities, women, and people in the southern U.S.[5,6]

Uptake in the southern U.S., specifically, is limited by large populations living in rural areas where access to PrEP may be more limited, lack of access to health insurance, low health literacy, stigma, lower numbers of primary care providers per person, and underestimation of HIV risk.[7–9] Furthermore, nationally, costs of PrEP medications can make access difficult, especially for the uninsured; a month's supply of branded TAF/FTC has a list price of approximately $1,900,[10] and a dose of long-acting cabotegravir is listed at over $3,800.[11] Given these regional factors and high costs, many people in the U.S. must use creative funding streams to access PrEP.

There are gradations of costs and coverage between insurance programs. PrEP medications are nearly free for Medicaid enrollees with incomes <150% of the federal poverty level, but Medicaid is limited by state-level policies. Costs for PrEP medications among those covered by Medicare can vary, with average annual costs estimated at $2,276−$2,430.[12] The Patient Advocate Foundation, a 501(c)(3) nonprofit, runs a Co-Pay Relief Program that offers $5,000 in rebates per year, but this is only available to insured individuals with annual incomes <500% of the federal poverty level.[13] Finally, the Affordable Care Act currently mandates that commercial insurance plans provide PrEP medications and care without patient cost sharing. These protections are currently at risk after a 2022 federal court decision.[14]

Uninsured individuals require other mechanisms of support.[15,16] Gilead Sciences, Inc. (Gilead), the manufacturer of brand-name TDF/FTC (Truvada) and TAF/FTC (Descovy), implemented the Advancing Access Patient Assistance Program (Advancing Access) to assist uninsured patients in accessing the manufacturer's medications. A similar patient assistance program for cabotegravir is supported by its manufacturer (ViiV Healthcare Ltd.),[17] and a federally managed program called Ready, Set, PrEP provided free oral PrEP medications (donated by Gilead) to uninsured patients, although this was recently discontinued.[18,19]

Clinical providers have developed local programs to support PrEP use for underinsured and uninsured persons using a federal drug discount program, the 340B program. Purchasers under the 340B Program, known as covered entities, may purchase medications (including brand-name PrEP) at a significant discount. Covered entities may also obtain third-party reimbursements at market value for the medications they purchase at discounted rates,[20] which generates revenue known as the spread. This spread supports the financial health of many 340B-covered entities, which are often safety-net providers.[20] The 340B program is a significant and growing part of the general healthcare economy. In 2020, medications purchased through the 340B Program represented approximately 7% of the U.S. drug market.[21]

Before January 2022, covered entities could generate a spread from prescribing PrEP medications. Obtaining third-party reimbursement through Gilead (Advancing Access) after purchasing PrEP medications at a discounted cost represented a major source of funding for community-based organizations (CBOs) to absorb unreimbursed costs of PrEP care for uninsured clients.[15,16]

Gilead altered this financial landscape in January 2022 by having Advancing Access reimburse only the discounted purchasing costs (with administrative fees), thereby greatly decreasing the spread, with potentially major financial implications for entities relying on these funds.[22] Gilead first announced this change in April 2021. Organizations that relied on the spread from prescribing Gilead's PrEP medications had 8 months to respond to this change. At the time, reports in the popular media foretold massive losses of revenue for PrEP providers.[23,24]

The authors surveyed members of diverse healthcare and community organizations involved in PrEP provision in Dallas, Texas, a city with high HIV incidence in a Medicaid nonexpansion state, to assess the impact of these financial changes on PrEP implementation. The authors then invited survey participants to attend a county-wide community-building PrEP summit with the goal of fostering a discussion of barriers and facilitators to financing and providing sustainable PrEP services.

METHODS

The authors followed a convergent parallel mixed-methods design in which the authors gathered and analyzed survey and focus group data and then compared and interpreted findings from those data.[25] Study procedures were approved by appropriate IRBs.

Study Population

The authors identified and recruited survey and summit participants from CBOs and healthcare organizations in

Dallas County that provide PrEP using multiple strategies: the authors leveraged the Dallas Fast Track Cities HIV prevention working group,[27] invited members of the professional networks of research team members on the basis of their experiences working locally in HIV prevention and care, and included other individuals recommended to the researchers through referral networking by any of these initial contacts. The authors emailed summit invitations with a hyperlink to the online survey, which was administered anonymously to minimize potential bias in responses. Responses were collected between February 17, 2023, and March 23, 2023, with up to 2 email reminders. Respondents were compensated with $25 gift cards. Survey responses were exported into Microsoft Excel and analyzed with descriptive statistics.

MEASURES

The authors developed an online survey about financial considerations in providing PrEP and administered it using REDCap, an online electronic data capture tool.[26] Survey topics included respondent and organizational characteristics, characteristics of the population served by the organization, challenges experienced in providing PrEP, usefulness of financial assistance programs for PrEP, use and impact of revenue from these programs, and impact of prior authorization or insurance enrollment services.

The summit was held on April 3, 2023 at the Dallas County Health and Human Services Department and was structured in three 1-hour sessions: (1) presentation of the survey findings, (2) facilitation of 2 concurrent focus group discussions, and (3) discussion among all attendees regarding how to carry forward findings from the summit to sustain and strengthen PrEP services in Dallas. Each participating organization was reimbursed $1,470, and in addition, individual participants received $25 gift cards.

Attendees of the summit were asked to self-divide into 2 focus groups, which were facilitated by members of the study team with expertise in qualitative research. Other investigator team members from various disciplinary backgrounds (e.g., infectious disease, epidemiology, public health practice, and implementation science) observed the focus groups and participated in interpreting study findings. Sessions were audiorecorded, and recordings were transcribed verbatim and deidentified for analysis.

Analysis

Three research team members reviewed both focus group transcripts and jointly drafted an initial codebook. They then individually coded 1 transcript and met to discuss and resolve discrepancies through consensus. They revised and finalized the codebook and then coded both transcripts with the final codebook. Finally, data associated with each code were exported from NVivo 12.0 (Lumivero) and were synthesized in summary reports. Two individuals reviewed each summary report and selected exemplar quotes. Reflective of the study's convergent parallel design, the authors organized results by colocating quantitative and qualitative findings on similar topics.

RESULTS

The survey yielded 20 unique responses, representing 12 different organizations. Three incomplete surveys were omitted from analysis. Six respondents were from a single large organization, and prescribing clinicians made up 47% of responses overall. Of the respondents, 61% described their organizations as having >50 employees. Of the 17 invited organizations, 14 individuals from 6 organizations attended the summit. Summit participants were diverse, with 29% self-identifying as Black, 36% self-identifying as White, 21% self-identifying as Asian, and 14% self-identifying as Hispanic/Latino.

On average, respondents estimated that 35.4% of their clients identified as Latinx/Hispanic, 33.9% identified as Black or African American, and 36.2% identified as White. The largest estimated proportion of clients' sexuality and gender was cisgender men who have sex with men (62.8%), followed by transgender or nonbinary persons (9%), and cisgender women (6.6%). Overall, 45.7% of clients were described as uninsured, and 38.3% were described as having private insurance. Reported client volume was variable, with 47% initiating PrEP for <20 persons in a month and 11% initiating >50 persons a month. Of the respondents, 42% estimated that their organization had >50 clients receiving follow-up PrEP care in each month. Demographic characteristics of survey respondents and their clients are provided in Table 1.

Regarding financial assistance programs for pre-exposure prophylaxis, in the survey and focus groups, Advancing Access and the 340B programs were considered the most helpful for facilitating PrEP provision. Ready, Set, PrEP and ViiV were less well known and generally considered less helpful. Overall, 65% of survey respondents rated Advancing Access moderately or very helpful in providing PrEP medications, and 76% of participants rated the 340B program the same way (Figure 1); 44% of those surveyed stated that they always help clients enroll with Advancing Access (Figure 2).

Table 1. Survey Participant and Client Characteristics (N=17)

Characteristic	n (%) or mean percentage (SD)
Survey respondent, n (%)	Total N=17
Race/ethnicity, n=16[a]	
Non-Hispanic Black	3 (17.6)
Hispanic or Latino/Black	4 (23.5)
Non-Hispanic White	4 (23.5)
Hispanic or Latino/White	1 (5.9)
Asian	4 (23.5)
Mixed race/ethnicity	2 (11.8)
Role, n=15	
Prescribing clinician	8 (47)
Organizational leadership	3 (17.6)
Registered nurse	1 (5.9)
Program manager	1 (5.9)
Program director	1 (5.9)
Compliance specialist	1 (5.9)
Duration at organization, n=15	
<1 year	4 (23.5)
1−2 years	5 (29.4)
3−5 years	5 (29.4)
6−10 years	1 (5.9)
>10 years	1 (5.9)
Reported client, mean percentage (SD)	
Race/ethnicity	
Latino/a/x or Hispanic origin	35.4 (17.6)
American Indian/Alaska Native	1.2 (2.7)
Asian/Asian American	3.2 (3.5)
Native Hawaiian/Pacific Islander	1.4 (2.9)
Black/African American	33.9 (24.0)
White	36.2 (25.9)
Other	7.9 (14.3)
Gender/sexuality	
Heterosexual cisgender men	6.0 (10.0)
Cisgender women	6.6 (8.4)
Cisgender men who have sex with men	62.8 (32.7)
Transgender or nonbinary persons	9.0 (11.6)
Insurance mix	
Uninsured	45.7 (35.8)
Private insurance	38.3 (34.1)
Medicaid	5.1 (6.4)
Medicare	4.9 (6.0)

Note: Survey recipients were asked to provide demographic information about themselves as well as background on their specific role within their organization. Each respondent also provided estimates of the proportion of clients that fit into specific categories: gender/sexuality, race/ethnicity, and insurance coverage. Data were collected through online survey instrument, open February 17, 2023, to March 23, 2023.
[a]Survey allowed for multiple responses in the self-reported race/ethnicity.

Focus group participants discussed the utility of Advancing Access for providing medications to uninsured clients. Providers reported positive experiences with the program, highlighting how quickly and reliably clients were approved, as follows: "I just work with Gilead, that's all that we've worked with since I've been with them [my organization] and I've had good experiences with Gilead . . . as far as getting them [people without insurance] approved." − Administrative Staff Member

When the conversation turned to Ready, Set, PrEP, few participants had heard of the program. Providers generally opted to direct applications for uninsured clients through Gilead's program and insured clients through private insurance.

Regarding patients' insurance and financial barriers to accessing pre-exposure prophylaxis, in both the survey and focus groups, participants indicated that prior authorizations were a barrier to providing PrEP to clients with private insurance: 38% of survey respondents considered prior authorizations a major barrier, and 37% considered them a moderate barrier to providing PrEP. Focus group participants highlighted the time commitment required to manage prior authorizations and the unpredictability of the process, as follows: "We spend . . . more than half of our time on prior authorizations." − Prescribing Provider

The labor associated with prior authorizations led some providers to describe a paradoxical burden in providing PrEP: they claimed it was easier to obtain PrEP medications for uninsured clients than for those with private insurance, as follows: "We find it easier to get people taken care of [provided with PrEP] who do not have insurance." − Prescribing Provider

Providers described several situations where insurance companies dictated which pharmacies clients must use to fill PrEP prescriptions. If these preferred pharmacies were not partner pharmacies for a specific organization, then the prescribing organization could not receive 340B reimbursement from that transaction, creating delays for clients and reducing revenue for PrEP organizations, as follows: "It depends on the insurance company and even then, it can depend on the plan, even within one insurance company, it can be different for different plans because they'll make you call different places." − Administrative Staff Member

Focus group participants described further barriers to comprehensive PrEP care after medications were prescribed, including clinician visits and quarterly laboratory testing.

In terms of the prescribing of differing pre-exposure prophylaxis options, TAF/FTC was the most prescribed PrEP medication, with a mean proportion of 39.7% of

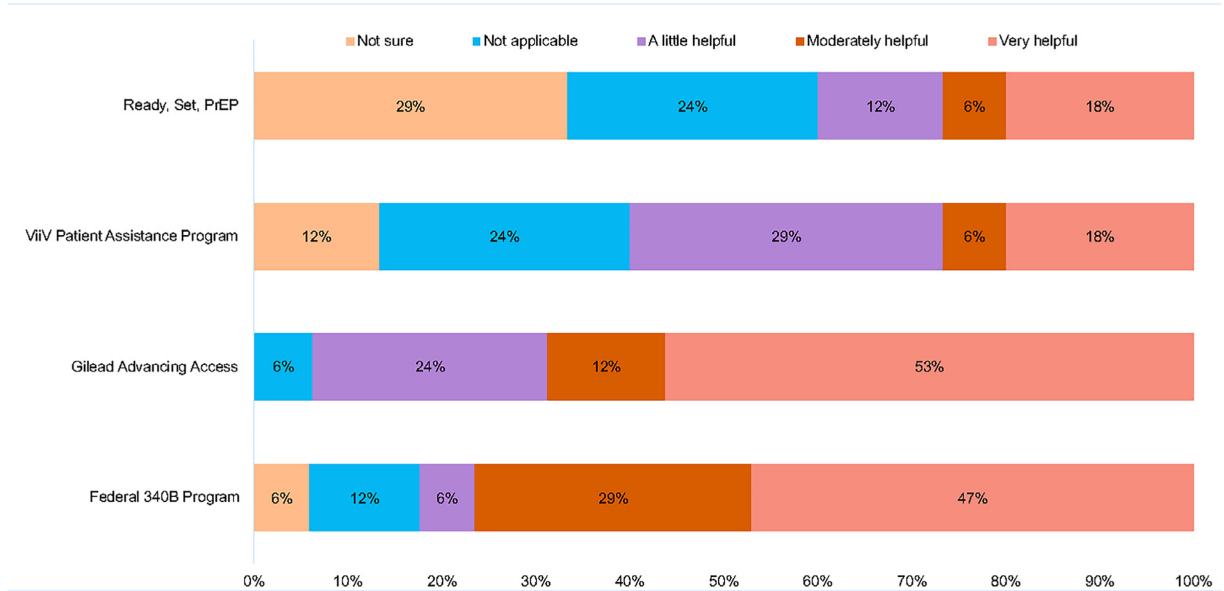

Figure 1. Respondent beliefs regarding assistance program helpfulness in providing PrEP in 2022 (N=17).
Survey recipients were asked to rate the degree to which different programs (Ready, Set, Prep; ViiV Patient Assistance; Gilead Advancing Access; and Federal 340B) were helpful (not sure, not applicable, a little helpful, moderately helpful, very helpful) in their organization's capacity to provide PrEP in 2022. Numbers within bars represent the percentage of the respondents selecting each choice. The choices are colored according to the degree of helpfulness, with orange and yellow representing mild helpfulness and green representing the most helpfulness. Not sure and not applicable are represented by gray and blue, respectively. Data were collected through online survey instrument, open February 17, 2023, to March 23, 2023.
PrEP, pre-exposure prophylaxis.

PrEP prescriptions across organizations. Branded TDF/FTC accounted for an average of 18.6% of prescriptions, whereas generic TDF/FTC (the only generic PrEP option) accounted for an average of 21.9%, and cabotegravir accounted for an average of 6.6%.

Focus group participants considered injectable PrEP a useful option in theory but described significant implementation challenges, as follows: "We don't provide prescriptions for it just because we don't have the protocols in place and the infrastructure to have

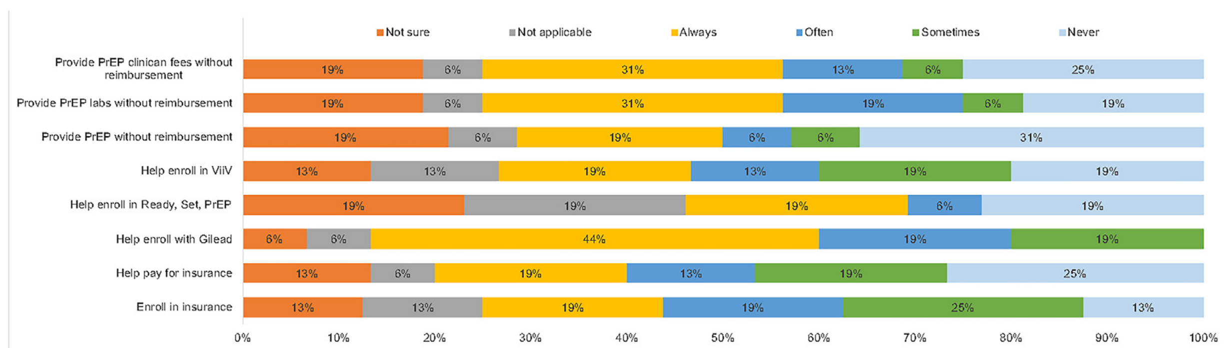

Figure 2. Reported frequency of providing PrEP-related services in 2022 (N=17).
Survey recipients were asked to report how often (not sure, not applicable, always, often, sometimes, never) the organization that they work for provided various PrEP-related services in 2022. Numbers within bars represent the percentage of the respondents selecting each choice. Frequency is represented with colors: green represents the most frequent, and red represents the least. Not sure and not applicable are represented by gray and blue, respectively. Data were collected through online survey instrument, open February 17, 2023, to March 23, 2023.
PrEP, pre-exposure prophylaxis.

someone there to give the injections and all that kind of stuff." — CBO Leader #1

Clients without insurance are unlikely to be able to pay for cabotegravir out of pocket, and for those with insurance, injectable cabotegravir is not always on insurance company formularies. Focus group participants explained that they have had difficulty in getting their clients with insurance a consistent supply of the medication.

I have patients... on Apretude [cabotegravir] since December, they cannot get their medication. It is...a shame, really like there is no way because they have ... insurance. They were so excited, but at the moment that they have insurance, it's like they're doing something wrong because we can never get them through the medication. — CBO Leader #2

These factors have led prescribers to express pessimism about expanding injectable PrEP; only a segment of insured clients can access the medication, limiting the population that can benefit.

When asked to describe the impact of Gilead discontinuing market-level reimbursements for PrEP prescriptions to uninsured clients in January 2022, one third (33%) of survey respondents described delivery of PrEP-associated care and PrEP medications as "much more difficult now" (Figure 3).

In the focus groups, several themes emerged surrounding Gilead's new reimbursement structure. First, the change has significantly affected the financial health of community organizations providing PrEP in Dallas County. Smaller organizations have been disproportionately impacted.

When I started our program, we started with mostly everybody that we saw were uninsured patients because that was the need... And then we started taking insured people as well ... But when Gilead changed the way that they do the funding for non-insured for the patient assistance program ... we had to ... figure out how to pivot to where we could still have PrEP for people and still keep the doors open. — CBO Leader #3

Second, laboratory costs have become a major source of financial strain. Community-based PrEP providers had largely covered theses costs using the revenue obtained from the pre-January 2022 reimbursement scheme. With loss of this revenue, new workarounds and partnerships have emerged to provide laboratory services to clients. CBO Leader #3 opined, "For us to do

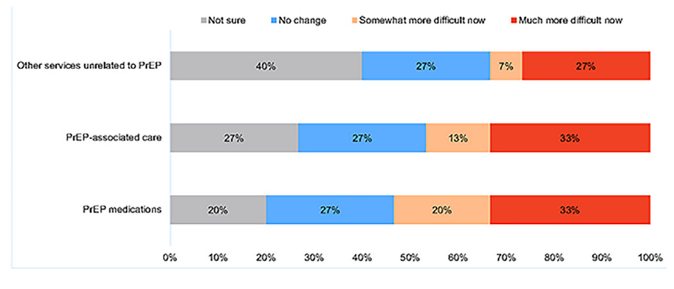

Figure 3. Perceived difference in access to services after Gilead Advancing Access reimbursement changes of January 2022 (N=15).

Survey recipients were prompted with information about Gilead's Advancing Access Program lowering reimbursement rates for PrEP medications for uninsured individuals in 2022. They were asked how this change affected (not sure, no change, somewhat more difficult now, much more difficult now) the ability of patients at their organization to access PrEP medications, PrEP-associated care, and other services unrelated to PrEP. Numbers within bars represent percentages of respondents selecting each choice. Data were collected through online survey instrument, open February 17, 2023, to March 23, 2023.
PrEP, pre-exposure prophylaxis.

a full set of PrEP [labs] that's 100 dollars, two to three months ... we do have partnerships with like Dallas County who help with some labs that we do - not all - but it does take off a little bit."

Finally, declining organizational revenues have led to a decrease in staffing for local community health organizations. CBO Leader #4 said "It's really been hard...we had to lay off 35 people. We have had to cut costs."

In terms of workarounds and facilitators to pre-exposure prophylaxis provision, community organizations have responded creatively to financial instability and decreased revenue: 19% of those surveyed described always helping clients enroll in insurance. Taking it 1 step further, 19% always helped clients by paying their insurance premiums.

Focus group participants described a shift in their goals with clients. Whereas before the goal may have been to enroll uninsured clients with Advancing Access, the new landscape necessitated navigating increased numbers of clients to commercial insurance. Administrative Staff Member said "If you're uninsured, our goal is to get you insured that way we can get you enrolled and signed up and then you can get your medication ... which in time helps us keep the program going. We are still seeing uninsured patients, but we can't see as many as we could before."

Several participants highlighted the plans available on Affordable Care Act exchanges as the most affordable insurance option for clients. The pathway to insurance and the associated premiums may be less desirable for some groups, such as younger patients, who may not

have health problems or take medications other than PrEP. CBO Leader #4 opined "It was actually economically viable to pay full price premium for a patient provided they actually receive their HIV drugs through our pharmacy . . . [It] is that cost-effective and they got the benefit of health insurance." CBO Leader #4 said "Many of the patients we serve, you've talked to maybe somebody that's in their 20s and has no other health conditions and may not be all in on PrEP in the first place. . .then you're gonna tell them they need to enroll in health insurance and start paying a monthly fee. I can see that that's gonna be a hard thing — a hard sell."

Another theme was that a considerable amount of organizational time and resources are spent on communication with clients and coordination between various local and national services that can help pay for PrEP.

DISCUSSION

This mixed-methods study provides evidence of recent financial challenges for the groups tasked with providing access to PrEP medications and care in Dallas, Texas, a southern U.S. city with high rates of new HIV infections and underuse of PrEP. Changes to reimbursement policies from a pharmaceutical manufacturer of PrEP medications have led to significant decreases in revenue for some CBOs, which have hindered their capacity to deliver PrEP care to uninsured clients.

The current system to access PrEP for uninsured individuals relies on a mix of private and public programs and funding sources. People without insurance rely on CBOs to help patch together funding for medications, laboratory services, and medical appointments. The authors found that many potential PrEP users and providers turn to manufacturer assistance programs to obtain fast and reliable access to oral PrEP. Specifically, Gilead's Advancing Access program was seen as efficient and effective among both patients and providers. The authors found that other programs are either less well known, perceived as less user friendly, or considered redundant for uninsured patients.

The authors found that CBOs in Dallas have had to cut costs, reduce staff, and change organizational priorities in response to reduced revenues. Prior to January 2022, organizational revenue from Advancing Access was estimated at $1,600 a month per patient prescribed one of Gilead's PrEP medications.[15] Gilead's reimbursement change was meant to rectify a revenue structure that was never intended in the first place.[23] Still, as the authors have found in the study's focus group discussions, many community organizations had come to rely heavily on these funds. An unintended consequence of Gilead's reimbursement change is to force organizations to respond to decreased revenues using various strategies. Participants reported that it was more financially feasible for their organizations to pay for some clients' insurance premiums than to continue providing PrEP through Advancing Access. Several reported that they regularly provide PrEP-related services at a financial loss. Reduced revenues, rearranged staffing, de-emphasized outreach, and provision of costly services without reimbursement may further weaken the financial strength of organizations and decrease their ability to expand and provide PrEP access.

The authors found that an increased emphasis on enrolling clients in insurance plans created new problems for CBOs. Some insurance companies require prior authorizations, presenting significant burdens for organization staff. Prescribers also conveyed patients' frustrations about lack of medication choice depending on formulary restrictions. The decision to pay for insurance is a personal one for clients to make; even when financially viable for a CBO, clients may not opt for coverage. Finally, although insurance may broadly facilitate PrEP access, there is evidence that acquiring PrEP medications through private insurance is prohibitively costly for some populations.[12] These difficulties suggest that reliance on private insurance plans is an imperfect solution to providing PrEP.

Importantly, there are ongoing attacks on requirements that private insurance plans cover PrEP. Paltiel et al.[14] examined the potential impacts of removing these protections and found that for every 10% decrease in PrEP coverage among U.S. men who have sex with men, there would be an additional 1,140 persons acquiring HIV in the following year. Future research could model the impact of the financial instability described in this paper and translate CBO viability into HIV prevention.

It is difficult to specifically quantify the number of clients connected to PrEP by CBOs statewide or nationally. Recent news reports have attempted to quantify the number of uninsured persons receiving PrEP from HIV prevention-focused clinics. They estimated that at minimum, 7,000 uninsured clients of 340B-covered entities nationally were recipients of free PrEP from Advancing Access.[23] This would equate to (at the time) a pending minimum loss of $100 million annually for the CBOs providing PrEP across the nation.[23]

On the basis of publicly available data provided by PrEP Locator, there are 15 organizations that provide PrEP to uninsured individuals within 30 miles of central Dallas.[28,29] Of those, 12 were represented in this study's qualitative survey. The U.S. Census Department estimates that 528,000 persons in Dallas County alone (23.6% of the population) were living without health insurance in 2022.[30] Data from AIDSVu, another

publicly available data set from Emory University, indicate that there are 8,000 persons taking PrEP in Dallas County.[31] Assuming that some proportion of those receiving PrEP in Dallas County are also without insurance, and the spread from a single PrEP prescription from a 340B-covered entity with pre-2022 reimbursement approached $1,600 each month, the financial implications are substantial.[15] If just 1,000 of these clients were receiving PrEP through local 340B-covered entities, that would be $19.2 million each year in the budgets of 340B organizations in Dallas County. There are clear limitations in these estimations, and more robust and longitudinal research is required to understand the evolving financial landscape and its impact on access to PrEP, particularly for populations with the greatest need.

This study was undertaken in the South, the U.S. region with the highest unmet need for PrEP, and specifically in a state that has not expanded Medicaid.[5,32] Expansion states have higher rates of PrEP use than states that have not expanded Medicaid.[6,33,34] If paying for PrEP becomes increasingly tied to insurance coverage, the PrEP gap between the South and other regions may widen. Evidence of significant financial instability resulting from a single pharmaceutical company's policies also shows the tenuous ground that southern CBOs currently stand on. This study suggests that the current system is not providing sustainable access to PrEP in this critical region.

Another important strategy for HIV prevention is implementation of long-acting injectable PrEP. Study findings suggest that this modality is highly desired by patients but difficult for CBOs to implement given variable insurance coverage and staffing cuts that impede access and administration of injections. Without broad coverage for this expensive medication, clients who cannot adhere to oral PrEP are left without options.

To alleviate financial challenges for PrEP providers, a robust response is required. Experts in PrEP research and policy have recommended implementation of a national PrEP program to support access to PrEP medications and care for uninsured and underinsured people.[10,35] CBOs are struggling in the current environment, and ensuring their financial stability will be imperative to any national PrEP program. Some CBOs have developed innovative solutions, but there has been little information published about these strategies. In the immediate term, PrEP summits in cities across the country could help sustain PrEP delivery until a centralized response materializes. The political climate in the U.S. is increasingly polarized, especially in the South. Recent developments have restricted access to HIV care and further stigmatized health care for members of the lesbian, gay, bisexual, transgender, questioning, and others community.[36,37] Additional investigations into successful strategies for PrEP outreach and delivery mechanisms are urgently needed. CBOs with short-term budget deficits may be forced to redirect their energies, cut their organizational capacity, or close. This may set back efforts to expand PrEP access over the coming years by limiting the number and diversity of practice settings and providers who are prescribing PrEP in communities.

Limitations

The generalizability of this study is limited by its small sample size from a single county in Texas. Participants represented a small subset of the employees at local PrEP-providing agencies, so additional perspectives from other employees at these or similar organizations may have been missed. Furthermore, the financial status of the organizations represented by this study's sample could not be independently assessed, and participants in the study who have nonfinancial roles at their organizations may not have accurately characterized the financial health of these organizations.

CONCLUSIONS

Financing PrEP medications and care for uninsured individuals relies on contributions from multiple entities. CBOs are at the forefront of PrEP delivery and expansion. A lack of centralized funding leaves these organizations vulnerable to financial strain. The authors found that recent changes to PrEP reimbursement policies have had a significant impact on the operations of CBOs in Dallas, TX. Organizations have responded to reduced revenues in innovative ways, often by expanding efforts to connect clients to insurance. Large disparities in PrEP uptake exist, and the South is at risk of falling further behind.

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CREDIT AUTHOR STATEMENT

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