ISSUE BRIEF | AUGUST 2019

BIG IDEAS

ENDING THE HIV EPIDEMIC —
SUPPORTING ALL PEOPLE WITH HIV AND REDUCING NEW INFECTIONS

ACHIEVING SUFFICIENT SCALE OF PrEP USE IS CRITICAL TO ENDING THE HIV EPIDEMIC

PRE-EXPOSURE PROPHYLAXIS (PrEP) is a relatively new technology that holds the potential to greatly reduce HIV transmission. Approved for use in the United States in 2012, it involves persons at risk of HIV infection taking a single pill, that when taken as prescribed, is about 99% effective at preventing HIV infection sexually.[1,2] Earlier this year, the Trump Administration launched its **Ending the HIV Epidemic (EHE) Initiative**, setting a goal of reducing HIV transmission in the US by 90% within ten years.[3] Expanded use of PrEP is a central pillar of the EHE Initiative.

Promoting awareness and initiation of PrEP is critical for scaling up PrEP use. Research indicates that reducing HIV incidence and disparities in PrEP use for Black gay, bisexual, and other men who have sex with men (MSM), for example, requires prioritizing PrEP awareness and initiation over other issues, such as adherence to PrEP and retention in PrEP care.[4] Financing PrEP medication and services is also a critical issue. This includes efforts to lower the cost of the medication, expand insurance coverage for PrEP, and finance laboratory and other services. Even in places that have taken steps to raise PrEP awareness and minimize financial barriers, however, uptake and use of PrEP among the groups with the greatest need still lag behind other populations.[5] For PrEP to contribute significantly to the EHE Initiative, the use of PrEP must reach sufficient levels to produce population-level outcomes.

40-50% COVERAGE OF PrEP AMONG PRIORITY GROUPS MAY BE A REASONABLE BENCHMARK FOR PUBLIC HEALTH IMPACT.

INCREASING PrEP USE TO IMPROVE POPULATION-LEVEL OUTCOMES

A greater focus on the scale of PrEP use is needed to achieve its promise. To get to scale:

Goals and Metrics Matter: Setting bold goals and measuring progress are important to achieve results within clinics, among populations, and across jurisdictions.

Reducing Population Disparities Is Essential: Focused efforts on priority groups, as well as a shift from focusing on behavioral risk assessments that may not capture an individual's need for PrEP to focusing on PrEP as an option for all individuals from priority groups, can help to reduce racial, gender, and geographic disparities in PrEP use.

Starting and Staying on PrEP Must Be Easier: Current models for delivering PrEP services can make it hard for individuals to initiate and remain adherent to PrEP and can demand too much clinical staff time to support the number of people who could benefit from PrEP. Innovative ideas are being tried, but they need to be quickly deployed.

Efforts Are Needed to Make PrEP Affordable and Expand Navigation Services: Greater investments are needed to support insurance and assistance programs and help people navigate the complex maze of programs.

WHY THE SCALE OF PrEP USE MATTERS

There is an interplay of three factors that are critical to the ability of PrEP to yield population-level impact: scale, adherence, and persistence. A modeling study of men who have sex with men (MSM) with an indication for PrEP found that if 40% of the population were on PrEP and 62% of those on PrEP were highly adherent, it would avert one in three expected transmissions over the next decade.[6]

To achieve this level of coverage, more must be done to raise the knowledge and comfort with prescribing PrEP among primary care providers and other clinicians, and more mass media and other education is needed to raise awareness of PrEP among the public and potential PrEP users. Many of the populations that could benefit most from PrEP have limited engagement with the health system[7,8] or have not been counseled about or offered PrEP.[9] PrEP engagement creates opportunities to improve health literacy, screen and treat other health conditions (including mental health and substance use disorders), and support sexual health. In attempting to address many of these ancillary goals, however, PrEP delivery models may become too cumbersome for clients and providers alike. Thus, a goal must be to develop flexible, streamlined, and differentiated models that enable programs to enroll and maintain large numbers of people on PrEP while offering enough education and supports to different populations to facilitate adherence to PrEP and its persistent use over time.

ACHIEVING POPULATION-LEVEL IMPACT WITH PrEP

Four principles can chart a path toward greater scale:

GOALS AND METRICS MATTER: Simply disseminating interventions is not enough. When state or local jurisdictions or the federal government establish meaningful goals, they can focus efforts in a way that can produce results. Goals must be tied to specific metrics so that progress can be monitored continuously. It is also important to keep stakeholders and the public informed of progress toward goals and highlight where improvements are needed.

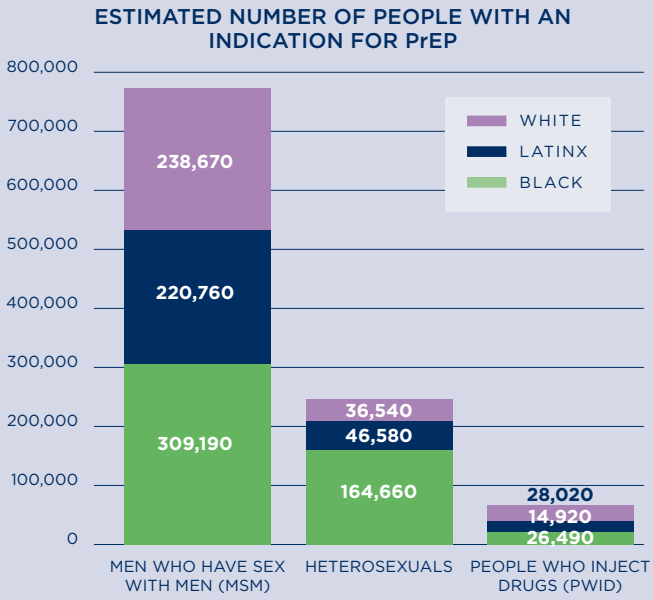
- **Implementation Ready:** The US Department of Health and Human Services (HHS) should convene stakeholders to streamline HIV clinical and financial reporting requirements across HHS agencies with the goal of eliminating low-priority metrics and reducing the reporting burden to facilitate the addition of PrEP metrics. HHS should issue standardized metrics for measuring PrEP starts and PrEP engagement at 12 months as two core metrics (where relevant) across HHS programs. HHS agencies and their partners also could consider buying pharmacosurveillance data from pharmacies and making that data available to state and local health departments for analysis.
- **Implementation Science Research Next Steps:** Research is needed to validate metrics and ensure that, as much as possible, they have durable usefulness, as PrEP users gain greater options for intermittent use (on-demand PrEP) and as long-acting products that do not require daily dosing become available. Modeling studies and other research are needed to assess the level of PrEP persistence and adherence needed to achieve transmission-reduction targets.

REDUCING POPULATION DISPARITIES IS ESSENTIAL: Because many social determinants of health are often arrayed against communities most impacted by HIV, it was predictable that implementation of PrEP would initially exacerbate existing disparities rather than mitigate them. Through focused initiatives, PrEP scale-up offers an opportunity to reduce disparities in PrEP use and HIV incidence and decrease the number of new HIV infections.

- **Implementation Ready:** As EHE plans are developed, specific goals, strategies, and investments must be made to overcome barriers to PrEP access for Black and Latinx gay and bisexual men, transgender people, Black women and other women with an indication for PrEP, people who inject drugs, and people younger than 24 years (with an emphasis on LGBTQ young people). In particular, more must be done to increase awareness of PrEP through community education and marketing campaigns and expand where people can access PrEP to more settings, including primary care facilities, STD clinics, family planning clinics, pharmacies, community-based organizations, criminal justice settings, and other places where priority populations are found. Research has demonstrated that PrEP guidelines do not capture many women who are in need of PrEP and that Black MSM are less likely to meet indications for PrEP than White MSM, despite having a disproportionately high risk for HIV.[10,11] To increase PrEP use among priority populations, public health programs and health care providers should focus less on behavioral risk assessments and consider demographics, local epidemiology, and network factors in assessing whether to recommend PrEP.
- **Implementation Science Research Next Steps:** More research is needed into the most effective and scalable strategies for improving PrEP use and persistence among priority populations.

STARTING AND STAYING ON PrEP MUST BE EASIER: More must be done to make it easier to start and stay on PrEP. New York City piloted immediate PrEP in their sexual health clinics and found that immediate starts with rapid HIV testing and medical screening before getting laboratory results back was safe and involved very few persons discontinuing PrEP for medical

A LONG WAY TO GO: WHO NEEDS PrEP AND HOW MANY PEOPLE ARE USING IT?



Current estimates are that 1,144,550 people in the United States have an indication for PrEP. In 2017, 158,183 people were taking PrEP, meaning **only about 15% of people with a PrEP indication were on PrEP**.

From 2014 to 2017, PrEP use among men who have sex with men (MSM) in urban areas increased from 6% to 35%. PrEP use is too low, however, among Black and Latinx MSM. It is also too low among transgender people, women, people who inject drugs, and young people.

SOURCES: (1) Smith DK et al. Estimates of adults with indications for HIV pre-exposure prophylaxis by jurisdiction, transmission risk group, and race/ethnicity, United States, 2015. *Ann Epidem* 2018;28(12):850-857. (2) Nguyen C et al. Utilization of emtricitabine/tenofovir disoproxil fumarate (FTC/TDF) for HIV pre-exposure prophylaxis (PrEP) in the United States by Age, Gender, and Race/Ethnicity (2014-2017). Poster presented at: International AIDS Society Conference on HIV Science; July 21-24, 2019; Mexico City. (3) Finlayson T et al. Changes in preexposure prophylaxis awareness and use among men who have sex with men – 20 urban area, 2014 and 2017. *MMWR Morb Mortal Wkly Rep* 2019;68(27);597-603.

reasons.[12] There also was substantial loss to follow up for persons with delayed PrEP initiation. Greater attention is needed to rapidly deploying models that reduce the burden of PrEP engagement for both PrEP users and providers. Task shifting from physicians to nurses and pharmacists has been used in some African countries, Australia, and parts of the US.[13] For example, a one-step PrEP program operates out of a community pharmacy in Seattle where persons can go for a PrEP enrollment counseling session, typically of less than one hour, and walk out with medication on the same visit.[14] More also can be done to deploy community members and assets in PrEP provision. In Thailand, about 85% of the country's estimated 6,600 PrEP users are receiving PrEP services from community health workers drawn from the affected populations served. Additionally, researchers are testing ways to use technology to increase knowledge and awareness of PrEP, facilitate PrEP starts, promote adherence, and support primary care providers, and they are exploring models for at-home PrEP. A recently published study found that an interactive text-messaging intervention significantly increased study-visit retention and PrEP adherence among young MSM.[15] PrEPTech is a program piloted in San Francisco targeting young MSM of color with telemedicine medical visits, home delivery of PrEP, and STI testing kits,[16] and the Iowa Department of Health is partnering with the University of Iowa to offer a TelePrEP program for persons in rural areas.[17]

- **Implementation Ready:** HHS can work with health departments to adopt same-day PrEP and offer short-term PrEP continuity. As HHS works with jurisdictions and clinical providers to expand PrEP access, priority should be given to adopting models that envision serving as many PrEP-eligible people as possible, with different models for different people. An initial target could be at least 40-50% of the PrEP-eligible population receiving PrEP. Jurisdictions targeted for the EHE Initiative should be tasked with consulting with community stakeholders on their preferences and concerns, and new PrEP programs should incorporate telemedicine and technology approaches to support a larger volume of PrEP clients.

- **Implementation Science Research Next Steps:** Not all of the ideas being tested will be equally effective, scalable, or acceptable to all communities. Further investments should be made in modeling studies to examine the benefits, risk, and differential cost-savings from task shifting and other alternative models of PrEP delivery (i.e., with less frequent clinical monitoring), as well as policy analysis to examine regulatory and legal barriers to practice transformation.

EFFORTS ARE NEEDED TO MAKE PrEP AFFORDABLE AND EXPAND NAVIGATION SERVICES: Our health system is complex, and changes in insurance policies and personal life changes can cause PrEP to be interrupted. Greater efforts are needed to make PrEP and associated clinical services affordable, help individuals navigate insurance and assistance programs, and support

STRUCTURAL BARRIERS TO PrEP IN THE SOUTHERN US CALL FOR PRACTICE TRANSFORMATION

Serving a much larger share of the population in need of PrEP will call for new approaches. Several factors illustrate challenges in achieving greater use of PrEP in the South, which highlight why practice transformation is critical:

- **Geography:** The region has more PrEP candidates with more than an hour drive to a provider.
- **Lack of Medicaid Expansion and More Uninsured People:** Five of six states with uninsurance rates above 12% are in the South.
- **Low Health Literacy:** Health literacy is lower in the South than other regions, and PrEP requires an understanding of risk, benefits of PrEP, and how to navigate complex health care programs.
- **Stigma:** PrEP stigma is intertwined with HIV stigma and anti-gay bias. Racism and HIV criminal laws in many southern states also create barriers to acceptance of PrEP.
- **Limited Health System Capacity:** There is a shortage of providers, with four of six states with the lowest ratios of primary care providers to the population in the South. PrEP delivery often requires multiple clinical visits for screening, counseling, and monitoring. When factoring in travel time and higher poverty (as well as less ability to pay cost-sharing and transportation costs), provider shortages create more barriers to PrEP.
- **Low HIV Risk Perception:** Black MSM, Black women, and trans women are all groups at elevated risk for HIV, yet research studies show that many of these individuals do not perceive themselves to be at high risk.

MODELS FOR OVERCOMING BARRIERS TO PrEP

Despite these challenges, successful models for increasing PrEP uptake have been implemented in the South. For example, the Fulton County Board of Health launched a PrEP clinic in October 2015 to provide PrEP to uninsured and underinsured people in Atlanta, Georgia. The clinic covers all costs associated with provider visits and PrEP lab monitoring. Between October 2015 and March 2017, the clinic screened 373 people for PrEP eligibility, almost all of whom were eligible in accordance with CDC guidelines, and more than half of whom returned and started PrEP. This model shows real impact on PrEP uptake and was effective at reaching Black gay and bisexual men, who are a priority population in need of HIV prevention services. Other models include the Open Arms Healthcare Center in Jackson, Mississippi, which distributes 80% of the PrEP pills in the state, and state PrEP assistance programs in Virginia and Florida that cover PrEP medication and clinical costs statewide.

SOURCES: (1) Sullivan PS et al. Implementation strategies to increase PrEP uptake in the South. *Curr HIV/AIDS Rep* 2019;16(4):259-269. (2) Rolle CM et al. PrEP implementation and persistence in a county health department in Atlanta, GA. Poster at: Conference on Retroviruses and Opportunistic Infections 2018. (3) Bernstein L. This HIV pill saves lives. So why is it so hard to get in the Deep South? *Washington Post*. March 11, 2019.

people in (re-)starting PrEP if their access to PrEP is denied or interrupted.

- **Implementation Ready:** States should consider opportunities for pursuing Medicaid expansion and establishing assistance programs, such as those implemented in Washington State, New York, Massachusetts, Florida, and Virginia to offset PrEP medication or clinical costs. At the federal level, HHS should expand funding and support for the provision of PrEP and assistance with PrEP navigation. While the Ryan White HIV/AIDS Program (RWHAP) cannot pay for PrEP medications or PrEP-related medical services, the program is well-suited to support PrEP navigation. RWHAP-funded clinics and community-based organizations have longstanding insurance navigation programs for people living with HIV that are often connected to legal services for complex cases. Using non-RWHAP funds, these clinics and community-based organizations can leverage their expertise and infrastructure to set up similar programs for people to access PrEP. Additionally, the Bureau of Primary Health Care (BPHC) funds health centers to provide primary and preventive health services and can help support PrEP delivery, including PrEP navigation services. The Centers for Medicare and Medicaid Services (CMS) could provide guidance and technical assistance for implementing PrEP navigation as a state Medicaid benefit (such as through the targeted case management services option). New policy options also are needed to maintain PrEP coverage when insurance is interrupted, such as during a job change or loss or when eligibility for Medicaid or Affordable Care Act (ACA) subsidies changes.
- **Implementation Science Research Next Steps:** A greater understanding is needed of how to reach people at risk for stopping PrEP and how to intervene in a cost-effective manner. Research can help identify the best policy reforms to ensure people who start PrEP will have access to it over time.

THE BIG PICTURE: A COMPREHENSIVE APPROACH TO PREVENTION

The evidence for PrEP's effectiveness is in the context of a comprehensive package of HIV prevention services.

Components of comprehensive HIV prevention:

- HIV testing (with HIV home testing options)
- STI testing and treatment
- Prevention counseling
- Male and female condoms and lubricants
- PrEP and post-exposure prophylaxis (PEP)
- Treatment as Prevention (TasP) or Undetectable=Untransmittable (U=U)

NOTE: U=U means that people with HIV who achieve and maintain HIV viral suppression by taking antiretroviral therapy (ART) as prescribed cannot sexually transmit the virus to others.

CURRENT MODELS FOR SCREENING PrEP CANDIDATES ARE FAILING WOMEN

No group is in more urgent need of scaled-up access to PrEP than women. Cisgender and transgender women continue to be deprioritized in PrEP awareness campaigns and clinical practice, even though women account for 1 in 5 new HIV diagnoses and Black women and trans women of color are disproportionately affected by HIV.

Efforts to reach women with PrEP have been limited, especially in the South. Health departments and providers must adopt innovative strategies for PrEP uptake and ensure that the HIV prevention needs of women are met.

WHICH WOMEN SHOULD BE ON PrEP?

PrEP is recommended for only a small fraction of all women. Determining which individual women are good candidates for PrEP is complex for both women and their providers. Black women have greater need for HIV prevention, including PrEP, than women of other races. Still, given that only 164,000 Black heterosexuals (including men) have an indication for PrEP and there are roughly 23 million Black women in the US, identifying the subset of Black women who are PrEP candidates is challenging.

HIV negative women in relationships with people living with HIV, women who engage in transactional sex, women who inject drugs, and women who have had a recent STI may be good candidates for PrEP. Guidelines-based criteria for screening, however, still leave out too many women and fail to acknowledge structural and environmental factors impacting women's unique vulnerability to HIV.

Research indicates that an emphasis on past risk behaviors is a limitation of current PrEP screening guidelines, leading to a failure to identify many women who could benefit from PrEP. Also problematic is that most screening guidelines require women to know their partners' risk behaviors, although research demonstrates women do not accurately know their partners' risks. Moreover, many women have not been given the tools needed for them to proactively assess their own sexual health and their need for PrEP or other prevention services. Providers are often uncomfortable discussing sexual health, and there are not clear scripts or validated screening tools to help. Competing priorities in women's lives, medical mistrust, and cultural norms further complicate the patient-provider dialogue and decision-making process. As an alternative to behavioral risk assessment, which may be uncomfortable for many women due to stigma around sex and drug use, assessment of demographics, local epidemiology, and network factors may better guide identification of women who could benefit most from PrEP. This could mean offering PrEP to all trans women of color, to all sexually active Black women, or to all women in certain neighborhoods.

HOW CAN WE DO BETTER AT GETTING PrEP TO WOMEN WHO COULD BENEFIT?

We need better tools, and we need to expand PrEP education and services within primary care facilities, STD and family planning clinics, obstetrics and gynecology clinics, and criminal justice settings. Investing in developing clinical tools and provider competency (including trans-friendly and trans-competent providers) will facilitate clinic capacity, and investing in community resources will better equip women and their trusted sources of information to assess needs and increase acceptability of PrEP.

SOURCE: Siegler AJ et al. The prevalence of pre-exposure prophylaxis use and the pre-exposure prophylaxis-to-need ratio in the fourth quarter of 2017, United States. *Ann Epidemiol* 2018;28(12):841-849.

REDUCING INEQUITIES IN PrEP ENGAGEMENT FOR BLACK MSM

MODELING STUDY EXAMINED THE IMPACT OF REDUCING RACIAL DISPARITIES ALONG THE PrEP CARE CONTINUUM

HIV prevalence is 3-6 times higher among Black men who have sex with men (MSM) than among White MSM. While PrEP use increased by 500% from 2013 to 2015, Black people accounted for only 10% of PrEP prescriptions.

THE MAJOR TAKEAWAYS FROM THE STUDY:

- **PrEP use can reduce HIV incidence and disparities:** Compared to no PrEP, implementing PrEP over 10 years at current levels of PrEP use for Black MSM would yield a 23% decline in HIV incidence. If Black MSM achieved the levels of PrEP use among White MSM, incidence among Black MSM would decline by 47% over 10 years, and the disparity between Black and White MSM would be nearly cut in half (46% reduction).
- **Awareness of PrEP is the most impactful step in the PrEP care continuum:** Increasing awareness of PrEP was the step along the continuum most strongly associated with reducing incidence for Black MSM.
- **Adherence is critical:** Adherence to PrEP is critical to its effectiveness and to the number needed to achieve population-level impact.

SOURCE: Jenness SM et al. Addressing gaps in HIV preexposure prophylaxis care to reduce racial disparities in HIV incidence in the United States. *Am J Epidemiol* 2019;188(4):743-752.

THE TIME IS NOW

Expanding the use of PrEP is rightfully an important part of the EHE Initiative. To achieve sufficient scale among the populations that can benefit the most from PrEP requires that we implement and innovate at the same time, while supporting adherence and strengthening the persistence of PrEP engagement. There is no time to waste.

ENDNOTES

1 Pre-Exposure Prophylaxis (PrEP). www.cdc.gov/hiv/risk/prep/index.html.
2 While daily PrEP is the only regimen approved for use in the U.S., "on demand" dosing, i.e., before and after sex, is also highly effective at preventing HIV infection among MSM. Molina JM et al. Efficacy, safety, and effect on sexual behaviour of on-demand pre-exposure prophylaxis for HIV in men who have sex with men: An observational cohort study. *Lancet HIV* 2017;4(9):e402-e410.
3 Ending the HIV Epidemic: A Plan for America. www.hiv.gov/ending-hiv-epidemic.
4 Jenness SM et al. Addressing gaps in HIV preexposure prophylaxis care to reduce racial disparities in HIV incidence in the United States. *Am J Epidemiol* 2019;188(4):743-752.
5 Scott H et al. Disparities in PrEP uptake among primary care patients screened for HIV/STIs in San Francisco. Poster at: Conference on Retroviruses and Opportunistic Infections 2018.
6 Jenness SM et al. Impact of the Centers for Disease Control's HIV Preexposure Prophylaxis Guidelines for Men Who Have Sex with Men in the United States. *J Infect Dis.* 2016;214(12):1800-1807.
7 Dangerfield DT 2nd et al. HIV testing and health care utilization behaviors among men in the United States: A latent class analysis. *J Assoc Nurses AIDS Care* 2017;28(3):306-315.
8 Dangerfield DT et al. HIV testing and healthcare utilization among U.S. African-American women. *J Natl Black Nurses Assoc* 2018;29(2):1-8.
9 Zucker J et al. Missed opportunities for engagement in the prevention continuum in a predominantly Black and Latino community in New York City. *AIDS Patient Care STD*. 2018;32(11):432-437.
10 Calabrese SK et al. Current US guidelines for prescribing HIV pre-exposure prophylaxis (PrEP) disqualify women who are at risk and motivated to use PrEP. *J Acquir Immune Defic Syndr* 2019;81(4):395-405.
11 Sullivan PS et al. Explaining racial disparities in HIV incidence in Black and White men who have sex with men in Atlanta, GA: A prospective observational cohort study. *Ann Epidemiol* 2015;25(6):445-454.
12 Mikati T et al. Immediate PrEP initiation at New York City sexual health clinics. Presentation at: Conference on Retroviruses and Opportunistic Infections 2019.
13 Pebody R. Six innovative models for PrEP services. *NAM aidsmap*. January 7, 2019. www.aidsmap.com/Six-innovative-models-for-PrEP-services/page/3411041/.
14 One-Step PrEP. www.kelley-ross.com/polyclinic/prep/.
15 Liu AY et al. Randomized controlled trial of a mobile health intervention to promote retention and adherence to pre-exposure prophylaxis among young people at risk for human immunodeficiency virus: The EPIC study. *Clin Infect Dis* 2019;68(12):2010-2017.
16 Refugio ON et al. Brief Report: PrEPTECH: A telehealth-based initiation program for HIV pre-exposure prophylaxis in young men of color who have sex with men. A pilot study of feasibility. *J Acquir Immune Defic Syndr* 2019;80(1):40-45.
17 TelePrEP. www.prepiowa.org/teleprep.

O'NEILL INSTITUTE FOR NATIONAL & GLOBAL HEALTH LAW
GEORGETOWN LAW

AUGUST 2019

Prepared by **Jeffrey S. Crowley** and **Sean E. Bland**

This brief is a product of the HIV Policy Project of the **O'Neill Institute for National and Global Health Law** and is supported by a grant from ***Gilead Sciences, Inc.*** Gilead Sciences, Inc. has had no input into the development of this brief. This brief was informed by a stakeholder consultation in March 2019.

bit.ly/USHIVpolicyproject