

# Blueprint for HIV Biomedical Prevention

STATE OF THE STATE REPORT  
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## Executive Summary

Conversations have begun about ending the HIV epidemic or dramatically curbing the impact that HIV has in the United States and around the world, in large part due to the effectiveness of biomedical HIV prevention tools. These tools include:



- **Treatment as prevention (TasP)**, wherein we provide early and sustained HIV treatment to HIV-infected people that first and foremost treats their HIV infection for their own health, but also a very powerful tool for preventing HIV transmission to others;
- **Pre-exposure prophylaxis (PrEP)**, wherein we give high-risk HIV negative individuals a reduced dosing of HIV medication (currently in a daily pill) and other services to prevent HIV infection;
- **Post-exposure prophylaxis (PEP)**, wherein we provide persons who may have had a very recent exposure to HIV a short course of treatment (usually around a month) to prevent them from becoming infected.

When combined with condoms and a variety of evidence-based behavioral interventions, biomedical prevention strategies offer an unprecedented opportunity to end the HIV epidemic in the US. While deployment of biomedical HIV prevention strategies is somewhat new for all populations, they are not being deployed effectively enough in communities of color, and we cannot allow our communities to be left behind.

This report highlights policies and programs that are critical to effective biomedical HIV prevention in communities of color. To increase the effectiveness of HIV prevention tools in communities of color, we need community members to know about these tools, find them acceptable, want to use them, and have access to them. We need providers who are knowledgeable and up-to-date about the latest research around all forms of biomedical prevention and who are willing and equipped to engage in honest conversations about sexual and

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other intimate behaviors, treat people with HIV, and prescribe both PEP and PrEP. We also need to ensure the health system meets the HIV prevention and other needs of communities of color. We urge community leaders, policymakers, funders, public health leaders, health care providers, and the private sector to consider taking action within three primary domains:

#### **Supporting the HIV Community in Overcoming Challenges and Barriers**

- Promote biomedical HIV prevention tools through community education and awareness campaigns
- Tailor efforts to effectively reach young people of color
- Clarify messaging about biomedical HIV prevention and more clearly state that PrEP is safe and effective
- Strengthen health literacy and actively counter mistrust of providers and the health system
- Bolster community resiliency
- Integrate HIV prevention into broader efforts to strengthen our communities

#### **Preparing Providers to Provide Leadership in a Changing Prevention Landscape**

- Expand efforts to train more providers to be equipped to navigate across cultures and communities and provide up-to-date and sensitive HIV prevention services
- Directly address provider attitudes around sexual behavior and concerns around STI transmission
- Work to build sustainable systems for PrEP enrollment and monitoring

#### **Building a Health System to Meet the HIV Prevention and Other Needs of Communities of Color**

- Push for expanded Medicaid in states that have not taken up this option
- Invest in increased capacity and effective models to deliver PrEP, PEP, and HIV treatment
- Work to ensure that insurance coverage is comprehensive and affordable
- Fund public health programs to fill in gaps left by insurance for biomedical prevention

#### **TasP, PEP and PrEP are not magic bullets.**

TasP, PEP, and PrEP are not magic bullets, but if we use these tools in a manner that recognizes that our health systems and programs were not built to equally benefit all of us and we take deliberate steps to tailor programs and services for communities of color, then we can seize the opportunity presented by the current moment in HIV prevention to reduce disparities, prevent HIV transmission, and heal our communities. There is much we need to do, but we are on our way.

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## Introduction

Conversations have begun about ending the HIV epidemic or dramatically curbing the impact that HIV has in the United States and around the world, in large part due to the effectiveness of biomedical HIV prevention tools. This is exhilarating and scary. It is exciting to contemplate the progress that we could make, but given that HIV so disproportionately impacts people of color, especially Black and Latino Americans, unless we

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approach this opportunity differently than in the past, we could squander it. Unless our approach to curbing HIV is built around meeting the needs of communities of color, we won't see the gains that we need.

Biomedical HIV prevention strategies offer a range of tools that can effectively prevent HIV infection. We are largely talking about three different strategies that can be used in different circumstances. This includes treatment as prevention (TasP), wherein we provide early and sustained HIV treatment to HIV-infected people that first and foremost treats their HIV infection for their own health, but is also a very powerful tool for preventing HIV transmission to others; pre-exposure prophylaxis (PrEP), wherein we give high-risk HIV negative individuals a reduced dosing of HIV medication (currently in a daily pill) and other services to prevent HIV infection; and post-exposure prophylaxis (PEP), wherein we provide persons who may have had a very recent exposure to HIV a short course of treatment (usually around a month) to prevent them from becoming infected. These tools, when combined with condoms and a variety of evidence-based behavioral interventions, offer an unprecedented opportunity to end the HIV epidemic in the US. Beyond the strategies that are currently available, new long-acting agents are on the horizon. These agents could be delivered orally or parenterally (both by injection and implantation under the skin) and would not require daily pill taking. As a result, long-acting agents have the potential to make biomedical HIV prevention even more effective.

While deployment of biomedical HIV prevention strategies is somewhat new for all populations, we must recognize that they are not being applied effectively enough in communities of color. While Blacks account for 12% of the US population, they represent 44% of new HIV diagnoses in the US.<sup>i</sup> Latinos account for 17% of the US population yet represent 24% of new HIV diagnoses.<sup>ii</sup> Rates of new HIV infections are especially stark among gay and bisexual men and transgender women of color. If current rates of new HIV infections persist, 50% of Black gay and bisexual men and 25% of Latino gay and bisexual men will be diagnosed with HIV during their lifetimes.<sup>iii</sup>

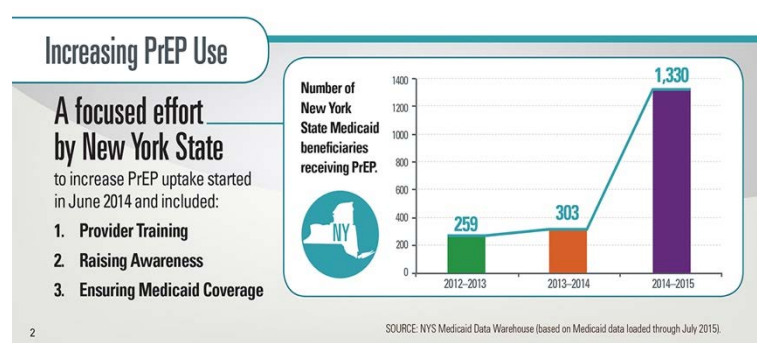
Despite the promise of PrEP and a trend toward increased use, uptake remains slow in communities of color. While PrEP uptake increased by more than 500% between 2013 and 2015, available evidence suggests that 75% of all prescriptions were filled by Whites, with only 10% and 12% filled by Blacks and Latinos, respectively.<sup>iv</sup> A racial disparity also was found among New York State's Medicaid beneficiaries who filled prescriptions for PrEP between 2012 and 2015. In New York State, Blacks account for 38% of new HIV infections, but only 22% of PrEP users in the state's Medicaid program were Black.<sup>v</sup> Among gay and bisexual men, racial disparities are particularly concerning because Black and Latino gay and bisexual men bear a disproportionate HIV burden. Only 7% of participants in a national PrEP demonstration project among gay and bisexual men were Black.<sup>vi</sup> In New York City, PrEP use among gay and bisexual men increased from less than 2% in 2012 to approximately 7% in 2014, but white men were more likely know about and use PrEP than men of color.<sup>vii</sup>

Although PrEP continues to make headlines, it is important to note that people of color often have low rates of HIV care engagement and viral suppression, which is detrimental for the health of those living with HIV above all, but also undermines treatment as prevention. Studies show that TasP is highly effective in preventing HIV infection. Results from the HIV Prevention Trials Network (HPTN) 052 study demonstrated that early versus delayed initiation of antiretroviral therapy (ART) reduced HIV transmission by 96% among serodiscordant couples – where one person is living with HIV and the other is not.<sup>viii</sup> A follow-up to HPTN 052 found no transmission from persons with fully suppressed viral loads to their partners.<sup>ix</sup> More recently, the PARTNER study reported that, among serodiscordant couples using suppressive ART, none had transmitted HIV to their partners.<sup>x</sup> Yet people of color, especially Black men, are less likely to receive on-going HIV care, making it

difficult to achieve viral suppression.<sup>xi</sup> This is particularly concerning among young Black gay and bisexual men who continue to be one of the groups most disproportionately affected by HIV.

The deployment of PEP outside of occupational exposures (such as when health care workers are exposed to blood through a needle stick) has been limited and uneven nationwide. There has been lack of clarity on which treatment regimens were best suited for PEP, there remain clear financial hurdles to financing PEP access, and there has been a bifurcated system for providing PEP medications that often involves emergency rooms giving an initial dosing of medication and requiring individuals to secure a full course of treatment later. For health departments, there has been ambivalence over how much priority should be given to PEP given extensive resource constraints, and the potential for greater prevention impact from prioritizing other prevention services. With the deployment of PrEP, however, there has come a new recognition of the importance of PEP, both as a means to prevent new infections, but also as a mechanism to recruit candidates for PrEP. Thus, there is a need for a fully developed approach to HIV prevention that begins with getting people with HIV engaged in care and that seamlessly integrates PrEP, PEP, along with condoms, and a range of behavioral services that can facilitate adherence to these interventions and improve prevention outcomes.

### *Communities of color must not be left behind in benefiting from biomedical HIV prevention strategies.*



Communities of color must not be left behind in benefiting from biomedical HIV prevention strategies. And, the news is not all bleak. When we look across the country at efforts to maximize the possibilities created by biomedical HIV prevention strategies, it is often people of color leading the charge. Indeed, many governmental initiatives, at all levels, have acknowledged the disproportionate

impact of HIV on these communities and are attempting new more tailored and targeted efforts. Yet, if we are counting now as the starting point, our communities are so far behind, we all must renew our efforts not only to deploy exciting new biomedical HIV tools, but also to do so in a way that aggressively reduces the disparities we experience. This report provides a snapshot of policies and programs that are critical to effective biomedical HIV prevention in communities of color. It is not intended to be a comprehensive overview. To inform the report, the authors conducted key informant interviews with a diversity of community members and advocates, researchers, clinicians, and services providers as well as representatives from a state Medicaid agency, and state and local health departments. Given that federal funding and leadership is also critical to our continued progress, the report includes descriptions of the roles played by selected federal agencies in supporting biomedical HIV prevention programs and identifies some of their key recent initiatives.

### *Now is the time to make a concerted effort to reduce disproportionately high rates of HIV infection in communities of color.*



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# Increasing the Effectiveness of HIV Prevention in Communities of Color

To simplify how we consider the range of issues and actions needed, we are organizing our discussion into three areas: issues for the HIV community (including community-based organizations and social services providers); issues for clinical providers; and issues for the health system (including both health care and prevention services).

## Supporting the HIV Community in Overcoming Challenges and Barriers

To take advantage of effective biomedical HIV prevention tools, we need community members to know about these tools, find them acceptable, want to use them, and have access to them. The longstanding disparities in access to health care services, together with numerous legacy issues that affect how many people of color engage with the health system, create dynamics that must be addressed. Communities of color have less engagement in care,<sup>xi</sup> they are less likely to know their HIV status,<sup>xii</sup> and they have lower rates of HIV viral suppression than whites.<sup>xiii</sup> They are often also less aware of PrEP, for example, than other groups.<sup>xiv</sup> More concerning, young Black and Latino gay and bisexual men, the demographic group where new HIV infections had the steepest increase over the past decade,<sup>xv</sup> often do not know about this biomedical prevention tool. Even as awareness of PrEP increases over time, gaps in PrEP awareness and education within communities of color persist. One Black female respondent stated that people of color outside of the gay community are not well aware of PrEP – the reasons for it, why they should take it, and why they should ask about it. And she stated that even within the gay community, PrEP awareness is low, especially among young Black and Latino men. Based on our review of relevant studies and consultations with key stakeholders, to move our communities forward, we need to:

### **Promote biomedical HIV prevention tools through community education and awareness campaigns**

Community education is needed to increase awareness and uptake of biomedical HIV prevention in communities of color. This includes educating communities about the importance of accessing health care and how to do so, the safety and effectiveness of HIV treatment, as well as the role of viral suppression in preventing transmission to others. PrEP and PEP also are important parts of a comprehensive HIV education and awareness initiative. Since many people of color do not know the difference between PrEP and PEP, explaining the role of these prevention tools and how they fit together alongside good health care is an essential component of community education.

One way to support community education is to undertake campaigns that speak directly to people of color about PrEP and other biomedical prevention tools. To be successful, a campaign must utilize messages and representations that are informed by and relevant to communities of color. If a campaign is not understandable, does not reflect real people, or does not register at all, communities of color will not respond. New York City, Chicago, and San Francisco have taken the lead in integrating information about biomedical prevention tools into effective campaigns. In December 2015, the New York City Department

of Health and Mental Hygiene launched its #PlaySure campaign, which blends messages about HIV treatment, PrEP, and condoms. As part of the campaign, the health department distributes #PlaySure kits for free at participating community-based organizations and at community events throughout the year, including the Pride events in all five New York City boroughs. The #PlaySure kits hold condoms, lubricant, and the prevention pill of a person's choice (e.g., PrEP, HIV medications, and/or birth control), so that users can combine and customize prevention strategies to fit their lifestyle and needs.

In February 2016, the Chicago PrEP Working Group developed an innovative social marketing campaign, called PrEP4Love, to support PrEP awareness and uptake, as well as to reduce stigma. The PrEP4Love campaign uses affirming and sex-positive messages and images and features real members of Chicago communities most impacted by HIV, including young Black gay and bisexual men, transgender women of color, and Black cisgender women of different ages and body types.

In June 2016, the San Francisco Department of Health launched its latest PrEP campaign, "Our Sexual Revolution." Aimed at increasing awareness and uptake of PrEP among young Black and Latino gay and bisexual men and transgender women, the campaign included digital, social, and print media and appeared throughout the city at the Civic Center Muni (subway) Station, in LGBT bars and establishments, on buses, trains, and billboards, and at San Francisco Pride.

Health departments and community-based organizations must continue to support community education and develop campaigns to raise awareness about PrEP, PEP, and treatment as prevention in communities of color. The AIDS Resource Center of Ohio, for example, recently launched a statewide campaign, "Let's Talk about PrEP," and the Louisiana Department of Health is currently developing a social marketing campaign, with the goal of increasing general awareness about PrEP while also targeting education at health care providers and the most vulnerable populations. Moreover, campaigns to raise awareness among Black women have been rolled out in Atlanta, Baltimore, and Washington DC. In the absence of citywide or statewide campaigns, community education is occurring through isolated PrEP programs in various cities, including Jackson, Mississippi and Birmingham, Alabama, but greater funding and resources are needed to support and expand these efforts.

### **Tailor efforts to effectively reach young people of color**

Ensuring that young people (ages 13-24) benefit from biomedical HIV prevention is critical to reducing disproportionately high rates of HIV infection in communities of color. Black and Latino Americans are at exceptionally high risk of acquiring HIV when they are young. Young gay and bisexual men account for the vast majority of new HIV infections among young people, and young Black and Latino gay and bisexual men are especially affected. Even as HIV infection rates declined nationally over the last decade, rates have increased among young gay and bisexual men of all races and ethnicities. HIV infection rates have increased most rapidly among people of color, especially among young Black and Latino gay and bisexual men.

Black and Latino gay and bisexual men, especially young men, experience disparities in access to health care and preventive services, which may contribute to their disproportionate HIV burden. According to data from the National HIV Surveillance System and the Medical Monitoring Project, 77.5% of all gay and bisexual men with HIV were linked to care, 50.9% were retained in care, 49.5% were prescribed antiretroviral therapy, and 42.0% had achieved viral suppression in 2010.<sup>xvi</sup> While almost 44% of White gay and bisexual men achieved viral suppression, only 37% of Black gay and bisexual men and 41.5% of Latino gay and bisexual men achieved it.<sup>xvi</sup> Even more alarming, less than 26% of young gay and bisexual

men achieved viral suppression, and the numbers are likely lower for young Black and Latino gay and bisexual men.<sup>xvi</sup>

Young people and young Black and Latino gay and bisexual men in particular struggle to obtain PrEP. Adults are able to consent to PrEP, but minors (age 17 and younger) often cannot. In most states, PrEP is not available to minors without parental consent. Only seven states and the District of Columbia allow minors to consent on their own to preventive or prophylactic services.<sup>xvii</sup> Parental consent requirements may be the biggest barrier for those minors who are most at risk for HIV infection because they may not have disclosed their sexual orientation or risk behaviors to their parents and may fear the repercussions of disclosure.

Limited payment options are another barrier for both minors and young adults. Truvada is indicated for adult use only. This can make it more difficult for minors to access and use insurance or patient assistance programs to pay for Truvada as PrEP. Moreover, minors typically access health care through their parent's health insurance. Young adults now can choose to stay on their parents' health insurance plan until they turn 26. Some young people, however, cannot readily access their parents' insurance plans, and those who do often worry that it may jeopardize their confidentiality if insurance companies mail explanation of benefits forms or other documents to their parents.

In addition to consent and payment issues, there are not enough resources dedicated to reach young people who need PrEP and engage them in care. Young people typically have poor engagement in health care.<sup>xviii</sup> They may have trouble taking a pill daily as prescribed and attending PrEP-related medical appointments. Specifically, they may need help understanding the requirements of PrEP, remembering their medications and medical appointments, and maintaining adherence between times of sexual activity. While most respondents noted that young people are good at maintaining a daily PrEP regimen, respondents also raised concerns around taking the medication indefinitely. Results from the Ipergay study on an intermittent PrEP regimen represent a major innovation in PrEP and may be particularly relevant to young gay and bisexual men of color. The Ipergay study showed that among gay and bisexual men in France taking PrEP before and after sex was just as effective as taking PrEP daily.<sup>xix</sup> Although the Centers for Disease Control and Prevention recommends daily PrEP and the highest level of protection comes after seven daily doses for rectally exposed men (and twenty daily doses for vaginally exposed women), the study provides the opportunity for users to prepare in a shorter period of time and not have to take PrEP every day for an extended period of time.



Young people of color face many of the same obstacles to adherence as people of color in general. These obstacles include poverty, unemployment, housing instability, mental health problems, substance abuse, and other acute life challenges. Even so, young people may face unique obstacles as well. For example, many young people are not used to accessing medical care on their own or may not seek care at all. Moreover, if young people live with their parents and do not wish to disclose that they are taking HIV medications (whether for treatment, PrEP, or PEP), they may experience obstacles in storing and accessing their medications while maintaining their confidentiality.

It is imperative to promote biomedical HIV prevention among young people, with a focus on young Black and Latino gay and bisexual men, the group at highest risk for HIV infection. Legislative and regulatory change also may be needed to allow minors to consent to health care and preventative services (in all states), so that they can access PrEP, PEP, and HIV treatment without parental consent. Policies are also needed to protect the confidentiality of minors and young adults who are on their parent's health insurance. Furthermore, research and resources are needed to implement services and programs specifically tailored to young people's needs.

Jackson, MS



Model for Community PrEP Leadership in the South

In January 2014, the Crossroads Clinic, a federally funded STI clinic, and Open Arms Healthcare Center, a community-based primary care clinic at My Brother's Keeper, which focuses on healthcare for the LGBT population and communities of color, established a collaboration to implement a PrEP program in Jackson, Mississippi.

The Crossroads Clinic screens clients for risk behavior, performs HIV and STI testing and discusses PrEP, while Open Arms does the initial PrEP appointment, clinical evaluation, and prescribing and monitoring over time.

All MSM who present at the Crossroads Clinic get educated about PrEP, and the clinic has developed a risk certification form to help MSM patients understand their HIV risk. Patients often did not perceive their own risk for HIV even though many had been diagnosed with multiple STIs. Clinic staff also did not always recognize the HIV risk among this population.

After implementing the risk certification form, 70% of MSM present at the Crossroads Clinic were identified as at risk for HIV and were referred to PrEP services at Open Arms.

### **Clarify messaging about biomedical HIV prevention and more clearly state that PrEP is safe and effective**

As we work to build support for PrEP and other biomedical prevention tools, several respondents expressed the need for greater clarity in messaging that PrEP is safe and effective. Based on early research findings, there was some concern about safety, including questions of whether Black people, in particular, were at greater risk of adverse side effects, such as loss of kidney function. More recent research studies, conducted since more people have begun using PrEP, have been reassuring on this front.<sup>xx</sup> While this is a valid clinical concern, evidence that we have accrued to date tells us that PrEP is well tolerated and is not associated with excess adverse clinical events compared to placebo.<sup>xxi</sup> We also know from these studies that PrEP works. When taken as prescribed, PrEP reduces the risk of HIV infection by more than 90%.<sup>xxii</sup>

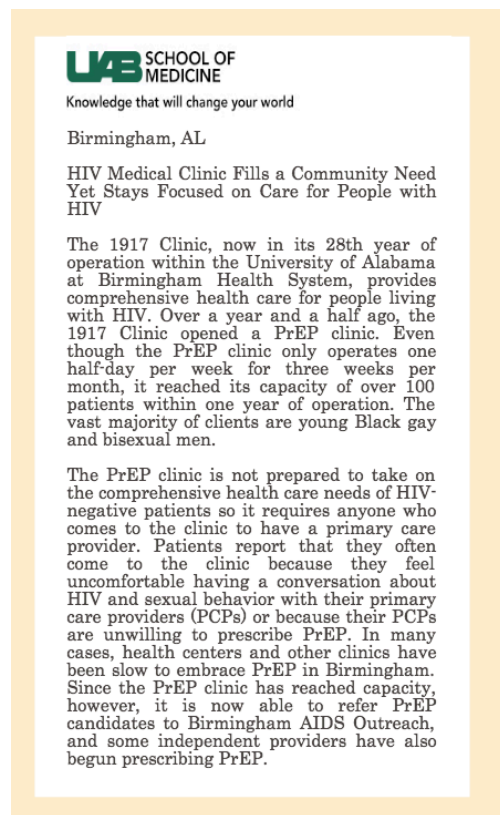
**A recent study among 657 people who initiated PrEP at Kaiser Permanente's San Francisco Medical Center found no new HIV infections among PrEP users during more than 2.5 years of observation.**<sup>xxiii</sup>

Because of the history of medical mistrust in many of our communities, there is a need for nuance and sensitivity in conveying this information. But many people believe that there has been too much focus placed on small changes in bone density and kidney function, as well as other side effects that are relatively minor, experienced by a small number of persons, and quickly go away when persons stop PrEP, and that we have not been clear and consistent enough when talking to the general public about the safety and effectiveness of PrEP. While most of the HIV community has embraced PrEP for its potential, there have been notable, and often vocal exceptions. One respondent stated that when a health care organization working in communities of color takes a strong stance against PrEP, it adds additional confusion, leading people to question whether PrEP works.

### **Strengthen health literacy and actively counter mistrust of providers and the health system**

Mistrust of the health care system is another potential barrier to biomedical HIV prevention in communities of color. Black Americans, in particular, may choose not to go to the doctor because they do not trust the health care system. This mistrust undermines efforts to promote PrEP, PEP, and TasP, but exists and persists due to real problems that continue, perhaps especially in parts of the South where HIV

transmission rates are especially high. Some mistrust of medical professionals likely stems from previous experiences of stigma and discrimination in health care settings. One Black gay male respondent said, “I think it’s really important to demystify PrEP, particularly for marginalized communities and communities who may already have historical distrust with medical institutions and new experimental medications.”



Respondents from community-based organizations emphasized health literacy as a necessary condition for supporting biomedical HIV prevention in communities of color. Health literacy refers to the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions. Many Black and Latino Americans have low health literacy because they lack experience with health information and services and may go long periods without engaging with the health system or thinking about their personal health. Black and Latino Americans, who are substantially less likely than white Americans to have a primary care physician or make regular clinic visits,<sup>xxiv</sup> may not be familiar with how to go into a clinic and interact with and ask questions of their health care providers.

An important goal of strengthening health literacy is to increase the capacity of individuals to navigate health insurance systems, including assessing available coverage options, enrolling in coverage, accessing services and troubleshooting if problems arise. One respondent from a state health department explained that most clients to the state’s drug assistance program were unaccustomed to working with a state-funded program. Therefore, some people do not know how ask for help or where to call, and some may feel uncomfortable with the health department knowing so much about them.

### **Bolster community resiliency**

Stigma associated with PrEP use and with HIV more generally impedes uptake of prevention services in communities of color. As PrEP was first being rolled out, it was unfortunate that some PrEP skeptics used negative and divisive tactics, including calling some persons seeking PrEP “Truvada Whores,” for the name of the drug currently being used for PrEP. Related issues arose of so-called “slut shaming” where persons seeking PrEP were accused of behaving irresponsibly. PrEP stigma is not the only form of stigma faced by gay and bisexual men or people of color. A 2015 study found that, among a sample of 544 Black gay and bisexual men, 29% experienced stigma related to race or sexual orientation in health care.<sup>xxv</sup> The implementation of PrEP and other forms of biomedical prevention, however, provides an opportunity to

Washington, DC and Nationwide

**BLACK WOMEN'S HEALTH IMPERATIVE**

Tailored Efforts to Reach Black Women with PrEP Awareness and Access

Women account for roughly 20% of all new HIV infections in the United States, and Black women represent 64% of all new HIV infections among women. Many women who would benefit from PrEP remain unaware of it and, if they do know about it, they often assume that PrEP is only for gay and bisexual men, the target population for most PrEP awareness campaigns and demonstration projects.

To increase PrEP awareness among Black women, the Black Women's Health Imperative created a national campaign, "Let's Talk About PrEP." First launched in Atlanta, Baltimore, and Washington DC, "Let's Talk About PrEP" specifically engages Black women in meaningful conversations about sexual health and HIV prevention and promotes PrEP by providing scientifically up-to-date and consistent information for and about Black women. The campaign encourages Black women to talk to their friends, family, and partners about the importance of taking charge of their sexual health and knowing the tools available to keep themselves safe. It also identifies organizations that provide resources Black women can use to access culturally appropriate care, including PrEP. In addition to multimedia platforms, including a website and print, radio, and digital ads, "Let's Talk About PrEP" uses street teams of Black women peer advocates to get PrEP messages to where women are - at hair salons, shopping malls, concerts, and festivals.

Building on the success of "Let's Talk About PrEP," more PrEP campaigns are targeting Black women. The District of Columbia, where 92% of women living with HIV are Black, launched the first citywide program to increase PrEP awareness and uptake among Black women. In June 2016, the DC Department of Health rolled out its #PrEPForHer campaign, which invites Black women to take charge of their sex lives by taking PrEP to protect against HIV and explains that PrEP is safe, effective, and available for everyone. The DC Department of Health had also established a public-private partnership with the Washington AIDS Partnership, the DC PrEP for Women Initiative. The DC PrEP for Women Initiative aims to increase knowledge and use of PrEP among women of color in DC, with a focus on reaching those at high risk for HIV as well as the health providers and community-based organizations that serve them.

turn these efforts to shame and stigmatize people on their head. Persons utilizing PrEP and biomedical prevention are actually community leaders and deserve to be applauded. One of the more exciting developments in recent years has been to observe gay and bisexual men of color stepping forward in efforts to communicate the benefits and acceptability of PrEP. At My Brother's Keeper in Jackson, Mississippi, Black gay bisexual men are leading the charge to educate their communities about PrEP and help individuals navigate insurance coverage and other issues.

Language and culture are also important factors that can determine acceptance of PrEP and biomedical prevention tools. Indeed, producing materials in the dominant language of the target population and developing culturally sensitive and responsive messages can be especially important for reaching Latino and other communities where PrEP uptake has been low. One Latino gay male respondent reflected on the importance of Spanish for PrEP access: "When you go to a clinic that specializes in HIV and LGBT health, they are very aware [of PrEP], but sometimes those places that are very aware, they might not either cater to the Latino community, [or] they might not have the language." Just as messages, key opinion leaders, and the way people prefer to receive information may be very different depending on the target population, women, transgender people, and gay and bisexual men with differing languages and cultural backgrounds may have different preferences or needs in terms of how services are delivered and how information is conveyed. Effective implementation of biomedical prevention demands more than translating brochures. Whether it is Spanish or other languages, it requires developing materials grounded in the cultural experience of the individuals a program is trying to reach, and engaging spokespeople who either come from the affected community or already are recognized as having the trust of the community to validate the information.

### **Integrate HIV Prevention into Broader Efforts to Strengthen Our Communities**

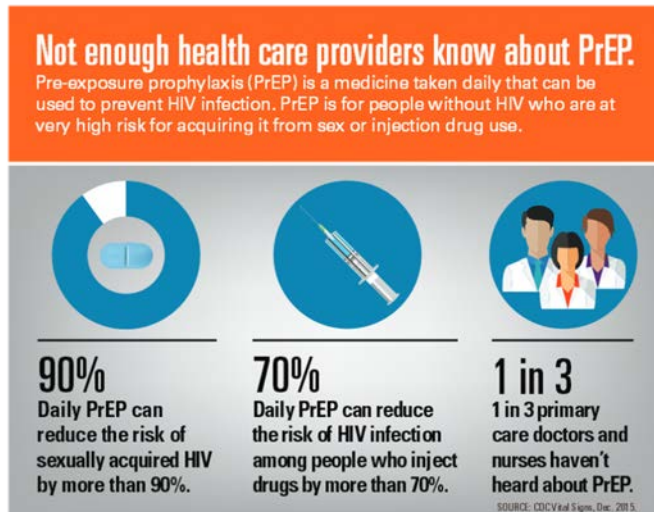
Preventing HIV transmission is an important priority for many people, but it may not always be the foremost concern of persons and communities at high risk for HIV infection. Therefore, as we begin our efforts to take advantage of new biomedical prevention tools, we need to integrate them with comprehensive health care and other critical services, such as housing, employment and vocational services, food and nutrition, income support programs, and legal services.

People of color often have competing or higher priority needs than PrEP. Transgender women of color, for example, offer a good illustration of how other life circumstances often are more urgent issues than HIV prevention. Transgender women experience disproportionately high rates of violence and discrimination. As a result, they face substantial obstacles to education, employment, and stable housing, and are more likely to experience mental health and substance abuse problems.<sup>xxxvi</sup> Transgender people of color also confront major challenges around accessing culturally competent and comprehensive health care. For many transgender people of color, it is more important to have hormones than to have PrEP, but if the provision of PrEP could be integrated with programs that provide safe and affordable access to hormones and other primary care and mental health services, there is an opportunity to promote client satisfaction and health.

People of color who are undocumented, likewise, experience a different reality at the margins of society and face a number of serious challenges. Undocumented people exist within all communities of color, but are most often associated with the Latino community. Not only must we not conflate being undocumented with being Latino, but we also must focus on the intersectionality of immigration status and other issues (i.e., race, ethnicity, sexual orientation, and gender identity) and work to meet the unique needs of undocumented Latinos in general and undocumented Latino LGBT people in particular. On top of the barriers that many Latino Americans encounter around language, health literacy, and stigma and discrimination, undocumented people have even more limited access to health insurance. Although the Affordable Care Act (ACA) has increased access to Medicaid and private health insurance, the law bars millions of undocumented people from these programs. Moreover, challenges for undocumented people extend beyond health insurance.

Often invisible and voiceless, undocumented people confront constant fear of being discovered and deported, financial hardship due to unemployment or underemployment, and a host of other issues related to their lack of legal status. Even when health programs and services exist for this vulnerable group, many undocumented people may not access them out of fear of deportation. Undocumented Latino LGBT people may be further deterred by experiences of homophobia or transphobia. As we work to build support for biomedical HIV prevention, it is important that we look at people of color with different and intersectional lenses and develop tailored interventions. For undocumented people of color, this means specifically addressing issues related to their legal status and advocating for policy reforms.

## Preparing Providers to Provide Leadership in a Changing Prevention Landscape



Health care providers, such as physicians, nurses, physician assistants, pharmacists, and other clinical providers are among the most trusted experts in our communities. As we work to scale-up access to biomedical HIV prevention, the tough demands we place on providers are only increasing. Nonetheless, they often have a unique knowledge and often carry unique responsibilities for providing guidance on how to deploy new health technology, including biomedical prevention tools. We need providers who are knowledgeable and up-to-date about the latest research around all forms of biomedical prevention, we need providers willing and equipped to engage in honest conversations about sexual and other intimate behaviors, we need

providers willing to treat people with HIV and willing to prescribe both PEP and PrEP, and we need providers who are personally comfortable with these new prevention tools and are not intentionally or unintentionally creating stigma or barriers around the use of PrEP and PEP. Many such providers exist, but our challenge today is to bolster existing providers who can do all of these things, and grow the network of providers with these skills so that they can be found across the health system and across the country. A renewed emphasis on bolstering our health care workforce is needed to:

### *Expand efforts to train more providers to be equipped to navigate across cultures and communities and provide up-to-date and sensitive HIV prevention services*

As efforts are made to expand appropriate access to PEP and broaden the availability of PrEP, we need to expand the number of providers willing and able to prescribe antiretroviral medications for prevention. In particular, we need to ensure that such providers provide respectful and appropriate care, free of stigma and judgment. Several of our respondents noted a dismissive tone among some providers toward PrEP, including providers who tell patients that they don't need PrEP without asking about their sexual behavior. Another respondent noted that PrEP raises issues of sexual morality for providers. Some providers are reluctant to prescribe PrEP because they feel it endorses condomless sex, and this reluctance often stems from homophobia, transphobia, and racism. These providers may not feel comfortable with LGBT people having sex. Racial biases also may affect their willingness to prescribe PrEP. One study, for example, found that medical students rated a hypothetical Black patient as more likely than a hypothetical white patient to engage in increased condomless sex if prescribed PrEP; this rating was associated with reduced willingness to prescribe PrEP to the Black patient.<sup>xxvii</sup>



In many cases, building an infrastructure of providers to prescribe antiretroviral medications for prevention is a new challenge. Adequate scale-up of access to these prevention tools means that we cannot rely exclusively on existing HIV treating physicians. We need to extend this capacity into health centers and other primary care clinics. This presents a two-fold challenge: We have to ensure these providers are knowledgeable about HIV and HIV prevention medications. We also have to make sure that providers understand their patient population and are comfortable serving diverse populations, including taking sexual histories and openly discussing patient sexual practices and beliefs.

People of color often struggle to find providers with whom they can establish an ongoing relationship of trust. This may explain, in part, the racial disparities in viral suppression rates observed in some settings. On top of issues related to finding a provider that a person wants to see, people of color also may have a hard time finding providers knowledgeable about and capable of prescribing and monitoring PrEP. This may be an especially acute challenge in rural areas and other underserved areas, such as some communities in the South that are already disproportionately impacted by HIV. In 2015, three years after the Food and Drug Administration approved Truvada for PrEP and a year after the Centers for Disease Control and Prevention (CDC) issued clinical guidelines for PrEP, one-third of primary care doctors and nurses had not heard about PrEP.<sup>xxviii</sup> As we look to primary care providers to take on new roles of prescribing PrEP, many providers have little motivation to promote PrEP, even though it is a powerful prevention method.

### **Directly address provider attitudes around sexual behavior and concerns around STI transmission**

The implementation of PrEP, especially among gay and bisexual men, has raised concerns that this will lead to fewer persons choosing to use condoms regularly. Some providers are concerned that PrEP may ultimately prove harmful if more persons acquire other sexually transmitted infections (STIs). By giving a consistent public health message for thirty years that non-monogamous individuals should use a condom for every sexual encounter, the availability of PrEP is for many persons a startling break from past practice and is perceived as risky. This tension has played out in community discussions and has fueled some of the aforementioned “slut shaming.” Similarly, many physicians have been trained to believe in the benefit of asserting norms and express concern that they are validating risky sexual practices by prescribing PrEP. Just as community stakeholders have shifted the dialogue around the role of PrEP and the benefits of PrEP in recent years, similar dialogues are occurring among providers and should be encouraged. Indeed, HIV experienced physicians and those most comfortable navigating conversations around sexual practices are often among the first to admit that condom fatigue was a real phenomenon before PrEP and that the steady state of new infections year after year was evidence that consistent condom use was either not possible or not desirable for many individuals. Therefore, we should encourage HIV experienced providers to provide training to or engage in dialogue with primary care providers who may have less experience engaging with patients around issues related to HIV, STIs, and sexual health issues.

STIs are common among gay and bisexual men of all races and they also disproportionately impact many communities of color. To date, clinical trials and demonstration projects have not found an increase in sexual risk behaviors after PrEP initiation.<sup>xxix,xxx</sup> Moreover, engaging with providers about their concerns over decreased condom use and increased STI acquisition raises fundamental questions over the legitimacy of pleasure in making decisions about condom use, as well as the relative prominence of concerns over becoming infected with an STI. Navigating this new environment is important and more efforts are needed to equip providers to serve as facilitators of patient decision-making. For community



members and providers alike, new biomedical prevention tools, along with the existence of online hook-up sites and other newer ways that people seek out sexual partners, are forcing a dialogue that is ongoing, yet incomplete. More efforts are needed to address provider concerns, but this has to happen in recognition of current evidence and the realities of affected communities.

### **Work to build sustainable systems for PrEP enrollment and monitoring**

If PrEP is going to act as a tool to reduce HIV-related health disparities, many more people of color are going to need to access PrEP services. This raises questions about the systems we are putting in place today to provide PrEP and whether they are capable of delivering the volume of PrEP services needed. The logistics of implementing PrEP can be time-consuming and intimidating for providers, who have concerns about providing risk reduction and adherence counseling, handling lab work and multiple clinical visits, and tracking follow-up in the context of busy practices. To manage these activities, providers have adopted different approaches for coordinating PrEP care, including cross-disciplinary collaboration and the appointment of PrEP coordinators. As PrEP becomes more routine and new medications and delivery mechanisms are developed, there also may be opportunities for streamlining PrEP care. One health department employee from a southern state said, “I’m hoping it [PrEP rollout] will follow the course of the way birth control has over the past many years in that it gets easier and easier for people to get it and they have less and less interaction with the healthcare system in order to have it and stay on it. And that’s how we are going to get utilization really to increase.” Indeed, we should examine and build on the lessons from reproductive health care and how new contraceptive options were deployed, when considering current and future PrEP strategies.

## **Building a Health System to Meet the HIV Prevention and Other Needs of Communities of Color**

The US health system is in a state of change. This is especially true as it continues to work through and gain experience from expanded coverage options created by the ACA. People with HIV are a small share of the US population. When considering all of the things we need the health system to do as the US moves toward more integrated systems of care, getting it to deal with the HIV prevention needs of a subset of the population is challenging. To effectively implement biomedical prevention for any community, not only in communities of color, however, we need the health system to engage and give this issue adequate attention.

Since many public insurance programs exclude non-citizens or undocumented immigrants, we need to remember to bolster non-insurance programs (such as the Ryan White HIV/AIDS Program and health center programs) and nongovernmental programs (such as pharmacy and patient assistance programs), so that we

Louisiana

#### Medicaid Expansion and Health Department Leadership Go Hand in Hand

In 2016, Louisiana became the 31st state to expand Medicaid, creating a new opportunity for PrEP access. More than 300,000 Louisiana residents, including many low-income gay and bisexual men, transgender individuals, and people of color, all of whom have significant HIV prevention and treatment needs, became eligible for Medicaid for the first time. With Medicaid expansion still underway, the Louisiana Department of Health has made the enrollment process a top priority.

In addition to linking people to Medicaid, which pays for PrEP and related medical services, the health department has developed various levels of training focused on building the clinical and non-clinical infrastructure needed to support PrEP. The health department offers a PrEP 101 to clinicians, nurses, and community-based organizations and stakeholders. Through its expanding PrEP awareness work funded by the CDC, the health department further retains six physician consultants to conduct more specialized clinical PrEP trainings. While these provider-to-provider trainings only began in fall 2015 and are limited to the New Orleans metropolitan area, the health department is documenting best practices and intends to expand them statewide. More generally, the health department mandates training on homophobia, transphobia, and institutionalized racism for its staff and partners and brings in subject-matter experts and members of affected communities to facilitate the training.

The health department also has been involved in a number of community awareness, education, and engagement initiatives around PrEP. At the end of 2015, the health department created four PrEP navigator positions in the New Orleans area as part of a demonstration project. PrEP navigators help people find public and private PrEP providers and assist with insurance navigation and coverage issues. The health department is currently working on a social marketing campaign and also has launched an online directory of providers who are ready and willing to prescribe PrEP. The directory designates those providers who have completed specialized PrEP training and training on homophobia, transphobia, and institutionalized racism. As of July 2016, the directory had approximately twelve PrEP providers, half in New Orleans, but many more providers had attended health department trainings.

leave nobody behind. To increase access to biomedical HIV prevention for communities of color, however, major emphasis is needed to examine structural components of the health system. The health system consists of the mix of public purchasers of health care, including Medicaid and Medicare, along with private insurers, state-based marketplaces, as well as our HIV and STI prevention and care programs, including the Ryan White HIV/AIDS Program and prevention activities of health departments.

We need the health system to build and maintain the capacity to deliver effective

biomedical prevention, we need it to make it easy for persons who need these services to obtain them, we need it to create broad awareness of the range of tools and the evidence for how effective they are, we need the system to ensure that these services are affordable, and we need the system to monitor utilization, outcomes, and trends with respect to the use of biomedical prevention services. To make all of this work for communities of color, we need the health system to adapt and tailor its services to our communities rather than having people of color adapt to a system that was not built with them in mind. To achieve our goals in a dynamic health care environment, we need to:

### ***Push for expanded Medicaid in states that have not taken up this option***

Ensuring that all people have access to stable, affordable, and comprehensive health insurance coverage is one of the most important actions we can take to improve health and reduce health disparities. The US has a large and complex patchwork of programs that make up the so-called US health system. Roughly half of Americans receive health coverage through employer-sponsored coverage. Others rely on a mix of public and private programs (such as Medicare and Medicaid, and marketplace health plans), Veterans Health Benefits, and other programs. Those who are left out of coverage include persons who are undocumented (for whom there is no single overarching program or strategy for delivering biomedical prevention services) and low-income people who are eligible or would be eligible for Medicaid if their states were to take advantage of the Medicaid.

Others rely on a mix of public and private programs (such as Medicare and Medicaid, and marketplace



health plans), Veterans Health Benefits, and other programs. Those who are left out of coverage include persons who are undocumented (for whom there is no single overarching program or strategy for delivering biomedical prevention services) and low-income people who are eligible or would be eligible for Medicaid if their states were to take advantage of the Medicaid expansion option. To date, the Kaiser Family Foundation estimates that almost 40% of people with HIV live in states that have not expanded Medicaid,<sup>xxxix</sup> and most states in the South are heavily burdened by HIV yet have not expanded Medicaid. 54% of Black Americans live in the South and therefore are more likely to reside in a state that has not expanded Medicaid. This means that they are less likely to have access to biomedical HIV prevention.

Although Medicaid expansion has been controversial in some locations, there remain strong economic and policy incentives for every state to take advantage of this option. Moreover, experience shows that it is an effective way to expand health coverage for low-income people. Of the interviews conducted with representatives from non-Medicaid expansion states such as South Carolina, Georgia, Alabama, and Mississippi, all rated Medicaid expansion as a top policy priority. A representative from Louisiana regarded the state's decision to expand Medicaid in 2016 as very important for PrEP access and noted that non-expansion held the state back over the past few years.

### **Invest in increased capacity and effective models to deliver PrEP, PEP, and HIV treatment**

In recent years, the first national estimates of viral suppression showed that only 25% of people with HIV

*"If you don't have a doctor...and you're trying to find one, good luck. The number of providers available that are taking new patients are so slim to none that it is unbelievable. The medical community is stretched so thin. We just don't have providers available."*

*- Respondent from a health clinic in the South*

were in care, on treatment, and virally suppressed. In a short period of time, viral suppression estimates have risen to 30%. While demonstrative of a lot of work ahead, the trend is in the right direction, and there are numerous efforts underway to more comprehensively support engagement in care along the HIV care continuum from diagnosis to viral suppression. TasP is a concept that was initially used to promote immediate initiation of treatment on diagnosis. As insurance coverage has expanded, this has created a new platform for financing HIV care and prevention services. Now, we need to take advantage of clear clinical recommendations.<sup>xxxix</sup> We need to build the capacity for the health system to deliver effective prevention services to a growing number of persons and also need to focus on not leaving people of color or other communities behind. This means expanding prevention education and services within pharmacies, STD and family planning clinics, and other places where people of color are.

Seattle, for example, has pioneered the concept of a pharmacist-run PrEP service in a community pharmacy setting. Pharmacists with the One-Step PrEP service – established in March 2015 – provide blood testing, counseling and PrEP during a single visit. Other jurisdictions are promoting efforts to train primary care providers to deliver more PrEP services. New partnerships with health centers, including family planning health centers such as Planned Parenthood, are seen as promising opportunities for delivering on the promise of biomedical prevention.

One issue that has stymied many health department leaders is how to integrate PEP in their prevention programs. Essentially, at a time of limited resources, it has been unclear how much attention and financial resources should be allocated to PEP when so much work is needed to effectively implement PrEP. One

researcher from the South told us, “In the case of PrEP, maybe you have increasing demand and still not great supply. In the case of [PEP], I think you have pathetic demand and pathetic supply.”


New York City has embraced PEP as an essential strategy in the HIV prevention toolbox and is making the medication available in a variety of non-emergency room settings, such as sexually transmitted disease (STD) and other clinics as well as pharmacies. In 2014, New York City first spearheaded the use of 3-day starter kits as a feasible way of providing PEP in STD clinics. Rather than referring patients to other facilities for the remainder of the standard 28-day course of PEP medication, STD clinics will now offer full courses of PEP. Second, New York City has created PEP Centers of Excellence in each of its five boroughs to streamline and provide better geographic coverage for PEP service delivery. PEP Centers for Excellence

are low-threshold, urgent care-based settings that provide access to PEP for individuals regardless of insurance or immigration status and also offer patient navigation and support services as well as linkage to PrEP if indicated. Third, health officials operate a citywide telephone number that connects individuals with a medical provider who can call in a prescription for a PEP starter kit to partner pharmacies. This program allows individuals to pick up as much as a 7-day supply of PEP free of charge before their HIV test.

We are in a phase of experimentation. As we try different things, we also need to recognize that innovative solutions in one place may not work as well elsewhere. New York City

and Seattle are not representative of the rest of the country, so it is important to develop models of biomedical HIV prevention that work for different jurisdictions. Even in these cities, white communities are more likely to benefit from biomedical HIV prevention than communities of color. Scaling up biomedical HIV prevention programs and service delivery practices requires investing resources and tailoring approaches to address the unique challenges in diverse settings and populations.

New York City

  
Health

A Model for Comprehensive and Positive Leadership in Biomedical HIV Prevention

The New York City Department of Health and Mental Hygiene places biomedical HIV prevention at center of its work and supports the adoption of PrEP and PEP within the health system. To streamline the flow of patients from HIV testing centers and community-based organizations to places that can prescribe PrEP, the health department cross-links these entities through funding and memoranda of understanding. The health department is also developing a protocol for implementing PrEP in all 8 STD clinics in the city and hosts PrEP implementation workshops, where clinic administrators and medical directors learn to develop curated PrEP protocols for their clinics. In some cases, the health department offers PrEP at no cost to people who are uninsured or underinsured at STD clinics and other sites. In addition, the health department has devised a number of community, provider, and broader public health engagement strategies, including:

- 1. Provider Detailing**

The health department contracts with pharmaceutical detailers to educate providers about HIV biomedical prevention strategies and teach them how to prescribe PrEP and PEP. Detailers visit clinical facilities to present targeted messages using the health department's PrEP and PEP Action Kit. The PrEP and PEP Action Kit includes provider and patient resources, such as clinical guidelines, billing codes, FAQs, pocket cards and posters as well as information regarding patient financial assistance through the Gilead Consumer Assistance Program and the New York State's PrEP Assistance Program. Between October 2014 and April 2015, detailers visited 692 clinical facilities and 1433 prescribing providers. New York City is now providing capacity-building and technical assistance to help states and cities start their own detailing programs. When adapting these efforts, health departments with limited resources can use internal staff rather than hire external detailers.
- 2. Status Neutral Navigation**

Using city funds, New York City has added team members to Ryan White Care Coordination Programs, and is moving toward framing HIV prevention and care as part of a continuum of status-neutral care coordination services. The goal is to adapt existing care coordination strategies for PrEP and PEP candidates and users to support HIV and STD prevention. This effort is also focused on connecting PrEP and PEP candidates and users to payer systems as well as linking them to services that help address the structural, social, and behavioral determinants of health.
- 3. Relationship Building**

Through consultation and collaboration with different stakeholders and stakeholder groups, the health department is able to build relationships to promote community mobilization and engagement. New York Knows, the nation's largest HIV testing initiative, has always relied on community partners and has expanded to be a gateway for referral to PrEP. The health department has conducted listening sessions with gay and bisexual men of color in Brooklyn and plans to expand these sessions to the other four city boroughs.
- 4. Adolescent PrEP Program**

The health department funds two clinical sites to launch a PrEP program for adolescents. Funding supports sites that have experience with adolescent patients and HIV to develop youth-focused combination prevention including PrEP and to identify best practices for expanding the program to additional sites.



### **Work to ensure that insurance coverage is comprehensive and affordable**

For people of color and those in communities at high risk for HIV infection, the health system often does reasonably well at delivering HIV treatment and associated clinical monitoring if they have insurance and have stable access to a provider. It often fails, however, in systematically removing structural barriers that impede people from accessing prevention and care services. In the case of insurance coverage for biomedical prevention services, a first hurdle is to make sure that people are enrolled in coverage that provides high quality, comprehensive benefits that are affordable to obtain.

Employer-sponsored insurance, Medicaid, and Medicare typically have reasonably good coverage for HIV medications for treatment, and while demand is low, presumably for PrEP. Coverage for PrEP is often good in some plans, but individual health plans have erected financial barriers to PrEP, as well as have imposed prior authorization review requirements that impede access. More work is needed to ensure uniform and timely access to PrEP for all persons requesting it. More significant concerns have arisen, however, with respect to health plans offering coverage through the marketplaces. While many plans have provided appropriate access, a troubling number of marketplace plans have placed all antiretroviral medications on the highest cost tiers. In some of these plans, this can lead to cost-sharing where individuals are asked to pay as much as 30% or more of the cost of these drugs, which could easily cost more than \$1,000 per month. Since section 1557 of the ACA requires health plans to be nondiscriminatory in their plan offerings and benefit designs, this provides a mechanism for federal regulators to create a level playing field for all health plans, but education and advocacy may be needed to urge federal officials to take these steps.

One respondent with a community-based organization in the Midwest said, “Unfortunately, we are starting to see a movement to insurers putting really onerous barriers like 53% co-insurance on Truvada as PrEP, which is really cost prohibitive.” A recent report found that 34% of all insurance plans available on the federally facilitated marketplaces placed Truvada on the specialty tier and one-third of plans place all covered single-tablet HIV regimens on the specialty tier, translating into higher out-of-pocket costs that place the drug out of reach for many patients.<sup>xxxiii</sup>

### **Fund public health programs to fill in gaps left by insurance for biomedical prevention**

Financing to secure access to biomedical HIV prevention remains challenging. Paying for PrEP, for example, requires having a system to fund enrollment and screening, ongoing clinical monitoring, STI screening, and other services, as well as paying for the medications used for PrEP. For health departments, different barriers to financing these different components of a comprehensive PrEP program have arisen from one jurisdiction to the next. While the long-term goal is to ensure that all people have access to stable insurance coverage, in the current phase of deployment, health departments, advocates and others are looking for all available sources of funding and assistance.

**The Centers for Disease Control and Prevention (CDC):** CDC is the primary funder of prevention services in the US, including HIV prevention services, and is also crucial to ensuring that PrEP and other biomedical HIV prevention tools are affordable. While CDC has been among the strongest supporters of PrEP and has provided laudatory leadership in funding research, quickly promulgating prescriber guidelines, and allowing federal prevention resources to be used for ancillary PrEP services, longstanding CDC policy has prohibited their funds from being used to purchase medications. Advocates and others have called for this policy to be changed, and indeed, the President’s budget for FY 2017 (awaiting final action by Congress) proposed a limited demonstration program to permit a small share of federal HIV prevention funds for health departments to be used for PrEP medications.

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**The Ryan White HIV/AIDS Program:** The Ryan White Program is critical to providing early and sustained HIV treatment to people living with HIV. The program is the cornerstone of national efforts to ensure access to high quality HIV care. Indeed, Health Resources and Services Administration (HRSA) data show that in 2014, more than 81% of their clients had achieved viral suppression compared to national estimates that only 30% of people with HIV are virally suppressed.<sup>xxxiv</sup> Further, while disparities exist in viral suppression rates along racial/ethnic lines, the program has narrowed these disparities with 77% of Black Ryan White clients achieving viral suppression compared to 87% of white Ryan White clients. The Ryan White Program, however, is restricted, by law, from paying for PrEP and PEP medications and services.

**340B Drug Pricing Program:** One potential way to ensure that PrEP and other biomedical HIV prevention tools are affordable is to ensure that health department programs seeking to provide PrEP medications and services have access to the 340B Drug Pricing Program. The 340B Drug Pricing Program requires drug manufacturers to provide outpatient medications at significantly reduced prices to certain safety-net providers, including Ryan White HIV/AIDS Program grantees, federally qualified health centers, and specialized clinics such as STD clinics and family planning clinics. In the context of HIV, the Ryan White HIV/AIDS Program relies heavily on the 340B Program to purchase medications to treat people living with HIV, but these programs cannot currently purchase medications for use for prevention for people uninfected with HIV.

It is important to educate health centers and clinics about the 340B Drug Pricing Program and importance of leveraging or obtaining a 340B designation. The program could be crucial for populations that are uninsured and underinsured or that reside in Medicaid non-expansion states because access to discounted prices can dramatically improve their access to biomedical HIV prevention. STD clinics may offer a compelling venue for comprehensive PrEP and PEP programs because they are eligible to register as 340B covered entities. STD clinics, however, may lack the infrastructure necessary to deliver PrEP to their patients. Implementing PrEP and PEP more widely at STD clinics could help people of color to access these prevention tools. Unlike STD clinics, HIV clinics have existing infrastructure that could facilitate access to PrEP and PEP, but they cannot use Ryan White funding or Ryan White 340B designation to provide the drug and related clinical services for PEP and PrEP.

**Patient Assistance Programs:** The pharmaceutical industry provides an additional funding mechanism to help people to access biomedical HIV prevention. Several patient assistance programs are available for PEP, but each pharmaceutical company has different policies for patient eligibility and delivery of the medications. Gilead Sciences, the manufacturer of Truvada, the only currently approved PrEP agent, also operates patient assistance programs for PrEP. Gilead's Medication Assistance Program provides free Truvada for PrEP to those without health insurance or prescription drug coverage regardless of immigration status, but limits eligibility based on income. Gilead's Co-Pay Assistance Program has no income requirement, but caps the amount of assistance an individual can receive each year. Pharmaceutical programs have become more generous and comprehensive over time. Furthermore, the initial experience with insurance coverage of PrEP often has been positive, but patients still face financial costs that operate as a barrier to accessing PrEP and PEP.



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# Roles of Federal Agencies in Advancing Biomedical HIV Prevention

The federal government has a critical role to play in addressing the challenges and barriers to biomedical HIV prevention faced by communities, providers, and the health system. The President-elect has stated very little about HIV policy during the campaign. He has a past history of supporting HIV causes, and when asked at a campaign event in 2015 whether he would pledge to work to double the number of people with HIV on treatment globally by 2020, while non-committal, he spoke positively of his support for fighting HIV, Alzheimer's Disease and other health conditions.

A hallmark of the National HIV/AIDS Strategy has been to focus on identifying and prioritizing scientifically valid, effective prevention and care interventions. Indeed, a central component of the updated Strategy, which guides our collective efforts through 2020, is a focus on full access to comprehensive PrEP services for those for whom it is appropriate and desired, with support for medication adherence for those using PrEP, based on new scientific evidence that has accrued in recent years.

Translating high-level policy commitments into tangible actions that support biomedical prevention uptake throughout the country requires a number of policy and programmatic actions throughout the federal government. The following is intended to outline key parts of the government and how different agencies support biomedical HIV prevention strategies.

## **The White House**

The White House Office of National AIDS Policy (ONAP) is responsible for coordinating federal HIV policy across the Administration. In the Obama Administration, ONAP led the development of the National HIV/AIDS Strategy and the Update to 2020 by engaging broadly with community stakeholders and convening HIV leadership from across the government to collaborate and coordinate efforts. ONAP is also responsible for pushing forward a President's HIV policy priorities. In a new Administration, this means working with the Office of Management and Budget (OMB) to ensure that financial resources are provided to meet the President's policy priorities, and working with federal agencies to advance a research agenda and implement policies and programs that will help achieve the goals of the National HIV/AIDS Strategy. This also means developing a PrEP indicator within with the National HIV/AIDS Strategy and working to clarify who are potential PrEP users. Notably, while ONAP has a role in supporting funding for program initiatives, ONAP does not award grants to specific agencies or governmental entities.

## **Department of Health and Human Services**

The Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) is responsible for coordinating, integrating, and directing the policies, programs, and activities related to HIV/AIDS across the Department of Health and Human Services (HHS). As an example of the type of role played by OHAIDP, following multiple national consultations and other reviews, HHS approved a set of seven common core indicators to monitor HHS-funded HIV prevention, treatment, and care services. This was a surprisingly complex effort to ensure that when agencies such as CDC and HRSA are tracking HIV indicators, they are using common terms and defining such terms in a consistent manner. These standards can be set across agencies to help standardize data and increase care outcomes. Through the development of agency-specific operational plans to implement these indicators, OHAIDP is helping to establish a framework of metrics that supports effective treatment as prevention. In terms of PrEP uptake, OHAIDP has a critical role to play in encouraging coordination and collaboration across HHS operating divisions. The following are selected HHS operating divisions with key roles in biomedical HIV prevention:

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### **Centers for Disease Control and Prevention**

The Centers for Disease Control and Prevention (CDC) is the Nation's lead HIV prevention agency and thus is at the forefront of federal efforts to promote access to evidence-based biomedical prevention tools. It has important roles to play in conducting research related to biomedical HIV prevention, providing professional guidance to PrEP prescribers and health care programs, educating community partners about biomedical and other forms of HIV prevention, and working with state and local health departments, along with community partners to effectively prevent HIV transmission. CDC also has important roles to play in integrating biomedical HIV prevention within STD clinics.

CDC's largest program is its funding initiative for state and local health departments through which it funds the majority of HIV prevention services in the United States. Its framework for working with health departments to have the biggest possible impact in preventing new HIV infections is called High Impact Prevention. This includes PrEP as a central component of a comprehensive HIV prevention program. With respect to PrEP, CDC is funding demonstration projects to enhance the ability of state and local health departments to identify men who have sex with men (MSM) and transgender persons who stand to benefit the most from PrEP, refer appropriate candidates to PrEP providers in their jurisdiction, and increase the number of health care providers who are knowledgeable and capable of offering PrEP to MSM and transgender persons at high risk for HIV infection, particularly persons of color. To encourage providers to make PrEP counseling part of routine care for certain patient populations, CDC also published clinical guidelines and a step-by-step checklist and guide for discussing PrEP with patients. The agency also set up a hotline to provide information to providers who plan to counsel patients on PrEP. CDC has not traditionally paid for medication or clinical care. It does, however, seek to understand financial barriers to PrEP and opportunities to reduce those barriers.

### **Health Resources and Services Administration**

Through its HIV/AIDS Bureau (HAB), the Health Resources and Services Administration (HRSA) administers the Ryan White HIV/AIDS Program, which is the largest dedicated program for the care and treatment of people living with HIV in the US, and is the third largest payer for HIV services after Medicaid and Medicare. Ryan White Program patients have achieved a viral suppression rate (81%) that far exceeds national averages.<sup>35</sup>

By law, the Ryan White Program's funding is largely restricted to providing services to people living with HIV. At the same time, HAB has recognized the critical role of PrEP and biomedical prevention to the comprehensive HIV care system of which the Ryan White program is the linchpin. While the Ryan White Program, including its AIDS Drug Assistance Program component, cannot fund the purchase of medications for PrEP, there are several ways that the program can facilitate PrEP uptake. HAB strongly encourages Ryan White grantees and providers to leverage the Ryan White Program infrastructure to support PrEP services within the parameters of the law. Ryan White Program grantees and providers, for example, can provide services such as risk reduction counseling and targeted testing, which should be part of a comprehensive PrEP program. HAB also has encouraged grantees and providers to support the implementation of PrEP by leveraging their existing expertise and administrative and clinical infrastructures to set up PrEP programs. This includes states building PrEP access programs using non-Ryan White funds within the AIDS Drug Assistance Program infrastructure, clinics developing comprehensive PrEP services using a percentage of HIV clinical and program staff that is not funded by the Ryan White Program to provide PrEP services, and accessing the AIDS Education and Training Centers

program to train clinicians and staff on PrEP. Furthermore, HRSA has provided guidance to notify states that state contributions to HIV prevention activities such as PrEP and PEP implementation count toward a state's maintenance of effort requirement for Ryan White Part B grantees.

Another part of the Ryan White Program, the Special Programs of National Significance (SPNS) Initiative, plays a role in developing outreach and intervention models that can promote biomedical HIV prevention for communities of color. SPNS initiatives can lead to best practices for underserved populations, including the need for strong community engagement and adherence supports.

In addition to HAB, HRSA's Bureau of Primary Care administers the Community Health Center Program and can help support adoption of biomedical HIV prevention within health centers. The use of telemedicine services may be one way to expand access to biomedical HIV prevention to patients across the country.

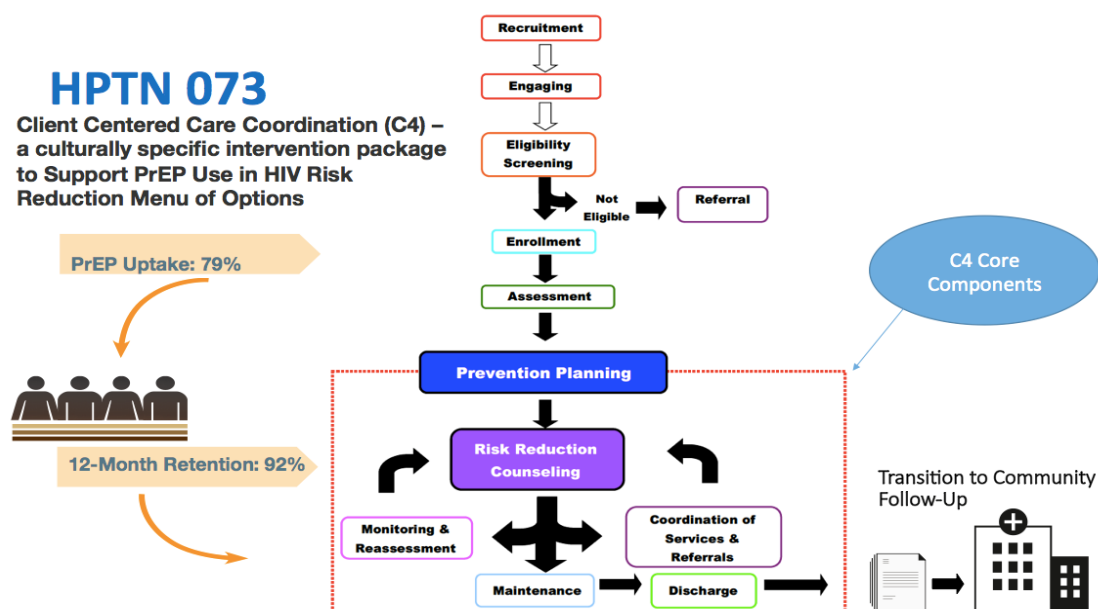
### **National Institutes of Health**

The National Institutes of Health (NIH) is the largest biomedical research institution in the world and has played a central role in virtually every major HIV scientific advance since the beginning of the epidemic. This includes the START Study, which published results in 2015 conclusively demonstrating the clinical benefits for people with HIV to begin ART as soon as possible after diagnosis, as well as the HPTN 052 study, published in 2011, that provides strong evidence of the effectiveness of early ART in reducing onward HIV transmission. NIH also has been a lead funder of iPrEX and all of the major PrEP studies that have documented the safety and effectiveness of PrEP and proven the effectiveness of treatment as prevention. Following the release of initial iPrEX results, after concerns were raised about the lack of adequate representation of Black MSM in the US component of the iPrEX study, NIH funded the HPTN 073 study, which demonstrated high uptake of PrEP among Black MSM when client-centered care coordination was utilized. NIH also supports implementation research to promote the uptake of effective program models so that PrEP can be incorporated into routine medical care and can improve the quality and effectiveness of health care for those at risk for HIV infection. In September 2016, NIH announced funding opportunities for research projects that will explore innovative strategies to increase PrEP access and uptake among individuals at risk for HIV, support PrEP adherence and persistence, and address key populations or age and racial/ethnic disparities in PrEP use.

Going forward, NIH is continuing to fund critical HIV prevention research through the HIV Prevention Trials Network (HPTN), the Adolescent Trials Network (ATN) and support leading academic institutions to engage in HIV research through the Centers for AIDS Research (CFAR) network. In addition to ongoing PrEP studies, NIH is continuing to support the development of effective microbicides and other biomedical prevention tools, and NIH is also investing heavily in research toward the development of long-acting agents for both prevention and treatment. Such agents could replace the need for a daily pill with implantable technologies or injections that would only require dosing every few weeks or months.

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One area of significant change in recent years has been the priorities set by NIH for AIDS research. Many advocates have expressed concern over the scope of the social and behavioral science research that NIH is funding, as well as the level of prioritization this type of research is given in the AIDS research portfolio. Social and behavioral science research informed by the needs of diverse communities is important to effectively implement biomedical HIV prevention within communities of color.



### Centers for Medicare and Medicaid Services

The Centers for Medicare and Medicaid Services (CMS) administers the Medicare, Medicaid and Children's Health Insurance (CHIP) programs, and is responsible for administering the federal Marketplaces.

CMS does not directly make many of the key decisions regarding coverage of PrEP medications and services through its programs. Medicaid programs, for example, are state-run programs subject to federal rules, so states have a lot of discretion in setting policy and individual health plans have a large role in determining which services are covered and when. Similarly, the federal government, through CMS, sets basic federal standards for the operation of health care marketplaces, but health plans retain broad discretion to establish their benefit structures and formulary and other coverage policies. Nonetheless, the role of CMS is critical. It sets baseline standards that can be very meaningful and that can improve or hinder access to PrEP services. In the context of marketplaces, there has been concern that some health plans have been placing all antiretroviral medications on their highest cost tiers, which creates significant affordability barriers for some persons seeking PrEP and disadvantages health plans that follow the evidence and provide good antiretroviral therapy access for both treatment and prevention. CMS has the authority to ensure that marketplaces are not discriminatory in the design of their plans, and this type of tiering policy could be prohibited. Thus, it retains meaningful tools to spur norms in insurance coverage that can have a large impact. Additionally, CMS has broad reach to educate health plans and providers about the safety and efficacy of TasP, PrEP, PEP, and other biomedical prevention interventions. In some cases, scaling up access to PrEP requires calling on CMS to take on new roles to which it is unaccustomed. CMS has begun new efforts in this regard. In June 2016, CMS, in partnership with CDC and HRSA, announced the launch of

a new HIV Health Improvement Affinity Group, which will bring together state public health and Medicaid/CHIP agencies to collaboratively identify opportunities to strengthen the HIV care and prevention continuum among Medicaid and CHIP enrollees. Participating state public health and Medicaid/CHIP programs will have an opportunity to learn about and share best practices and promising approaches with their state peers to improve viral load suppression among people living with HIV who are enrolled in Medicaid and CHIP. The affinity group was created through CMS's Medicaid Prevention Learning Network, which supports state Medicaid agencies in improving access to, utilization of, and quality of preventive services.

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## Conclusion

Biomedical HIV prevention is exciting because it presents the tools that we need to curb the impact of HIV on our communities and produce happier, healthier people. We know, however, that HIV exposes the inequities and the discrimination affecting people of color, including parts of our communities, such as young women and girls, transgender women, gay and bisexual men, and others, which have built up over decades and generations. The deployment of TasP, PEP, and PrEP is not a magic bullet that will make all of this better. But if we use these tools in a manner that recognizes that our health systems and programs were not built to equally benefit all of us and we take deliberate steps to tailor programs and services for communities of color, then we can seize the opportunity presented by the current moment in HIV prevention to reduce disparities, prevent HIV transmission, and heal our communities. There is much we need to do, but we are on our way.

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