The Path Forward for a National PrEP Program

A Report by PrEP4All

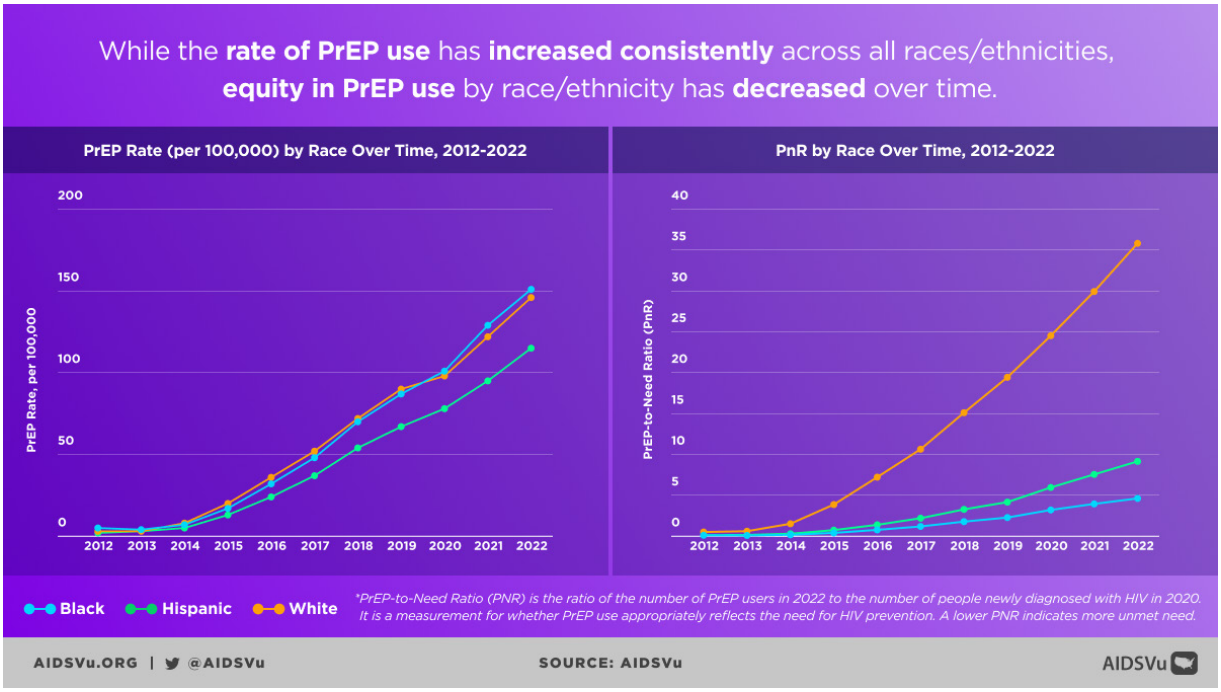
October 2024

PrEP4All

I. Background

The need to respond to a growing health equity crisis

In July 2012, the first antiretroviral medication for pre-exposure prophylaxis (PrEP) to prevent HIV acquisition was approved by the Food and Drug Administration (FDA) based on data that showed it to be safe and highly effective. Oral tenofovir-based PrEP was heralded as a gamechanger in the fight to end new HIV infections in the United States and globally. Yet twelve years later, the promise of PrEP has not been fully realized. Rates of new HIV infections remain high among the most at risk groups in the United States—as they do worldwide. But most people who need PrEP do not have it. PrEP access across the United States is reaching far fewer than the 1.2 million people the Centers for Disease Control and Prevention (CDC) estimates would benefit from PrEP.



What's worse is that PrEP use in America replicates patterns of health disparities that plague our health systems and communities. The people who need PrEP most do not have it, according to data illuminating the growing disparities across race and ethnicity, geography, gender, and gender identity. According to Emory University, Black people represented 39% of all new HIV diagnoses in 2022 but accounted for only 14% of PrEP users in 2023. Hispanic/Latinx individuals made up 31% of new diagnoses, but only 18% of PrEP users. By comparison, white people represented 24% of new diagnoses but 64% of PrEP users. CDC data also indicate that while 41% of males who would

benefit from PrEP are receiving it, only 15% of females are doing the same, despite significant HIV transmission rates, especially for Black/African American women. Transgender women in particular continue to face barriers to PrEP use, despite a higher incidence of HIV within this community. Transgender men and nonbinary individuals remain neglected in the national PrEP response.

> ***The need to focus on the uninsured is clear, especially in states that have not yet expanded Medicaid, most of which are in the deep South where disparities around HIV incidence and disparities are most acute.***

A program that provides a safety net for un- and underinsured individuals is critical to addressing inequities. Recent research out of Johns Hopkins University (JHU) has shown that even small increases in cost sharing lead to large increases in rates of PrEP abandonment, particularly for individuals that are presently underrepresented in PrEP access. The need to focus on the uninsured is clear, especially in states that have not yet expanded Medicaid, most of which are in the deep South where disparities around HIV incidence and disparities are most acute. This is a question of equity, as uninsured individuals in America are more likely to come from communities of color and undocumented communities. Notably, a 2019-2020 CDC survey of HIV negative transgender women found that 22.6% did not currently have health insurance, a rate that is more than three times the national estimates of uninsured Americans. Rates are likely to move in the wrong direction, with Medicaid "unwinding" following the end of the COVID-19 public health emergency jeopardizing coverage and access for millions of Americans.

Underinsured individuals also face barriers to PrEP access for a variety of reasons, including widespread insurer non-compliance with the Affordable Care Act's mandate that PrEP be covered without cost-sharing and young adults' reticence to use their parent's insurance for PrEP. Recent legal challenges to the Affordable Care Act (ACA) mandate for coverage of preventive services could exacerbate this issue. At the time that this report went to press, these challenges were still in the judicial system, with uncertain timelines and possible Supreme Court review. Additional threats to existing pathways to access have emerged as the result of inappropriate reliance on pharmaceutical manufacturers to support equitable access. Beginning in January 2022, Gilead Sciences singlehandedly eliminated hundreds of millions in funds for clinics serving un- and underinsured individuals living with or vulnerable to HIV. The company has also just communicated that it will end its manufacturer assistance program for Truvada in 2025, creating undue pressures for health departments and organizations that continue to rely upon it for medication access.

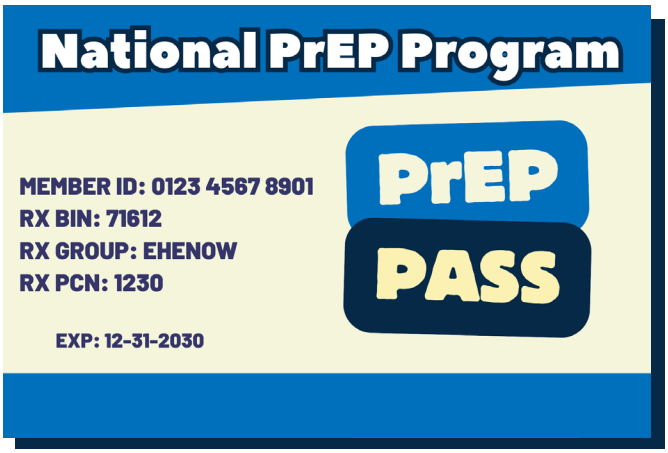
Though this patchwork of coverage options and mandates for un- and underinsured individuals has always been woefully inadequate, it has supported some PrEP use among under-served populations. Losing even this scant set of supports would increase disparities, and the current threats make a National PrEP Program an even more urgent priority.

At a time where the complexity of American healthcare shows no signs of improving, there is an urgent need for alternatives, including ambitious, innovative health justice-based approaches that make access easy and equitable. This is a strategic moment for a comprehensive public health approach to PrEP scale up that avoids the past complexity, fragmentation, and dependence on pharmaceutical manufacturers. As there is bipartisan support for lower drug pricing, it is also a chance to show the transformative potential of generic competition when it is paired with reasonable public investment and a strategic approach to scale up. In a time of innovative but expensive long-acting PrEP formulations, this is also the time to increase government capacity to negotiate a public health price that allows for equitable access as part of a public health program. And importantly, at a time when other infectious disease threats continue to present themselves to the same marginalized communities that are shut out of the current PrEP response, a National PrEP Program presents an opportunity to build federally funded infrastructure that can also be leveraged to improve national biosecurity and pandemic preparedness for all Americans.

Advocates gather at Emory University Rollins School of Public Health, Summer 2024, to discuss PrEP equity, provider expansion, and demand creation.

A National PrEP Program as a solution

The reasons behind PrEP disparities are many – systemic racism, stigma, and a fundamentally broken United States health care system all contribute to our collective failure to leverage PrEP for the communities who would most benefit from it. At the center of these failures is a system characterized by fragmentation and inefficiency that is hampering our ability to mount an integrated, comprehensive, and equity driven response to PrEP, especially for uninsured and under-insured individuals. Our current national approach to PrEP access expects individuals to jump through numerous hurdles to access an intervention for a disease they do not have. For someone who is uninsured, accessing PrEP requires identifying a coverage pathway for the medication via a state PrEP program or a manufacturer assistance program and applying for that program, and then identifying a separate program for PrEP clinical and ancillary services, including labs. PrEP providers are devoting scarce financial resources to pay for full-time employees whose job it is to navigate this complexity. This complexity is not only an incredibly inefficient use of resources, it has direct equity consequences. If we truly want to reach communities who have been historically marginalized and left out of traditional health care systems, we must remove the barriers and make it simple.



PrEP4All and other partners have called for a National PrEP Program to do just that – create an integrated and simple delivery system for PrEP that leverages an efficient and centralized financing system for PrEP. This concept is crystalized in a "*PrEP Pass*," a printable or virtual card that allows un and underinsured individuals to access the PrEP services they need at zero cost. Such an approach would be accompanied by other critical interventions to increase access to PrEP prescribers, including the innovative use of telehealth to expand into nonclinical touch points within communities, and campaigns made by and for priority communities. President Biden has amplified this call, including a National PrEP Program in his proposed budgets for FY2023, FY2024, and FY2025. And most recently, the Senate appropriations bill released in the summer of 2024 has also taken up this policy goal, including language to fund a National PrEP Program in its FY24 appropriations package.

The CDC has also heeded the call to support an integrated approach to PrEP, awarding $10M in funding in October 2024 for five HIV prevention grantees currently eligible for Ending the HIV Epidemic initiative funding to develop a comprehensive PrEP program in their jurisdictions.

The initiative has the potential to reduce PrEP disparities in some of the states with the highest levels of uninsured individuals, with four of the five jurisdictions having not expanded Medicaid. Momentum is building for integrated PrEP initiatives, with more local initiatives, such as the ones funded by CDC in their recent notice of funding, providing a possible blueprint for a broader National PrEP Program.

It is worth noting that at the time of writing the World Health Organization has once again declared a public health emergency for mpox, leading to concerns of a repetition of the 2022 worldwide outbreak. At the same time, the US is confronting an out-of-control syphilis epidemic and struggling to find access pathways for doxyPEP– a highly promising new approach to bacterial STI prevention– and imported generic benzathine penicillin G treatment meant to alleviate a multi-month treatment shortage in the US. Having infrastructure in place for PrEP would create pathways for access to other critical interventions for our communities, making our advocacy for a National PrEP Program relevant to ongoing discussions of national biosecurity and pandemic preparedness.

II. Discussion and Recommendations: National PrEP Program Pillars

The following four pillars are essential components of a National PrEP Program. Each pillar was discussed at length during the two consultations and those discussions helped to inform the considerations for local implementation via pilot and jurisdictional integrated PrEP programs, building toward a comprehensive National PrEP Program.

> ***Four Pillars of a National PrEP Program***
> 1. ***Medication Access***
> 2. ***Lab Access***
> 3. ***Provider Expansion***
> 4. ***Demand Creation***

All of these pillars must be operationalized concurrently for the National PrEP Program to be effective. Creating elaborate access systems without effective community campaigns will lead to underutilization of innovative delivery methods. Similarly, releasing awareness campaigns before comprehensive systems are in place could lead to increased demand without access options, ultimately discouraging potential PrEP users.

Additionally, any PrEP program – whether it is initiated at the federal or state and local levels – should also provide access points and support for underinsured individuals, including individuals who have insufficient PrEP coverage and those that continue to receive cost-sharing bills for PrEP.

Pillar 1: Medication access

Antiretroviral medication is the core component of PrEP interventions. Formulations currently include a once-daily pill and a long-acting provider administered injection. TDF/FTC has also been found to be effective for preventing sexual acquisition via "on demand" or "2-1-1" dosing for cisgender gay and bisexual men. The three formulations available for PrEP in the United States at the time of the writing of this report (late 2024) are described in the following table:

PrEP Medications Approved by the FDA in the United States and List Price (August 2024)

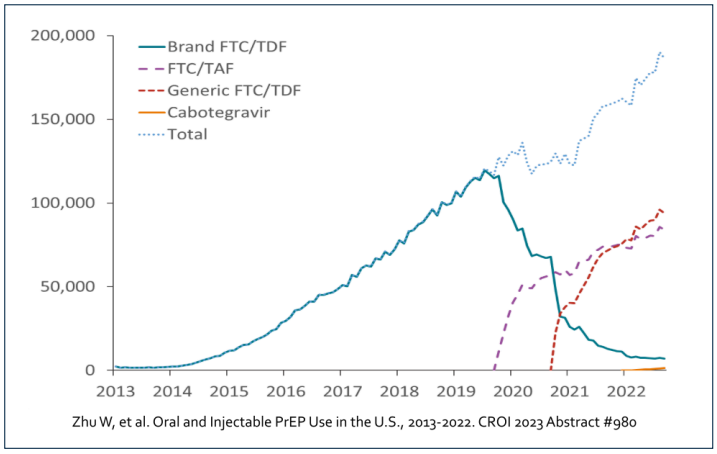
Medication	Approval date	List price
TDF/FTC (sold under the brand name Truvada by Gilead Sciences and also available as generic from multiple manufacturers)	July 2012 for Truvada (brand) and October 2020 for generic TDF/FTC	Generic TDF/FTC = $23/month Truvada = $1,800/month
TAF/FTC (sold under the brand name Descovy by Gilead Sciences)	October 2019 (not approved for individuals at risk of vaginal exposure)	$2,200/month
Long-acting cabotegravir (sold under the brand name Apretude by ViiV Healthcare)	January 2021	$1,900/month

The consultations identified a set of priority areas and related action steps that will be key to ensuring medication access in the context of a National PrEP Program:

Priority Area 1: Leverage generic TDF/FTC

In the story of PrEP in the United States, the advent of generic TDF/FTC was another turning point that ultimately did not turn. Available since 2020, generic TDF/FTC is safe, highly effective, and available for less than $1 a pill, yet it accounts for only 50% of all PrEP prescriptions (see figure). This is far less than might be expected given that the generic medication is more affordable than branded formulations and entirely equivalent to branded daily oral formulations in terms of safety and efficacy. Instead, thanks to Gilead's extensive marketing, around 40% of PrEP users were on Descovy, Gilead's brand-name product, as of December 2023. This percentage likely includes many

PrEP users who could use the cheaper generic TDF/FTC safely and effectively. 2021 findings out of Fenway Health found that, among PrEP users being switched to F/TAF, 93% did not have clinical indications requiring a change, and 14% of users may have experienced a harmful switch based on the increased cardiovascular and weight gain risks associated with Descovy.



Zhu W, et al. Oral and Injectable PrEP Use in the U.S., 2013-2022. CROI 2023 Abstract #980

Participants in PrEP4All's consultations largely agreed that generic TDF/FTC was not being leveraged to the extent it could be, for a variety of factors, including large marketing pushes from Gilead for Descovy, reservations among some PrEP users about the equivalence and quality of generic medications, and 340B incentives that reward 340B entities with savings when they provide higher-cost drugs to insured patients.

Overall, these factors have dampened enthusiasm for the use of generics even though these low-cost medications can be used, unlike expensive branded versions, to expand access in affordable, sustainable, and novel public health programs, including for un- and underinsured populations that do not always have access to community health centers with funding available to address gaps in cost coverage. The only federal program that has attempted to centralize access to PrEP medication has been Ready, Set, PrEP, a program initiated in 2019 with donations of brand-name medication from Gilead Sciences. The program aimed to expand access to PrEP medications for underinsured individuals. This laudable objective failed to show impact, and the program overall may even have undercut the generic market for PrEP since the program only included brand-name medications even after generics became available. After advocacy from the HIV community who pointed to low uptake of the program and a disturbingly high administration price tag, Ready, Set, PrEP closed to new participants in July 2024. It is still unclear how the infrastructure of that program could be used for a new endeavor.

Priority Area 1 Action Steps:

1. **CDC should allow other HIV prevention funding to be used to purchase affordable generic PrEP medications.** Historically, CDC has not allowed funds to go toward antiretroviral medications, however it changed this policy in a limited way for the new PrEP funding announcement released in August 2024. There is still a longstanding policy barring use of broader CDC HIV prevention funding that goes to state and local health departments to be used for the PrEP medication.

2. **As part of the new CDC funding opportunity, state and local health departments managing PrEP programs should incorporate a strategy to leverage the opportunity provided by low-cost generic TDF/FTC,** coming up with creative delivery approaches and novel access points that ensure that PrEP program participants are accessing a medication that is both clinically indicated and cost effective. This should be a priority of a health department receiving new PrEP funding from CDC to implement an integrated PrEP program.
3. **CDC should invest in collecting and sharing data and best practices** on provision and uptake of generic PrEP in order to help inform future efforts.

The PrEP program pilot programs have an opportunity to leverage new CDC funding to increase PrEP access points through the pathways described below. Where possible, these pathways should be used to support programs that offer rapid-start and point-of-care PrEP medication, rather than asking clients to fill initial prescriptions at a pharmacy or undergo lengthy wait times for lab results:

- Utilize a central health department pharmacy to purchase PrEP medication and expand access pathways via community-based touch points. This pathway would allow for a centralized bulk purchase model and distribution via mail order, similar to how several AIDS Drug Assistance Programs (ADAPs) operate.

  Or

- Provide sub-grantee funding to providers in the jurisdiction to purchase generic TDF/FTC using the provider's usual procurement processes. This pathway would support a decentralized provider network model that allows providers and service points that may not have access to dedicated funding for PrEP (e.g., family planning clinics) to use their existing procurement processes to do so.

Note that the PrEP Pass discussed throughout the rest of this document as originally conceived would function at a national level as a reimbursement to pharmacies for generic medications they purchase. With newly funded CDC pilots where funds will be given in advance to either a central pharmacy and/or new/novel sub-grantees, such a Pass would not be necessary for reimbursement; however it may still be of use as an intuitive engagement mechanism for enrollees to help them navigate their options for medication and lab access in a locally established network.

4. **Create a centralized federal *PrEP Pass* centered on generic PrEP.** Following the extremely low enrollment in Ready, Set, PrEP, future federal initiatives must include generic TDF/FTC and prioritize access based on clinical evidence, not manufacturer marketing or systemic disincentives to scale up high quality affordable generic medications. Advocates remain interested in seeing if any of the Ready, Set, PrEP infrastructure can be repurposed or if the Gilead donation could serve as a pathway to Descovy for the small percentage of PrEP users who have clinical indications for it, however at the time of writing there was no indication of any such repurposing of Ready, Set, PrEP medications or infrastructure. By being able to prioritize access without manufacturer biases, the program could be integrated within a more comprehensive public health approach to PrEP scale up that includes labs and doctor visits; Ready, Set, PrEP was notably unable to do this.
5. **Emphasize simplicity, comprehensiveness, and flexibility.** The *PrEP Pass* concept would ideally be accessed through only minimal application paperwork that is also accessible to undocumented individuals, avoiding financial eligibility forms or overly cumbersome renewals. The Pass should function as easily as a manufacturer assistance card when presented at the pharmacy and lead to zero cost sharing for generic TDF/FTC access.
6. **Counteract false messaging around generic TDF/FTC and address concerns about generic medications in general.** Despite the fact that 9 out of 10 prescriptions accessed by Americans are generic, there are still concerns among potential PrEP users about generic equivalence. These can, however, be surmounted. Notably, a successful telePrEP program out of Iowa has not seen pushback on generic medications, and in general participants emphasized that we should avoid assumptions that the majority of community members would reject generic PrEP. However, in communities that have been particularly targeted by pharmaceutical marketing or some other form of mis- or disinformation, some counternarrative and trust building may be necessary. Strategic use of community health workers and provider education may be of use here.

Priority Area 2: Prepare for new PrEP products that could improve adherence

The PrEP pipeline is incredibly dynamic, with new products currently undergoing clinical trials. The first long-acting injectable product for PrEP, long-acting cabotegravir, was approved by the FDA in 2021, but so far uptake has been relatively low in the United States. A new long-acting injectable, lenacapavir, manufactured by Gilead Sciences has been shown to be highly effective in preliminary results from two clinical trials and shows promise to perhaps have a bigger impact on uptake than long-acting cabotegravir because it is taken every six months and is available in a subcutaneous rather than intermuscular injection. Clinical trials for cisgender women and gay, bisexual, other men who have sex with men, transgender, and nonbinary populations show strong efficacy and adherence for lenacapavir. But the price tag for lenacapavir is likely to be high, creating the same financing and fragmentation conundrum that the very first PrEP medications created.

While participants said it was too soon to know how widely demanded such products will be and that oral options will likely remain of central importance for the foreseeable future, the group identified several considerations for potential action in light of new, high-cost but highly effective PrEP products.

Priority Area 2 Action Steps:

1. **The federal government should leverage its buying power and the alternative of generic PrEP to negotiate a fair public health price for new PrEP products.** Without a fair price, uninsured and underinsured individuals will continue to be forced to jump through the hurdles that characterize a fragmented delivery system. Manufacturer assistance programs are not a substitute for a well-functioning public health delivery system for PrEP.
2. **State and local PrEP programs, including the pilots that will be funded starting later this year, should work collaboratively to negotiate sub-340B discounts with manufacturers to ensure access to low-income individuals who need and want long-acting injectable products for PrEP.** While generic TDF/FTC should still be prioritized as a safe and effective and highly cost-effective intervention, long-acting products may be preferable for patients who struggle with adherence. ADAPs have used a similar model to negotiate for public health prices for medications, creating the ADAP Crisis Task Force in the early 2000s as a negotiating bloc made up of ADAPs with the largest market share of clients. The Task Force has been successful in securing millions of dollars in discounts from manufacturers and the model could be replicated for PrEP.

Pillar 2: Lab access

Another key component of PrEP is access to the laboratory services that are part of the PrEP intervention. The cost of these services varies considerably depending on the area of the country and the type of contract a health department or clinic has negotiated with a lab. And yet, these labs are essential to the clinically recommended standard of care for PrEP.

Pillar 2 Action Steps:

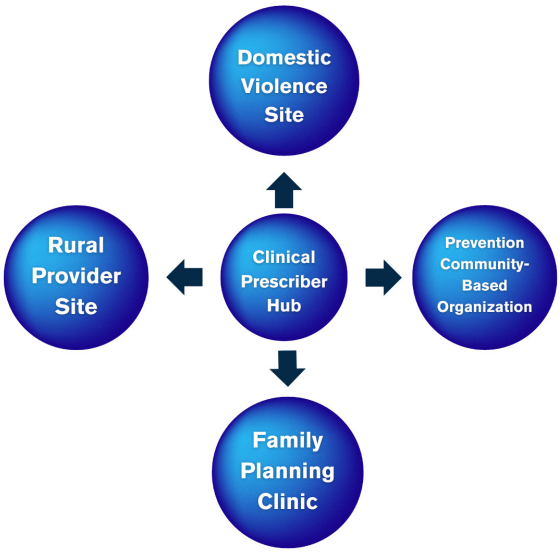
1. **State and local PrEP programs should secure partnerships with both brick-and-mortar labs** and self-testing labs to provide PrEP users with a range of options that truly meet them where they are. Local challenges with specimen transport and unique considerations for different tests should be assessed and resolved. Initiatives like *"Together, Take Me Home"* are good ways to increase access to self-testing. Health department programs that are paying for labs for uninsured people on PrEP should also consider developing fee schedules aligned with Medicaid to expand lab access to participants at a cost-effective price point.
2. **A federal National PrEP Program should also explore centralized contracting options with a range of public health, commercial, and self-testing labs** that would enable a uniform fee schedule (pegged to Medicare, for instance) for PrEP labs and would ensure various access points for participants in the program.
3. **PrEP programs should consider the capacity of America's public health labs to support PrEP access, though billing capacity will need to be assessed.** However, costs are typically lower than for profit labs, and existing relationships with health departments may be leveraged.
4. **For end user consistency, the same *PrEP Pass* that allows for access to generic medications would be used for lab access.** Historically, utilizing multiple programs to cover all PrEP-related expenses has discouraged equitable uptake.
5. **Telehealth and virtual options for lab collection remain of interest for expanding PrEP access.** Ongoing discussions related to FDA regulation of self-collected testing samples have the potential to be disruptive to such systems and must be monitored.

Pillar 3: Provider expansion

Provider expansion for PrEP is a key facet of equitable access. There are simply not enough touch points for PrEP that are meeting communities that have been historically marginalized and left out of traditional health care systems where they are. Federal funding initiatives through the Ending the HIV Epidemic initiative have prioritized community health centers to increase PrEP access. While community health center PrEP efforts are essential, they are in no way sufficient. Data released on the impact of the community health center PrEP investment indicates that more is needed to expand access. Creative and innovative strategies to build a culturally competent and expansive provider network must include multiple options for access, including through telehealth, community touch points, and primary care.

Priority Area Three Action Steps:

1. **Identify and select provider networks based on community input and state and local expertise.** In most states, PrEP requires a prescription from a licensed provider. However, the sites where clinical prescribers for PrEP are most likely to be may not be the community touch points where people most in need of PrEP are seeking care or other services. PrEP programs should consider a hub and spokes model for access, supporting (and requiring) clinical prescriber hubs to set up contractual and funding relationships with a network of community touch points. Such an approach can also creatively leverage telehealth; in such a model, patients can consult with and receive a prescription from a provider virtually at a nonclinical site, without needing to go to a clinic that may be inaccessible due to distance, stigma, medical mistrust, or other factors. The funding component is essential as it is simply not workable to expect smaller, underfunded organizations to take on PrEP alongside other essential services without any additional funding to do so.



2. **Evaluate and scale telehealth activities to maximize equitable and affordable access.** Telehealth capacity is increasing, meeting a need to expand PrEP access beyond the four walls of a clinic. Health department tele-PrEP programs have proliferated in recent years and may provide models for replication. However, telehealth capacity building requires funding and technical expertise. From the end user perspective, telehealth should be seamless and simple, but developing that interface requires an investment in technological infrastructure, staffing capacity, legal compliance, and operational processes. Telehealth delivery of PrEP care has shown promise in providing equitable access to PrEP in some contexts, but it is clear that this mode of delivery can be complex to implement and will not work well for people with no or poor internet access, those without a stable address, and people preferring face-to-face communication for personal or cultural reasons. It will be essential to carefully consider which telehealth approaches will work best for local communities.

   For national, state, and local implementation of telehealth activities, an initial assessment of what platforms and approaches are already being successfully utilized could help minimize costs and ensure that telehealth expansion works well within the existing ecosystem. In some contexts, community-based organizations or health care institutions may be well placed to offer telehealth locally. In combination with a *PrEP pass* affording access to free lab tests and medication, a free national PrEP telehealth service, if well implemented, might streamline access to care for many. Building upon effective national platforms such as *Together, Take Me Home* or the CDC's National Prevention Information Network *PrEP locator* may also be a great option for CDC funded pilot jurisdictions. Incorporating the capacity for automated PrEP adherence reminders may also improve outcomes.

3. **Invest in community-based infrastructure, especially in organizations, including nonclinical and non-HIV entities, that serve Black/African-American, Latino/Hispanic, undocumented immigrant, and transgender communities.** This investment should include capacity building activities that build expertise, staff, and best practices for PrEP access in community-based and faith-based settings. Best examples for across the country should be promoted and shared through dialogue and conversations.

4. **Partner with local health departments and sexually transmitted disease clinics.** Engaging local health departments should include analysis of all PrEP funding streams, including CDC EHE funding and flagship health department HIV prevention and surveillance cooperative agreements, to leverage new resources to fill in gaps and maximize existing funding. In some cases, local health departments may be receiving funds to provide some PrEP services but may need assistance providing an integrated access point for all PrEP services someone might need.

5. **Consider additional clinical access points including urgent care, family planning, and college-based clinics.** Using automated notifications as part of electronic medical records to alert providers that an individual may be a good fit for PrEP may also be productive, as has been demonstrated within a large Atlanta-based integrated health system.
6. **Continue to explore and expand pharmacy access points,** including through state and federal policies that support the ability of pharmacists to provide services within the full scope of their licensure and the ability of pharmacists to get reimbursed for those activities.
7. **Invest in provider detailing and education** to increase the number of providers knowledgeable about PrEP and able to provide PrEP services. This should include the gamut of provider types where people most in need of PrEP seek care, including primary care providers. Many existing educational resources could be tapped, such as the AIDS education training centers, to advance this work.

Pillar 4: Demand creation

Any PrEP program needs to answer the question of whether, once the PrEP program is built, will people actually come to it? Up until now, demand creation has not been front and center of public health efforts around PrEP because public health access points and availability of PrEP have been fairly limited. Additionally, the price of PrEP may have limited willingness to broaden PrEP messaging for key populations such as cisgender women and transgender and gender nonconforming individuals. A fully functioning integrated and comprehensive PrEP program at either the national or state/local level will be able to test whether a corresponding demand creation program can move the needle on PrEP access, especially for communities we are currently leaving behind.

Priority 4 Action Steps:

1. **Include funding for demand creation activities as a standard part of all comprehensive PrEP programs.** These activities should be informed and driven by communities most impacted by PrEP disparities and should identify messages and community messengers who represent these communities. However, some more progressive and sex positive messaging may require funding provided by non-governmental entities. Too often, HIV prevention messaging is centered around a public health motivation and not an end user motivation, such as anxiety reduction, romantic connection, or pleasure.
2. **Support a mix of national and locally- or community-tailored campaigns to broaden knowledge of and demand for PrEP.** National campaigns have the benefit of shifting overall cultural narratives on effective HIV prevention, while tailored campaigns can resonate with specific motivations for PrEP usage among key populations.

3. **Demand creation for PrEP should be paired with sexual health education,** particularly in the South, where sexual health education is limited.
4. **PrEP awareness campaigns should include not only information about the intervention, but also information about how and where individuals can access PrEP.** Pairing messaging with a link and/or a hotline that directly connects them to a provider and a *PrEP Pass* will be much more effective than endless awareness building.
5. **Marketing for PrEP should be targeted to specific communities, including women, transmasculine individuals, Latino/Hispanic communities, undocumented individuals, and young Black/African-American gay men.** In all cases, the best approach is for campaign designers to have some personal connection to the populations we are trying to reach as well as a proven track record of successful message delivery within these communities.
6. **Messaging should be developed with attention to the need to address misinformation and disinformation about TDF/FTC and generic medications in general.**
7. **Campaigns must be accessible in the languages spoken by communities disproportionately impacted by HIV.**
8. **Oversimplified social media approaches should be avoided.** Blending social media approaches with in-community and artistic campaigns will be more effective. Homing in on niche social media and dating/hook up sites may help messaging stand out.

III. Federal Actions and Policy Recommendations

The following are recommendations for federal actions to advance a National PrEP Program.

1. **Congress must fund all HIV programs, including allocations for a National HIV Program, at the levels necessary to continue the nation's effort to end new HIV transmissions.** Recent proposals to cut HIV funding included in appropriations bills from the House of Representatives threaten not only progress on PrEP, but on US ability to mount effective public health responses to infectious diseases.
2. **Congress must authorize a National PrEP Program the size and scale of the initiative included in President Biden's FY2023, FY2024, and FY2025 budgets.** We strongly support an allocation of funding to ensure that the program is sustainable over the long-term and should include funding for all aspects of the PrEP intervention, with a focus on expanding access to un- and underinsured individuals. The ability of the federal

government to negotiate a fair public health price for new brand-name products is critical to avoiding the access and equity barriers that have plagued PrEP access in the United States for over a decade.

3. **CDC must provide comprehensive support to the jurisdictions who receive funding through its new PrEP funding initiative to ensure they are successful.** Support should include technical assistance to program implementers and evaluation activities that are able to discern how these programs can be replicated in other jurisdictions and nationally. Ideally, technical assistance will include opportunities to convene and discuss implementation across jurisdictions and in partnership with organizations that have lead advocacy for equitable PrEP access via a National PrEP Program.
4. **Greater transparency from HHS/CDC on current federal PrEP expenditures and their impact may improve synergy with CDC's new pilot initiative and identify additional funding to immediately expand PrEP access in other jurisdictions.**

IV. The Costs and Benefits of a National PrEP Program

As part of our expert convenings, we also discussed what is known about the potential costs and benefits of a National PrEP program and what remains to be explored. Here, we examine what answers came out of our discussions and raise some of the priority areas for exploration. We also highlight recent literature that brings new insights to the discussion.

Costs

In a December 2021 publication outlining a novel financing and delivery model for PrEP delivery in the US– later published in the Journal of Law Medicine and Ehtics– JHU and PrEP4All authors estimated that at a national scale and taking into account a mix of patients with varying needs of medication, lab, and provider coverage, 6,000 monthly prescriptions and associated direct services would cost less than $500,000 per year. Additional discussions since that time have led us to expand costing estimates to include expenses for a state/local pilot, build in limited insurance assistance, and include demand creation activities.

Within our discussions we broke down these potential investments on a state/local level in order to receive feedback:

Integrated PrEP Program Supplemental Awards (Estimated annual funding for one jurisdiction = ~$2-3.5M)		
Program Component	**Justification**	**Estimate**
Generic TDF/FTC Purchase	Assuming 2,000 individuals served in high need jurisdictions.	Assumes current average generic price of $23/mo. -purchased by PrEP supplemental award grantee or eligible sub-grantees.
Lab purchase	Assuming 2,000 individuals served in high need jurisdictions	Assumes average PrEP lab costs of $600 per person per year.
Insurance assistance	Assuming assistance for 200 individuals	Assumes average premium assistance of $200/month for 12 months
PrEP clinical and non- clinical services, including provider capacity building	Each grantee of the supplemental award would be required to initiate a competitive process open to health departments, clinical organizations, or other entities to build a hub and spoke model of a PrEP prescriber paired with non-clinical CBOs with expertise and reach into communities underserved by PrEP providers currently	Each grantee would establish 2-3 “hubs” with networks of at least 4 non-clinical CBOs each. Funding allocation would depend on anticipated PrEP utilization
Demand creation activities	Activities to ensure knowledge of PrEP across communities most at risk for HIV acquisition.	Competitive grant process open to vendors with demonstrated capacity to increase knowledge of and demand for PrEP in underserved communities

Participants supported these estimates for scale up of PrEP for 2000 individuals at a price of around $2 million to $3.5 millon per jurisdiction. The figures also align well with the experience of the Washington State Department of Health, which through its state-based assistance program has created effective scale up of PrEP for over 3,150 active individuals– as well as other preventive and treatment services– with only $2 million invested annually.

As previously discussed, our estimates only look at generic TDF/FTC pricing as branded price points are extremely cost inefficient, making them impossible to justify in conversations with policymakers. A key 2020 cost effectiveness analysis indicated that for Gilead's F/TAF (brand name Descovy) to be cost efficient it would need to be priced at no more than $370 above generic TDF/FTC per person per year. A 2022 analysis of long acting cabotegravir as PrEP found that to be cost saving it could cost no more than $1900, well below the $23,000 annual price tag. In contrast, a recent model found generic PrEP to be cost saving for young men who have sex with men across several different hypothetical background incidence levels. This does not mean that expanded choice of PrEP modality should be abandoned; however it does re-emphasize the importance of securing a public health price for new PrEP medications via government negotiation.

Benefits

Our February discussion explored the potential impact of widespread PrEP scale up on population-level incidence (rates of new HIV infections). Studies out of Australia and England have highlighted the potential for PrEP as a public health level intervention, particularly when scale up has been targeted, rapid, and achieved high overall coverage. However, participants acknowledged that the populations reached by these interventions are less diverse in terms of race, class and gender than the US populations in need of PrEP, and that these programs scaled up in the context of national health coverage schemes of a breadth absent in the US. However, even within the US context, there is evidence that PrEP is key to bringing down new HIV cases. A 2024 study conducted by researchers at Emory University found that, after controlling for levels of viral suppression, jurisdictions in the US that have the lowest levels of PrEP uptake have on average continued to see new diagnoses increase year on year between 2012 and 2021. In contrast, jurisdictions that have more successfully scaled up PrEP have seen annual declines of 8%. This is not particularly surprising when looking at other key intermediary indicators for ending HIV as an epidemic (EHE); at present, all other major methods of epidemic control remain largely static within the US. PrEP likely has the greatest immediate potential for helping the US to get back on track for the 2030 EHE targets. However, participants agreed that specific attention to best practices for equitable scale up would be necessary to ensure benefits for all communities in the US.

Next Steps in Assessing the Costs and Benefits of Equitable PrEP Scale Up

Our expert consultations affirmed that widespread PrEP scale up can likely be achieved at a cost effective or even cost saving level based upon current generic pricing. PrEP has an essential role in reducing HIV incidence in the US, however, given the lack of diversity we have seen across settings where PrEP scale up has been shown to reduce new infections, equitable access will require specific attention to the best implementation practices listed in this report. Building on this discussion, PrEP4All intends to advance additional analysis:

- Jurisdictional modeling based upon real world data from state-level PrEP assistance programs that can assess potential costs and benefits of PrEP initiatives at the state and local level
- More in depth projections on the potential costs and benefits of a national program, taking into account potential savings compared to state/local programs achieved through improved price setting for labs via national contracts and centralization of *PrEP Pass*, telehealth, and other infrastructure.
- The impact of different PrEP price points on access via a national PrEP program and the potential effect on HIV incidence.

Regaining EHE momentum with the assistance of cost effective– and likely cost saving– generic medications should be of financial interest to bipartisan policymakers in the US. Financially, every new HIV case has been estimated to result in lifetime healthcare costs of $501,000, meaning that at present incidence levels we continue to add more than $17 billion in lifetime costs to the American healthcare system each year.

Beyond dollars and cents, the political benefits of revitalizing our national progress on reining in new HIV infections cannot be overstated. At a time when political attacks on HIV funding are increasing, missing the 2030 target by a wide margin would almost certainly endanger all future efforts to end HIV as an epidemic for all US populations. That would have lasting and enduring emotional and financial costs for the communities being left behind.

Conclusion

The US has an opportunity to correct a decade of inequities in PrEP access by building PrEP infrastructure that can make affordable generic PrEP widely available and set the stage for the financing, pricing, and delivery discussions that will be necessary to provide equitable access to long-acting injectable versions of PrEP for un- and underinsured populations. The first step is to secure federal funding with the flexibility to successfully implement all core pillars of a National PrEP Program. The CDC took a significant step in the right direction with the recent $10M supplemental PrEP grant to five key jurisdictions; policymakers need to see this through by fully funding a national program. This investment has the potential to, with reasonable investment, lead to averted infections and costs for the US healthcare system and disproportionately impacted communities.

With funding, federal agencies and state and local health departments can implement the key recommendations within this report to address the major barriers to PrEP awareness, medication, labs, and providers that have thwarted efforts to scale up equitable access in all communities. By centering an approach that is led by and for key populations and defined by simplicity for end-users, the US can reduce and even eliminate disparities. Regardless of race, gender, income, or geographic location, un- and underinsured individuals should have access to a *PrEP Pass* with minimal eligibility requirements that can comprehensively and simply cover medication and lab costs. Providers should be widely accessible too, through expanded hub and spokes networks that bring prescribers to where PrEP users already receive clinical or nonclinical services. And awareness building must be built around messaging that resonates with the interests and needs of PrEP users via community-led national and local campaigns that provide information on clear, direct pathways to access.

Hear the stories of PrEP users in the US

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