



# Implementation Strategies to Increase PrEP Uptake in the South

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## Abstract

**Purpose of Review** Seven years after TDF/FTC was approved for pre-exposure prophylaxis to reduce risks of HIV infection, there have been large increases in the number of persons using PrEP in the USA. However, recent data on pre-exposure prophylaxis (PrEP) use at the state level indicate that people living in the Southern United States are underserved by PrEP relative to their epidemic need. We sought to review possible reasons for inequitable uptake of PrEP in the South and identify implementation approaches to increase PrEP uptake in the South.

**Recent Findings** Published literature, data on the locations of PrEP service providers, recent data on PrEP utilization from pharmacy prescription databases, HIV surveillance data and government data on healthcare providers, and health literacy indicate a confluence of factors in the South that are likely limiting PrEP uptake. A variety of approaches are needed to address the complex challenges to PrEP implementation in the South. These include considering alternative PrEP provision strategies (e.g., pharmacy-based PrEP, telemedicine-delivered PrEP), conducting gain-based stigma-reduction campaigns, increasing capacity for reimbursement for PrEP medications and services through policy change to expand Medicaid and to preserve access to Affordable Care Act–compliant health plans, expanding STI screening programs and improving integration of PrEP offering with delivery of positive STI results, using mHealth tools to screen groups at highest risk for HIV (e.g., men who have sex with men) periodically to increase correct perception of risk, and streamlining clinical procedures to allow same-day PrEP starts for patients without obvious medical contraindications.

**Summary** Overcoming the structural, capacity, and policy challenges to increasing PrEP uptake in the South will require innovations in clinical approaches, leveraging technologies, and policy changes. The South has unique challenges to achieving equitable PrEP uptake, and addressing key barriers to expanded PrEP use will require multisectoral responses.

**Keywords** Pre-exposure prophylaxis (PrEP) · HIV prevention · Multisectoral responses

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## Introduction

Pre-exposure prophylaxis (PrEP) to reduce HIV acquisition risk is a proven biomedical intervention strategy and is a critical component of a comprehensive approach to reducing new HIV transmissions. Increasing appropriate PrEP use has been identified as a critical strategy in both the US National HIV Prevention Strategy [1] and the 2019 HHS plan for Ending the HIV Epidemic [2]. Since TDF/FTC for PrEP was proven efficacious in 2010 [3] and approved for use in the USA in 2012, PrEP use increased more than 10-fold in the USA through 2017 [4]. However, the uptake of PrEP has not been consistently realized in different regions and demographic subgroups [5]. For example, in 2016, more than half of new HIV diagnoses occurred in the Southern United States [6], but only 30% of PrEP users were in the South [4]. The important relationship of PrEP use to HIV epidemic impact has been

formalized as the PrEP-to-need ratio (PNR), which is calculated as the number of PrEP users in a period divided by the number of new diagnoses in the period [7]. Lower numbers in the PNR indicate inequitable PrEP uptake. For example, the PNR for the Southern United States in 2017 was 1.5, compared to the higher PNRs in the West (3.0), Midwest (3.4), and Northeast (4.7). To address this inequitable uptake of PrEP, it is important to examine barriers to PrEP uptake and to consider implementation strategies to address those barriers.

### Why Is PrEP Uptake Lower in the South?

There are a variety of reasons why PrEP is underutilized in the South, and understanding these reasons is an important starting point for considering implementation strategies to overcome them. Major challenges to PrEP uptake in the South include geography, low rates of health insurance coverage, low health literacy, stigma, low healthcare system capacity, and low HIV risk perception.

**Geography** The South, as a region, has the highest proportion of the regional population living in rural areas (32%) [8]. Furthermore, compared to other regions, non-urban counties in the South have higher rates of new HIV infections (a proxy for risks of new infection and need for PrEP) compared to non-urban counties in other regions. Access to PrEP in rural regions is limited by the lack of proximate PrEP providers: the South as a region has the highest proportion of PrEP-eligible persons living a 60-min drive away from the nearest PrEP provider [9]. Key populations living in rural areas of the United States are generally underserved by HIV prevention services (HIV and STI testing, receipt of free condoms, receipt of individual prevention services) [10] and less likely to have used PrEP [11].

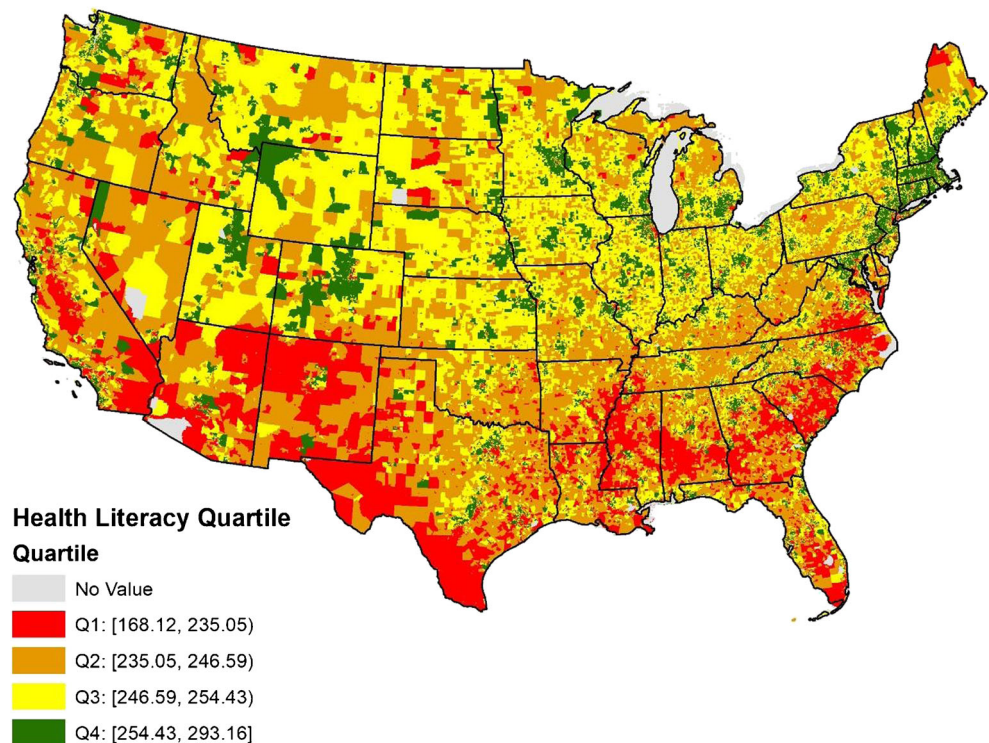
**Low Rates of Health Insurance and Lack of Medicaid Expansion** As a region, the South has higher rates of population living without health insurance than in any other US region: 5 of the 6 US states with more than 12% of the population uninsured are in the South, and over half of the US states below the average rate of insurance coverage are in the South [12]. Lack of individual health coverage has been directly linked to PrEP discontinuations among men who have sex with men (MSM) in the South [13]. Furthermore, 9 of the 14 states that have not yet adopted Medicaid expansion are in the South [14]. Because costs of paying for medications and medical visits are frequently cited by potential PrEP users for not adopting or sustaining PrEP [15–17], lack of access to Medicaid is a barrier to broad PrEP uptake. If the current US Preventive Services Task Force (USPSTF) draft recommendation of PrEP as a Grade A preventative service becomes final [18], PrEP will be available without out-of-pocket costs to those with an Affordable Care Act–compliant health plan

(including Medicaid recipients). Given the relatively low health insurance rates and lack of Medicaid expansion in the South, the USPSTF recommendation might result in increasing disparities in PrEP utilization for the South. Although manufacturer assistance programs currently support the costs of branded TDF/FTC medication for those meeting need criteria, the expiration of the TDF/FTC patent and the promise of new PrEP medications [19] introduce uncertainties into how accessible PrEP medications might be for those without health insurance in the future.

**Low Health Literacy** PrEP can be a complex prevention service for clients and in most cases requires multiple visits to a PrEP clinician for screening, counseling, and monitoring. Understanding complex information about the intervention and about how health insurance or other mechanisms might pay for some or all PrEP services requires a substantial level of health literacy and healthcare system navigation. Health literacy is lower in the South than in other Census regions: according to US census data [20], the median health literacy was 242 in the South, significantly lower than in other Census regions (West: 246; Midwest and NE: 249). Furthermore, low health literacy in the South is especially prevalent in more rural areas of many Southern states (Fig. 1), co-occurring with lack of proximate PrEP providers and higher rates of poverty. For those who need PrEP, some PrEP-specific health literacy (e.g., awareness, knowledge of how to seek PrEP) might also be important. In the South, the audience for such PrEP-specific health literacy includes large numbers of women. The South accounts for most new HIV diagnoses among women (50%) and among Black women (62%) [21]. Although PrEP indications are prevalent among MSM (25%), the proportion of women with indications for PrEP is much lower (0.4%) [22]. This suggests that basic information about PrEP and how to seek it must be provided to many women in the South.

**PrEP Stigma, Anti-HIV Stigma, and Anti-Gay Stigma** PrEP stigma is unfortunately common despite the relatively recent introduction of PrEP, and has been the topic of several excellent literature reviews [23–25]. PrEP stigma is intimately tied to stigma regarding sex and HIV, which are higher in the Southern United States at structural [26] and interpersonal levels [27]. HIV and anti-gay stigma disproportionately impact African American MSM and these factors influence medical trust and willingness to uptake PrEP [28•, 29]. For example, MSM in Jackson, MS, reported that taking PrEP would raise suspicions among friends that a person had male partners, or might lead some to believe that a person was living with HIV and taking medications for treatment [28•]. Concerns about being “outed” as gay if parents or friends saw a prescription assistance card or how members of religious communities would react if they see the pills were also

**Fig. 1** Levels of health literacy by census block groups and quartile, Southern United States, 2015



cited as reasons not to start PrEP, or not to continue it [29]. Because African-Americans account for 20% of the population in the South (compared to 13% in the Northeast and 6% in the West), the stigma present within Southern Black communities has a more pronounced effect in shaping local uptake of PrEP [30].

Anti-HIV stigma and anti-gay stigma act to discourage those in need of PrEP from seeking it. Stigmatizing beliefs about PrEP (e.g., PrEP is for promiscuous people) and experiencing anti-HIV stigma and racism are reported as discouraging PrEP use among MSM [28•, 31]. Southern women reported that they might not take PrEP because of fears that family or friends might assume that they were taking medications because they were living with HIV [15]. Stigma is also related to HIV criminalization [32]; 14 of 16 Southern states have some HIV-specific statutes [33]. HIV criminalization laws are hypothesized to increase anti-HIV stigma [34] and National Association of City and County Health Officials has argued that criminalization statutes decrease the use of HIV prevention services and HIV treatment [35].

**Healthcare Capacity and Capacity for Multiple Healthcare Visits in the South** PrEP is a prevention intervention that requires a detailed risk assessment, and a preliminary assessment of eligibility, including laboratory studies of kidney function and infectious disease serologies [36]. In most PrEP practice settings, the algorithm for establishing negative HIV serology, assessing kidney function and evaluating Hepatitis B serology requires at least a 2-visit process, with initial

assessment and collection of samples occurring on the first visit and interpretation of those results and PrEP prescription in a subsequent visit. Adding to the complexity of the provider scarcity is the need for providers to deliver these services in a patient-centered, culturally competent, sex-positive, non-judgmental environment with a message that is focused around managing HIV risk and preventing HIV infections.

In the South, less than half (49%) of the needs for health providers are met [37]. The South includes four of the six US states with the lowest ratios of primary care provider to population; the lowest ratio of primary care providers to population is in Mississippi [38]. The capacity for multiple healthcare visits for PrEP is exacerbated by multiple factors, as discussed herein: lack of proximity of PrEP providers, lack of health insurance to pay for multiple visits, and unmet healthcare capacity. Furthermore, the South has a higher proportion of people living in poverty (15.3%) than other US regions (West: 13.3%; Midwest: 11.7%; Northeast 12.4%) [39]. Attending multiple healthcare visits for PrEP also requires more time away from work, which is harder for people living in poverty.

**Low HIV Risk Perception** For decades, research studies in groups at increased risk for HIV have documented low risk perception, even among those who become HIV infected, leading to lack of uptake of HIV prevention services [40–42]. Similarly, MSM in demographic groups at elevated risk of HIV acquisition report low HIV risk perception as a reason not to start PrEP [17, 43]. Young Black MSM in Atlanta cited beliefs that PrEP was only for people with very

high levels of risk, widening the gap between under-perceptions of one's own risks and over-ascertainment of the appropriate level of risk for PrEP indication [44]. Lack of identification of risk and communication about risk within the community are also cited as barriers to PrEP uptake among Black women [45] and transwomen [46].

## Implementation Strategies

To achieve a high scale of PrEP coverage in the South, we propose several strategies to address the barriers to PrEP uptake in the South. Strategies are summarized in Table 1, organized around the principal domains of the Consolidated Framework for Implementation Research (CFIR) [47].

**Alternative PrEP Provision Strategies** To address long travel distances to PrEP clinics in the South, PrEP can be made more accessible through alternative provision strategies, including pharmacy and home care options. PrEP is currently available from clinicians at walk-in clinics for the nation's two largest pharmacy providers [48]. A related model of PrEP care is directly managed by pharmacists and conducted through collaborative drug therapy agreements (CDTAs). In these agreements, pharmacists work with physicians and other prescribers to develop a program wherein the pharmacist can initiate, modify, or discontinue therapy without the patient having to see a prescriber. The model has been used for many years for pharmacists to manage health conditions such as hypertension. It allows patients who might not otherwise be

**Table 1** Barriers to PrEP uptake in the Southern United States, proximate causes, and possible implementation strategies to mitigate barriers

CFIR domain	Barrier	Barrier pathways	Possible implementation strategies
Intervention characteristics	<i>Complexity</i> •PrEP initiation and maintenance is challenging for patients and providers in the South	•Need for multiple visits •Intensive monitoring requirements •Need to miss multiple days of work to attend appointments •Financial concerns	•Streamlining of clinical procedures •Same-day PrEP initiation •Minimize repeat clinic visits (ePrEP, PrEP@Home) •Flexible PrEP regimens (e.g., on-demand PrEP, long-acting PrEP) •Financial navigation programs
	<i>Relative advantage</i> •Clients do not perceive the need for PrEP or do not see risk/benefit ratio as favoring PrEP •Misconceptions regarding PrEP indication	•Low-risk perception •Lack of recognition among patients that PrEP is a relevant option	•mHealth screeners •Peer navigation •Repeated offering of PrEP •Increased STI testing frequency and linkage to PrEP •Novels ways to enhance PrEP education
Outer setting	<i>External policy</i> •Lack of Medicaid expansion	•Low insurance coverage •Lack of political will for Medicaid expansion	•Medicaid expansion or waivers •PrEPDAP programs
	<i>Peer pressure</i> •Stigma—anti-PrEP, anti-gay, anti-HIV •Peer norms	•Lower willingness to carry antiretroviral medication •Lower willingness to present for care in facilities that also treat people living with HIV	•Streamlining of visits •Campaigns with empowering messages tailored to highly impacted and stigmatized communities •Peer navigators
	<i>Patient needs and resources</i> •Low health literacy	•Fear of being identified as gay or misconstrued as living with HIV	
	<i>External incentives</i> •Larger rural population at risk	•Long distance to PrEP provider	•Novel ways to access PrEP (pharmacies/CDTAs, telehealth, hub and spoke system)
Inner setting	<i>Structural characteristics</i> •Lower capacity for healthcare services •Challenging to navigate health care system	•Fewer PrEP providers •Longer wait for appointments •Harder to get appointments •Failure to complete paperwork, secure payment for PrEP •Failure to navigate healthcare appointments and medication fills	•Streamlining of clinical procedures •Same-day PrEP initiation •Alternate PrEP regimens (e.g., on-demand PrEP) •Minimize need for repeat clinic visits (ePrEP, PrEP@Home) •Peer navigators for PrEP initiation and persistence •Automated recommendations identifying optimal PrEP provision settings based on patient-identified needs
	<i>Executing</i> •Lack of development of programs to expand access in most Southern states	•More difficulty in arranging funding for care visits and drugs •Lack of coherent public health response and promotion •Lack of linkage to other public health service settings (e.g., STI or family planning clinics)	•Advocacy and education to create political will to engage policymakers •Promote PrEPDAP programs •Create seamless pathways for entry to PrEP care from existing public health touch points (e.g., STI or family planning clinics)

able to attend a clinical visit to benefit from medications to manage health conditions [49]. CDTAs are legal in 49 states; Alabama is the only state without a CDTA law as of this writing. It has shown strong promise in implementation settings; in Seattle, WA, 695 patients were initiated into PrEP care out of 714 patients evaluated (97%) [50]. There would be value in evaluating a CDTA approach in the South.

Another change of venue option is to provide at-home service, an option preferred by most PrEP-naïve MSM [51]. One system for home care, PrEP@Home, has been conceptualized as an annual in-person clinician visit supplemented by three quarterly home check-ins with home specimen collection and electronic behavioral assessments [52]. In a pilot test of PrEP@Home for a single 3-month PrEP follow-up period, 40% of participants (22/55) indicated that they would be more likely to persist in PrEP care if such a home care system were available, and over 80% of participants opted for home care kits in the future [52]. Providing PrEP services for initiation and/or for periodic PrEP monitoring at home could also alleviate stigma associated with attending some PrEP provision locations.

To address the substantial rural population in the South, full telemedicine PrEP may also be a promising avenue. Commercial services are available to offer PrEP (NurX, Plushcare) through telemedicine consultation and either referral to a local laboratory for testing or at-home specimen collection. These approaches are provided as clinical services and have not been evaluated with respect to their effect on increasing PrEP uptake in underserved populations (e.g., young, rural MSM). Electronic PrEP (ePrEP) is an experimental approach to assess the impact on PrEP uptake of telemedicine initiation and remote PrEP delivery, focusing on young (18–24 years old) MSM who live in rural areas or small towns in three Southern states [53]. Both PrEP@Home and ePrEP are currently under assessment through clinical trials, with outcomes of uptake of and maintenance in PrEP care as determined by biomarkers [53, 54]. Alternative provision approaches, both pharmacy and telemedicine, face sustainability considerations. These approaches definitionally are outside usual care and therefore may need changes in policy (CDTA) or billing standards and systems efficiencies; continued work is needed on these issues.

Other promising strategies to improve access to PrEP care are telemedicine hub-and-spoke systems and public health detailing. The hub-and-spoke approach has been successfully implemented to support HIV treatment in areas of the South with lower access to healthcare providers [55]. In this system, a private exam room in a Community Health Center (CHC) or Federally Qualified Health Center (FQHC) and an attending nurse allow clinical assessment and discussion of treatment options with a remote expert physician. Because CHCs and FQHCs are used for multiple treatment and prevention services, this approach also addresses concerns about stigma

associated with seeking PrEP from an infectious disease specialty service [15]. Public health detailing involves providing clinician or non-clinician “detailers” to assist clinicians and practices with clinical implementation of PrEP programs [56].

There are emerging alternatives to daily oral PrEP prescription such as “on-demand” PrEP, which has been shown to have at least comparable effectiveness to daily oral PrEP. On-demand PrEP might be an important option to increase PrEP uptake in the South by limiting pill burden and medication costs and by providing an option for PrEP for people whose risks for HIV are intermittent and who might assess their risks for HIV as sufficiently infrequent to justify a daily oral pill.

**Improving Health Literacy/PrEP Education** Published reports of PrEP-specific health literacy interventions are scarce. The 2010 National Action Plan to Improve Health Literacy, however, provides a general framework within which we can consider approaches to improve health literacy. For example, the Action Plan calls for integrating health information within health care delivery systems, increasing basic research on interventions to improve health literacy, and leveraging evidence-based interventions to improve literacy [57]. A systematic review of health literacy interventions suggests that future interventions for health literacy in general should evaluate approaches to increase motivation, deliver information in formats other than writing, and utilize patient advocates [58]. In the PrEP field, new technologies are available that might help to provide basic information about PrEP and inform decisions to seek PrEP care but have not been evaluated in controlled trials against outcomes of improved PrEP knowledge or uptake. For example, a publicly available video, “What is PrEP” ([www.whatisprep.org](http://www.whatisprep.org)), explains the basics about how PrEP works and has been viewed thousands of times. An evaluation of a comprehensive prevention mobile app for MSM focused on improving self-efficacy around PrEP as part of a social cognitive theory-based intervention documented that 40% of users accessed information about PrEP within the app over a 4-month period, and 9% of PrEP-eligible men started PrEP [59]. Qualitative approaches have been used to develop insights into how PrEP educational materials might be tailored for specific groups (e.g., women, MSM) [60, 61]. In New York, Black and Latina women were shown several example PrEP action messages for PrEP and provided feedback about their reactions to the messaging and preferences for messages [60]. In Providence, MSM participated in focus groups to develop meaningful language around PrEP efficacy and to assess comprehension of language around the protective effects of PrEP [61]. Research funding agencies should consider focused opportunities for discovery science and rigorous

evaluation of approaches to improve PrEP literacy in populations in high need of PrEP services.

Peer navigators are another possible mechanism to increase PrEP literacy and to facilitate health system navigation using trusted peers. Peer navigation has been reported to be acceptable to HIV negative MSM [29, 62] and a randomized trial of a “peer change agent intervention” was developed and enrolled in 2018 [63]; results are pending.

**Addressing Stigma** Considerations for expanding access to PrEP should account for both the stigma that discourages PrEP uptake and for the empowerment that can facilitate its uptake, a unique circumstance termed the “PrEP-stigma paradox” [64]. Two meta-analyses of prevention messaging found that gain message framing that emphasized the benefits of the prevention behavior was more effective than loss framing that focused on the negative impact of not performing the behavior [65, 66]. This suggests that communications should focus on gain frames, such as those on the empowerment side of the PrEP-stigma paradox. Messages that detail the empowerment inherent to PrEP as a highly efficacious and acceptable prevention method should not only be promoted through campaigns but also by clinicians and health officials. In the Southern United States, gain messages tailored to highly impacted communities may be the key to altering the current PrEP-stigma landscape. Effectively addressing the stigma faced by Black MSM living in the South due to their multiple stigmatizing identities may require building upon interpersonal relationships that are affirming and accepting. However, the larger stigma faced at a community-level must be effectively combated and might be mitigated by innovative use of key stakeholders and opinion leaders to change public attitudes.

**Increase Healthcare Reimbursement Capacity** Multiple strategies are available to increase the extent to which PrEP costs can be covered by health insurance. First, there is an urgent need to pursue Medicaid expansion or targeted Medicaid waivers in the South. Currently, 89% of all people in the USA living in the “coverage gap” between health insurance and Medicaid live in the South [67]. Second, Southern states should consider programs such as those implemented in New York (PrEP-AP) [68], Massachusetts (PrEPDAP), and Washington State (PrEP DAP) [69] to offset prescription or clinical costs associated with PrEP uptake. New York, Massachusetts, and Washington established these programs before other states, and as of 2017, these three states were among the four states scoring highest in PrEP uptake rates [4]. Only Florida and Virginia of 15 Southern states currently offer any form of PrEP assistance [70]; the District of Columbia also offers such a program.

**Better Integration with STI Screening** STI screening and biomedical HIV prevention have inherent interdependencies and

synergies. Bacterial STI diagnoses are indications for PrEP [71], and bacterial STI infections themselves increase HIV susceptibility [72]. Yet, in 2016, over 847,000 bacterial STI diagnoses were made in the South [21], but only 20,665 people in the South used PrEP [4]. Even assuming conservatively that half of STI diagnoses were concurrently diagnosed in one person and half were among people living with HIV, this suggests that less than 10% of people with STI diagnoses started PrEP. Theoretical frameworks to promote uptake of prevention interventions suggest that steps such as standing orders or prompts to consider PrEP in electronic medical records might support clinicians to recognize and capitalize on PrEP offering opportunities [73]. Beyond increasing PrEP prescriptions for people already being diagnosed with STIs, there are important opportunities to recognize more STIs in key populations. For example, less than half of US MSM tested for any STI in 2016 [74]. A randomized study of online ordering and mail distribution of STI test kits in London showed a doubling rate of STI testing and STI diagnoses [75]. Similar mail-out STI kits have been shown to have high acceptability and completion rate of specimen return among MSM [76, 77] and women [78] in the USA. Studies suggest that electronically administered self-quizzes or risk screeners might increase the uptake of recommended health services [79, 80]. Health departments and community HIV/STI prevention providers should consider how mail-out kit distribution approaches could augment existing STI screening programs, especially for people with high risks for STIs and HIV as a strategy to increase STI screening in the South. It is critical that systems are put in place to ensure that positive STI results are used to engage clients in discussions of PrEP [80]. When kits are mailed to people in rural areas, positive diagnoses might be followed up with alternative PrEP prevention strategies such as electronically/remotely administered PrEP (ePrEP) [53].

**Frequent PrEP Screening and Repeat PrEP Offering** There is a growing understanding that PrEP assessment and offering must be a sustained process for those at highest risk for HIV infection. Indications for PrEP are dynamic, and clients who do not meet eligibility at one screening may become eligible for PrEP based on new sex partners living with HIV or new STI diagnosis [81, 82]. This is particularly true in the South, where the prevalence of HIV among potential sex partners is high, especially in for some sexual networks and demographic groups [83, 84]. In a cohort of young Black MSM in Atlanta, researchers offered PrEP to eligible men every 3–6 months [13]. Although nearly half of the men eventually initiated PrEP, there was a median 4-month delay between the first offer of PrEP and PrEP initiation [85]. About half of the men who eventually initiated PrEP care were offered PrEP more than once before they initiated PrEP [85]. The need to screen for PrEP eligibility frequently and to offer PrEP to eligible clients will require a large effort and potentially

significant amounts of staff and provider time. Several eHealth tools to assess for PrEP eligibility and encourage PrEP referrals have been described, mostly focusing on MSM at risk for HIV [80, 86, 87].

**Streamlining Clinical Procedures** After almost 7 years since Truvada for PrEP was initially approved by the FDA in 2012, we have learned a lot about the safety of PrEP from clinical trials, demonstration projects, and clinical experience of those prescribing PrEP. Efforts to scale up PrEP can be facilitated by implementation and evaluation of processes that streamline clinical PrEP initiation procedures for individuals without obvious contraindication after a medical and medication history has been obtained, and pending results of related laboratory tests. The New York City Department of Health and Mental Hygiene found that immediate initiation of PrEP at sexual health clinics after a medical history, physical exam, and negative rapid HIV test was safe and resulted in fewer at-risk individuals lost to follow-up [88].

Similarly, follow-up visits can present a substantial burden to patients, clinicians, and healthcare systems. In some scenarios, individuals on PrEP could be scheduled for follow-up laboratory testing only, minimizing provider time and costs to patients. In addition, clinician visit time can be decreased by engaging ancillary clinic staff in the provision of PrEP education, medication adherence, and risk reduction counseling. Individuals with abnormal laboratory results or clinical, behavioral needs identified by screening questions can be referred for a clinical visit.

**Increasing Risk Perception** Multiple implementation approaches already discussed offer the potential to increase awareness of risk. For example, routine screening for PrEP eligibility with mobile apps [80, 86], peer navigation [29, 62], repeat offering of PrEP over time [85], and improving PrEP literacy might all result in more accurate risk perception.

## Conclusion

The reasons for inequitable PrEP uptake in the South are complex and the approaches to increasing PrEP uptake must be multisectoral, use multiple methods to effect change, and be sustained. There is an urgency to improve PrEP uptake in the South given the ongoing disproportionate impact of new HIV infections in the region [89]. So although all the answers about how to approach PrEP implementation are not yet available, it is critical to take steps to address what is addressable now, as we invest new resources in discovery science to develop new evidence-based approaches to tough challenges such as improving PrEP-specific health literacy or mitigating the impacts of stigma on willingness to take PrEP. Efforts to improve the policy environment are needed concurrently—for example, by working

to repeal criminalization statutes, expand Medicaid coverage, or obtain Medicaid waivers to allow people without insurance to obtain HIV prevention services and support ongoing access to ACA-compliant health plans.

It is important that future efforts to address the reasons for suboptimal PrEP uptake in the South adopt rigorous implementation science approaches [90] to ensure that we learn as much as possible about the best ways to implement PrEP programs and develop rigorous evidence to support investments in scaleup. Furthermore, implementation studies should be developed with an understanding that PrEP scaleup research in the South will occur in the setting of intersectional inequities in PrEP access, with Black people, people living in rural areas, and poor people experiencing inequitable PrEP coverage [90]. New implementation approaches must be conceived, designed, and evaluated to ensure that they improve PrEP access among the groups experiencing the greatest inequities in access.

An important context for considering implementation approaches is an understanding of how the population-level impacts of new approaches will be measured. Rigorous evaluation of new approaches to increase PrEP use is critical. Both outcomes (e.g., PrEP uptake) and mediators of those outcomes (e.g., knowledge, trust in providers, reductions in anticipated stigma, increased use of STI testing services) can be assessed directly within controlled studies. At the population level, population-based data sources should be used to monitor high-level trends in use of PrEP (as counts and rates of users) [4] and as PNR values (to account for varying epidemic need) [5]. Population-based minimum estimates of PrEP users at state and county levels are available through [AIDSVu.org](http://AIDSVu.org) and are updated annually [4]. Using data at finer geographic levels (e.g., county-level data versus state-level data) is an important means to identify areas that have experienced success or failure in achieving parity in PrEP access (i.e., improvements in PNR) and querying successes and failures to identify promising approaches and challenges to ongoing PrEP expansion [55].

There are also broader contexts in which improved implementation approaches to PrEP programs will occur in the South. Efforts to improve PrEP implementation will happen while the landscape of HIV care continues to shift under our feet. The USPSTF recommendation of PrEP as a Grade A prevention service, if finalized, will be a major inflection point to mitigate concerns about out-of-pocket costs and could jumpstart PrEP initiations for people with ACA-compliant health plans. PrEP programs will also operate in the environment of national focus on improving outcomes on the HIV care cascade, resulting in improvements in levels of viral suppression. U = U campaigns are increasing awareness of the prevention benefits of achieving viral suppression for people living with HIV [91]. We must be rigorous in innovating PrEP implementation approaches, steadfast in advocating in parallel for improving HIV treatment access and programs, and clear-

eyed that improving HIV treatment outcomes is imperative, but is not a substitute for enough coverage and smart targeting of PrEP. PrEP scale and targeting of PrEP will be necessary components to end the epidemic [2].

Disparities in the HIV epidemic in the South and inadequacies in our prevention responses are national shames. The reasons for suboptimal PrEP uptake mirror the reasons for high HIV epidemic force in the South, finding common roots in social determinants of health, economic and social marginalization, and structural challenges that breed poor health outcomes for the disenfranchised. It is easy to feel that we are fighting an uphill battle against social structures and forces that are rooted in decades of inequity, against problems that are bigger than the resources we have been offered to improve PrEP programs, and without the time and the money that we need to make foundational changes. It is understandable to feel frustrated that at a time when we have all the right tools to end the epidemic, we struggle to get the tools we have to the people that need them most. Successes will come from a combination of discovery science to build new tools, implementation science designs to understand new implementation approaches and evaluate them rigorously, evaluation approaches to monitor high-level outcomes in communities, and advocacy to change unjust policies that frustrate the dissemination of PrEP and perpetuate inequities.

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## Compliance with Ethical Standards

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- Of importance
- Of major importance

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