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2017

The
State
of AIDS
in
Black
America

Black
Lives
Matter

What's
PrEP
got to do
with it?

An Annual Report 2016
Black AIDS Institute

**Black Lives Matter:
What's PrEP Got to Do with It?**
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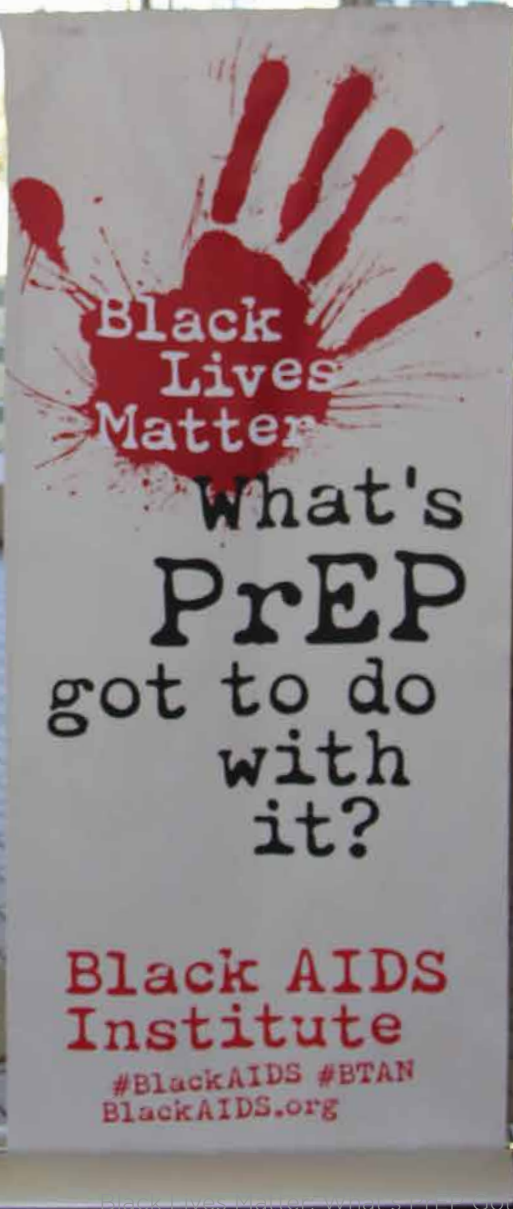


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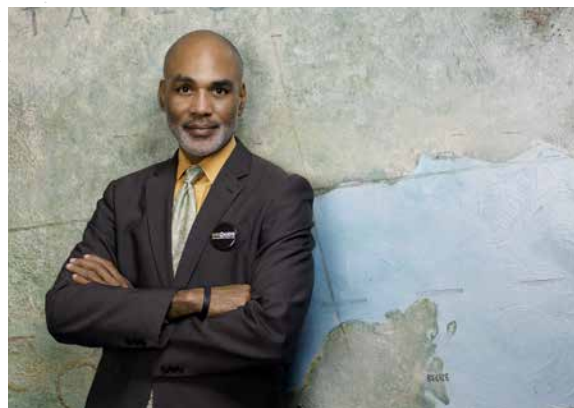


Introduction

Welcome to the 2016 State of AIDS in Black America report. Beginning in 2000, the Black AIDS Institute has published seventeen reports on the state of the HIV/AIDS epidemic in Black communities. Over the years we have focused on Black youth, Black women, Black gay and bisexual men and other men who have sex with men, HIV testing, HIV/AIDS infrastructure in Black communities, HIV science and treatment literacy, and ending the AIDS epidemic in Black communities. This latest update focuses on the important role of bio-medical interventions and an extraordinary new tool to prevent new HIV infections—pre-exposure antiretroviral prophylaxis, or PrEP.

The emergence of PrEP represents but the latest in a startling series of advances in biomedical tools to prevent new HIV infections. On its own, PrEP is up to 99% effective in preventing HIV acquisition, when used as prescribed. Combined with antiretroviral treatment for people living with HIV (treatment as Prevention or TasP), PrEP has the potential to stop the epidemic in its tracks.

Yet while PrEP has garnered considerable attention among the media and excitement in the LGBT community lately, it has yet to make a dent in the AIDS crisis in Black America. While Black Americans account for 13% of our nation's population, we represented 49% of all new HIV diagnoses in the U.S. The burden in Black America is especially heavy in the South. 54% of all Black Americans live in the south. Black Southerners account for 20% of the population in the south, but 62% of new HIV diagnoses in the south are Black. The proportion of Black Southerners living with HIV is more than three



times greater than the share of the South's population that is Black (20%).

The sad reality is that Black people have been largely left behind every time a major scientific breakthrough in the fight against AIDS has occurred. Since the advent of Highly Active Antiretroviral Therapy (HAART) in the mid-1990s, racial disparities in HIV-related health outcomes have actually widened here in the U.S. In 2016, Black Americans living with HIV are still less likely to know their HIV status, to receive antiretroviral therapy, or to achieve viral suppression. While the rest of America seems at times to have largely moved on from the AIDS fight, HIV remains a leading cause of illness and death in Black communities, with the heaviest burden often occurring among young adults in the prime of their lives.

In 2015, determined not to allow the same story of neglect to repeat itself in the case of PrEP, the Black AIDS Institute embarked on a series of PrEP summits across the country. This national PrEP tour has already made a dozen stops—from Los Angeles to Boston, and from the shores of

Lake Michigan all the way to the southern tip of Florida—and an additional five summits are already planned for later this year. These summits have offered the Institute an opportunity both to assess what Black communities know about PrEP and how they are responding, as well as a chance to educate and prepare communities to seize this opportunity and help lay the foundation to end the epidemic in Black America.

What we've learned has been both exciting and sobering. When made aware of PrEP, Black communities all across the country are enthusiastic about getting more information about PrEP and committed to taking action to make sure it is available and accessible in our communities. Already, many Black communities are mobilizing to educate their constituents about PrEP and developing innovative strategies for promoting and delivering PrEP to those who need it most.

But these summits and the other research we conducted in the preparation of this report have also highlighted the many challenges we face in making PrEP available in Black communities. Far too many Black Americans at high risk of HIV infection don't even know about PrEP. And when they learn about PrEP, they don't have a primary care physician and are uncertain about how to find a physician who can prescribe it. Too many health care providers who care for Black patients are unaware of PrEP, resist assessing their patients' sexual risk or have moral judgments that hinder their ability or willingness to recommend or prescribe PrEP to their patients.

Although options exist to help consumers pay for PrEP, many Black Americans are unaware of them, and many of these options don't cover the costs of doctor visits, lab costs and other expenses. Tragically, in the South, where the need for PrEP in Black communities is especially acute, financial barriers are exacerbated by the failure of most Southern states to expand their Medicaid program.

Although considerable, these and other challenges can and are being overcome in some communities. Indeed, the long history of Black America is one of surmounting the barriers in our way, and we need to show the same kind of determination in making PrEP a reality for Black communities all across the country.

If this report has any message, it is that Black Lives do Matter! Black lives matter on the streets, in the schools, in the work place and in health

settings. At a time in our history when activists are demanding that the intolerable can no longer be tolerated, we must ensure the Black America isn't left behind in the fight to end the AIDS epidemic once and for all.

But seizing the opportunities afforded by PrEP will require more than demands. We'll need strategies and action, and all of us have a part to play. Political leaders, public health officials, community leaders and institutions, health care providers, private industry and grassroots activists, and, most importantly, those of us who are living with HIV or at risk of HIV infection, must come together to bring PrEP to scale throughout Black America.

The goal of this report is not to be a PrEP propaganda track for or against PrEP. Our goal is to make sure Black communities have all the information available and access to every tool in the HIV prevention and treatment toolbox. We are fighting for our lives. We don't believe we should leave any weapon behind. This report aims to further awareness and commitment about rolling out PrEP in Black America where appropriate. PrEP is not a silver bullet. Searching for "the silver bullet" has undermined progress in our communities. Bio medical interventions, including PrEP clearly work, but they must be combined with behavioral interventions, community infrastructure, progressive public health policies and investments in Black organizations.

We at the Institute hope you enjoy reading this report and that you will learn a lot from it. We especially hope you enjoy the personal profiles of Black Americans who are using PrEP, health care providers who are prescribing it, and of public health officials working to expand PrEP in Black communities. Most importantly, we hope and trust that you will use this report to strengthen efforts in your own community to ensure that those who need PrEP receive it and benefit from it. At the end of the day we hope you agree that "Black Lives Matter!" and it is clear, "What's PrEP got to do with it!"

We invite you to join our Black PrEP working group. We look forward to hearing from you, or seeing you at an upcoming Black PrEP summit, or BTAN meeting. Until then, please take care of yourself and your blessings.

Yours in the struggle



Phil Wilson

Black Lives Matter: What's PrEP Got to Do With It?

Key Messages

■ **PrEP works.** Research studies and demonstration projects have shown that pre-exposure antiretroviral prophylaxis (PrEP), when used as directed, is extraordinarily effective in preventing new HIV infections—among gay and bisexual men, heterosexuals and people who inject drugs, with indications that PrEP also may be effective for transgender women. Protection against HIV infection approaches 100% for people who take PrEP as prescribed.

■ **PrEP can help end the AIDS epidemic in Black America.** On its own, PrEP can prevent one in five new HIV infections through 2020. Combined with scaled-up HIV treatment, PrEP could avert 70% of all new infections over the next five years.

■ **Black America needs PrEP the most.** America's HIV epidemic is a Black epidemic. Accounting for 13% of the population, Black Americans make up 49% of all new HIV diagnoses. Black gay and bisexual men stand a 50% chance of acquiring HIV in their lifetimes, Black women are 18 times more likely to be HIV-positive than white women, and Black transgender women are three times more likely to acquire HIV than their white or Latina counterparts. Bringing PrEP to scale is especially urgent in the South, which accounts for 54% of all Black Americans and 62% of new HIV diagnoses among Black Americans in 2014.

■ **When it comes to PrEP, Black America is being left behind.** Every available measure

indicates that while Black communities need PrEP the most, they are far less likely to receive PrEP than other racial or ethnic groups. Several factors explain this intolerable disparity— inadequate awareness of PrEP in Black communities, too few providers who understand and are prescribing PrEP, challenges in paying for PrEP (especially in states that have not expanded Medicaid), an HIV/AIDS workforce with low PrEP literacy and low familiarity with PrEP, medical mistrust, life challenges that make it difficult to adhere to PrEP regimens (such as poverty, unemployment and housing instability), and specific social and economic obstacles confronted by young people, women and transgender people.

■ **New scientific evidence suggests that robust PrEP uptake is achievable in Black America.** New clinical trial findings indicate that programs that are specifically tailored to the needs of Black gay and bisexual men and that proactively address barriers to uptake and adherence can promote strong PrEP utilization in Black communities. Insights derived from this research are likely to be applicable to other groups of Black Americans that are not well served by existing health systems. Service systems need to adapt to Black Americans rather than expect Black patients to adapt to service systems that were not devised for them.

■ **An urgent national initiative is needed to expedite the uptake of PrEP in Black America.** The ongoing AIDS crisis in Black America necessitates an urgent national initiative—combining the efforts of policy makers, funders, public health agencies, health care

providers, community organizations and Black communities. Specifically, steps are needed to:

1. Invest in community education and awareness campaigns. These campaigns will need to simultaneously encourage Black Americans to speak to their providers about sex and sexual health and to help Black Americans understand the availability and benefits of PrEP.

2. Educate health care providers about PrEP. Providers, including primary care doctors, must be familiar with and understand PrEP, be able to conduct sexual histories of their patients and identify and prescribe PrEP for their patients who could benefit and who desire to take PrEP. PrEP-related training and education needs to be integrated in all existing educational options for providers, and innovative approaches (such as providing accessible quick-reference materials for physicians) should be used to enable providers to prescribe PrEP when it is indicated.

3. Adapt delivery systems to facilitate PrEP uptake. Through use of client-centered counseling and other approaches, providers need to serve the whole person, situating PrEP within a broader effort to promote sexual health, and taking account of life issues their patients experience beyond the risk of acquiring HIV. Navigation and other adherence support services should be available and reimbursable in clinical settings, clinics should partner with community-based organizations for PrEP referral and support services, and steps should be taken to expand the universe of health care providers able to prescribe PrEP. PrEP should be integrated

in community health centers in majority-Black neighborhoods.

4. Remove financial barriers to PrEP use. All states should expand Medicaid, and further efforts are required to increase awareness of patient-assistance options for people who take PrEP. The CDC should establish a funding mechanism, patterned on the AIDS Drug Assistance Program, to cover non-drug related out-of-pocket costs associated with PrEP use.

5. Undertake specific efforts to address the PrEP needs of cisgender and transgender women. Intensified outreach and education are needed to increase awareness of PrEP as an option for women, and the CDC should clarify its guidance on PrEP use among women. Where age-of-consent laws impede adolescents' ready access to preventive services, state laws should be reformed to enable at-risk young people to obtain PrEP to protect their health.

6. Strengthen the ability of PrEP programs to maximize STI control. People receiving PrEP should receive laboratory screening for STIs every three months.

7. Continue to pursue a robust research agenda on PrEP. While available evidence is more than sufficient to warrant urgent efforts to bring PrEP to scale now, additional implementation research is needed to identify and document best practices in PrEP uptake and adherence in Black communities. Continued research is needed for the development of additional PrEP options, including long-acting, injectable PrEP regimens.



Black Lives Matter: What's PrEP Got to Do With It?

In recent years, it has become increasingly clear that we have the highly effective tools we need to end the AIDS epidemic. Unfortunately, as the persistence of unacceptably high rates of new HIV infections underscores, these tools are not being applied effectively enough in Black communities. While new HIV diagnoses in the U.S. as a whole fell by 19% from 2005 to 2014,¹ new diagnoses among Black gay and bisexual men increased by 87%.²

One of the most powerful weapons we have to fight HIV/AIDS is PrEP. The more we learn about PrEP, the more potent this HIV-prevention tool appears to be. Indeed, if used properly and consistently, PrEP is perhaps the most effective prevention method available for people who are HIV-uninfected. Just as the emergence of protease inhibitors in the mid-1990s helped usher in the era of Highly Active Antiretroviral Therapy, the emergence of PrEP has inspired hopes that a combination of prevention approaches may cripple the HIV/AIDS epidemic and lay the foundation for its eventual end.

But science isn't the only consideration when it comes to ending AIDS. Scientific advances also have to be translated into real options that can be used by real people in the real world. And here, in the real world, is where the promise of PrEP has the potential to succeed or fail.

Of all racial and ethnic groups, Black people need PrEP the most. Accounting for only 13% of the U.S. population,³ Black Americans represented for 49.4% of all new HIV diagnoses nationwide in 2014.⁴ If the U.S. is to meet the challenge set forth in the updated National HIV/AIDS Strategy (NHAS) to renew the national AIDS response and lay the groundwork to end the epidemic once and for all,⁵ it must

dramatically strengthen HIV prevention efforts in Black America.

But there are disturbing signs that Black America is being left behind in the national effort to expand access to PrEP. In every available measure for PrEP access, Black people finish behind other racial and ethnic groups.

Sadly, this is not a new narrative. Two decades after the emergence of Highly Active Antiretroviral Therapy, Black people living with HIV continue to be less likely than other racial or ethnic groups to receive life-saving HIV treatment or to have achieved viral suppression.⁶ Although HIV treatment has resulted in sharp declines in HIV-related illness and death nationally, racial disparities in HIV health outcomes have actually increased in the 20 years that antiretroviral therapy has been available. While anxieties in American society as a whole about HIV/AIDS have largely dissipated, the epidemic remains a profound health threat in Black communities and an important cause of premature mortality among Black people.

The same scenario we have seen in the case of HIV treatment access cannot be allowed to unfold in the case of PrEP. If our country is serious about winning the war against HIV/AIDS, urgent and sustained action is needed to ensure that Black people who need PrEP receive it and that they are provided with the means to adhere to PrEP regimens.

This report describes the case for an urgent national campaign to bring PrEP to scale in Black communities. It summarizes evidence for the effectiveness of PrEP, describes the barriers in Black communities to PrEP uptake that must be overcome, and outlines a priority action agenda to ensure that we effectively leverage PrEP to end the epidemic in Black America.

What is PrEP?

In 2012, the U.S. Food and Drug Administration (FDA) approved the first regimen for PrEP—Truvada, a medicine manufactured by Gilead Sciences. Truvada is a single pill containing two antiretroviral drugs that have long been used in the treatment of HIV—tenofovir disoproxil fumarate (commonly called tenofovir or TDF) and emtricitabine (commonly called FTC). In 2014, the CDC issued clinical guidelines to guide providers in administering PrEP.⁷ To date, Truvada is the only medicine approved for PrEP.

For purposes of PrEP, Truvada is taken orally every day. Among HIV-negative people, the CDC recommends PrEP for:

- Individuals in a serodiscordant relationship with an HIV-positive partner;
- Gay and bisexual men who have had anal sex without a condom or been diagnosed with a sexually transmitted infection (STI) in the last six months;
- Heterosexual men and women who do not regularly use condoms during sex with partners of unknown serostatus who are at substantial risk of HIV infection; and
- People who have injected illicit drugs, shared injection equipment, or been in drug treatment for injection drug use in the last six months.⁸

PrEP is the culmination of decades of research on the preventive uses of antiretroviral drugs. Other antiretroviral-based prevention methods include use of antiretrovirals to prevent mother-to-child HIV transmission, post-exposure antiretroviral prophylaxis (for both occupational and non-occupational



exposures), and HIV treatment as prevention, or TasP (minimizing the risk of HIV transmission by suppressing viral replication in people living with HIV). The effective application of PrEP and TasP, in combination and at sufficient scale, has the potential to break the back of the HIV/AIDS epidemic by virtually eliminating both transmission and acquisition of the virus.

PrEP is intended for people at substantial risk of acquiring HIV. In addition to having a sex partner known to be HIV-positive, factors to consider when determining if an individual

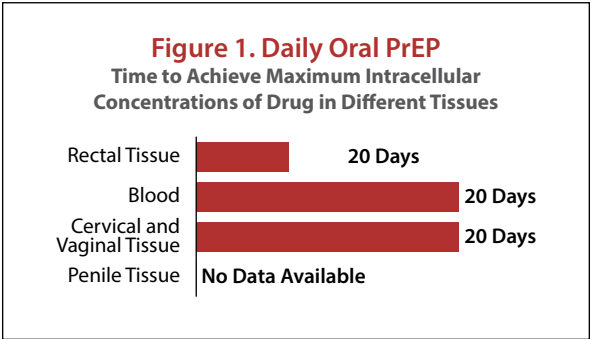
might be suitable for PrEP include reported inconsistent or no condom use, an STD diagnosis, exchanging sex for money or drugs, incarceration and excessive use of or dependence on drugs or alcohol.⁹

As PrEP is only for people who are HIV-uninfected, a potential PrEP user must test negative for HIV before starting PrEP. Providers should also rule out signs and symptoms of acute HIV infection, which may not be detected by some HIV testing technologies; as Truvada on its own is insufficient to treat HIV infection, a person who is infected when he or she begins PrEP may develop drug resistance, which can hinder future treatment options. Before prescribing PrEP, providers also need to confirm that the individual has normal renal function.

When prescribing PrEP, providers should counsel patients to assist them in adhering to the daily PrEP regimen. Providers also need to question prospective PrEP users regarding any medications they are taking to avoid coupling PrEP with another drug that might interfere with Truvada's effectiveness. PrEP does not work

immediately after the first dose, but takes time to achieve sufficient concentration to confer a prevention benefit; Truvada tends to reach adequate concentrations sooner in rectal tissue than in vaginal tissue (Fig. 1).⁷

Individuals who take PrEP will need to return to their health care provider every three months to receive a refill for their prescription. At these quarterly follow-up visits, PrEP users are tested for HIV, assessed for STI symptoms and counseled regarding medication adherence and behavioral risk reduction. Renal function is also monitored—at the first three-month follow-up visit and every six months thereafter. Every six months, PrEP users are screened for bacterial STIs.⁸





Black America Needs PrEP the Most

PrEP is not meant for everyone but rather for those at highest risk of acquiring HIV. Indeed, carefully focusing PrEP roll-out on the highest-risk groups is essential for maximizing the health returns on investments in PrEP—a critical consideration in a world of finite resources for HIV prevention.¹⁰

The CDC estimates that more than 1.2 million people nationally would benefit from using PrEP to reduce their risk of acquiring HIV.¹¹ This includes roughly one in four (492,000) gay and bisexual men, nearly one in five (115,000) people who inject drugs, and 0.4% (624,000) of heterosexual adults.¹¹

Black America is at the top of the list when it comes to those who need PrEP the most. Black men are almost seven times more likely to acquire HIV than white men, while Black women are more than 18 times more likely to become infected with HIV than white women (Figure 2).¹²

Even as HIV-related deaths have plummeted among most groups in the HIV treatment era, AIDS remains among the top five causes of death among Black women ages 25-54.¹³

If America is to optimize the effectiveness of PrEP, Black America needs to be prioritized when it comes to access. Within Black America itself, several groups warrant special attention with respect to PrEP scale-up.

A Focus on Black Gay and Bisexual Men

Few groups in the entire world have been more heavily affected by HIV/AIDS than Black gay and bisexual men in the U.S.¹⁴ While Americans in general stand a 1 in 99 chance of acquiring HIV during their lives, the lifetime odds that a Black gay or bisexual man in the U.S. will become infected are an astonishing one in two.

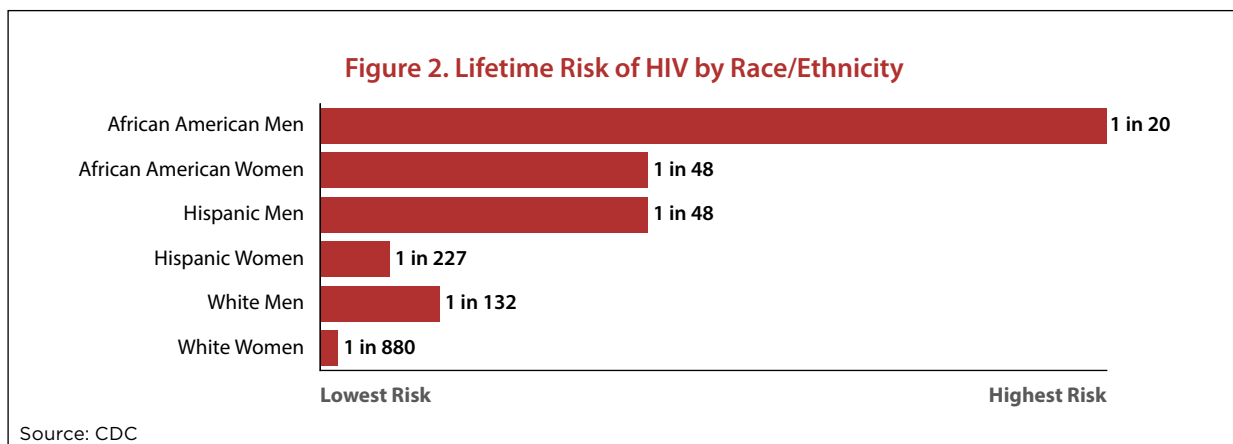


Figure 3. Lifetime Risk of HIV Diagnosis among MSM by Race/Ethnicity



Source: CDC

Black gay and bisexual men are more than five times more likely to become infected with HIV than white gay or bisexual men and twice as likely as their Hispanic counterparts (Figure 3).¹²

Biology only partially explains the disproportionate risk experienced by Black gay and bisexual men. Receptive condomless anal intercourse with an infected partner is more than 17 times more likely to lead to HIV transmission as receptive condomless penile-vaginal intercourse and more than twice as likely as needle-sharing during injection drug use.¹⁵ Yet among gay and bisexual men generally, the disproportionate HIV burden experienced by Black men is harder to explain, as Black gay and bisexual men actually seem to engage in less risk behaviors on average than white gay and bisexual men.¹⁶

A Focus on Black Women

Although Black America accounts for 13% of the U.S. population, it represents 64% of all new HIV infections among women.¹⁷ Three out of four Black women living with HIV acquired the virus

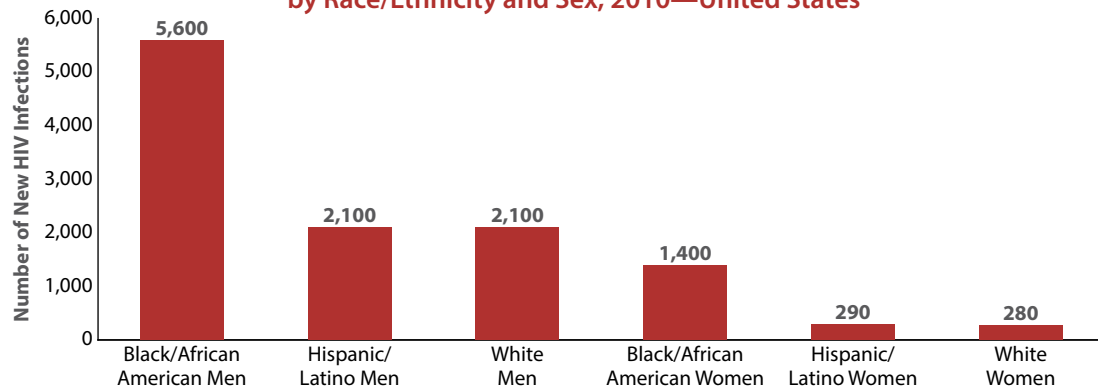
through sexual contact.⁴ Black women are twice as likely to acquire HIV during their lives as the average American.¹² Among Black women newly diagnosed with HIV in 2017, 91% acquired HIV through heterosexual contact.¹

A Focus on Black Young People

Compared to other racial and ethnic groups, Black Americans are at exceptionally high risk of acquiring HIV when they are young. Young people (ages 13-24) generally account for 17% of the U.S. population but for 26% of new HIV infections, and Black youth represent 57% of all new HIV infections among young people.¹⁸ Although whites continue to account for a majority of the U.S. population, the number of Black youth newly infected with HIV each year is more than twice the number of white youth who acquire HIV (Figure 4).¹⁸

Young Black gay and bisexual men confront particularly high risks of acquiring HIV. Over the last decade, even as HIV infection rates have declined nationally, new diagnoses among young

Figure 4. Estimates of New Infections among Youth Aged 13-24 Years by Race/Ethnicity and Sex, 2010—United States



Source: CDC

Black gay and bisexual men (ages 13-24) rose by 87%.²

A Focus on Black Transgender Women

Transgender women have the highest HIV prevalence of any group, with 21.6% of transgender women in the U.S. and other high-income countries having HIV infection.¹⁹ Globally, transgender women are 49 times more likely to have HIV infection than the general population.¹⁹ In the U.S., HIV prevalence among Black transgender women is more than three times higher than among white or Latina transgender women.²⁰ Factors that contribute to transgender women’s disproportionate HIV risk include risky sexual behaviors (especially condomless

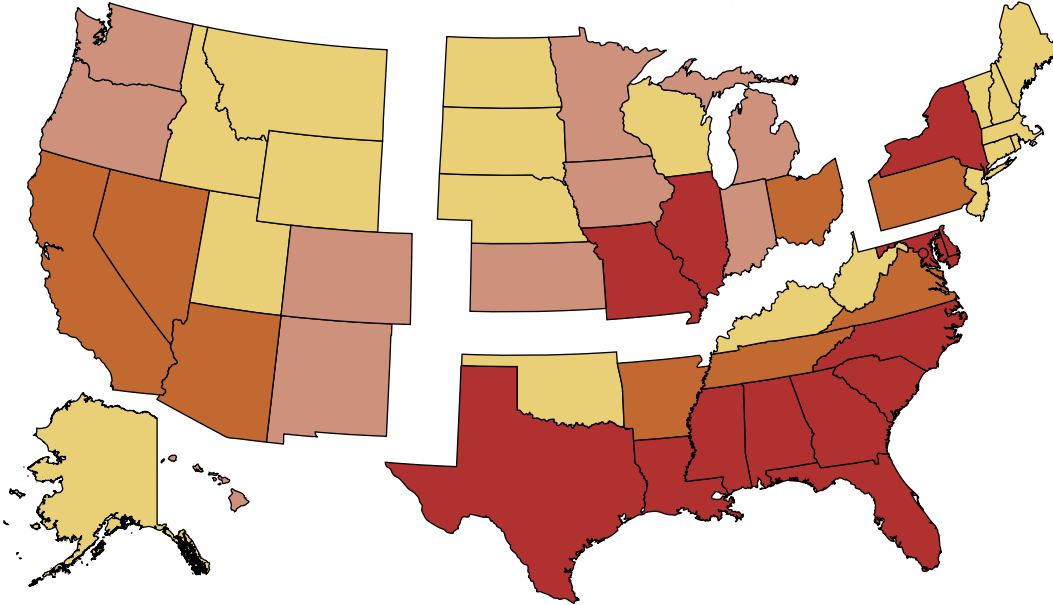
anal intercourse), injection drug use (including use of hormones or silicone), sex work (often stemming from the lack of other employment opportunities), untreated STDs, and vulnerability to violence.²¹

A Focus on the South

Bringing PrEP to scale is an urgent priority across the U.S., but the need for this new prevention tool is especially acute in the South, where the lifetime risk of HIV infection is notably greater than in other parts of the country (Figure 5).¹² Of the 12 states with the highest lifetime risk of HIV infection, eight are located in the South.¹²

In cities large and small, rates of new HIV diagnoses are higher in the South than in other regions (Figure 6).²² People living in large metropolitan areas in the South are roughly twice

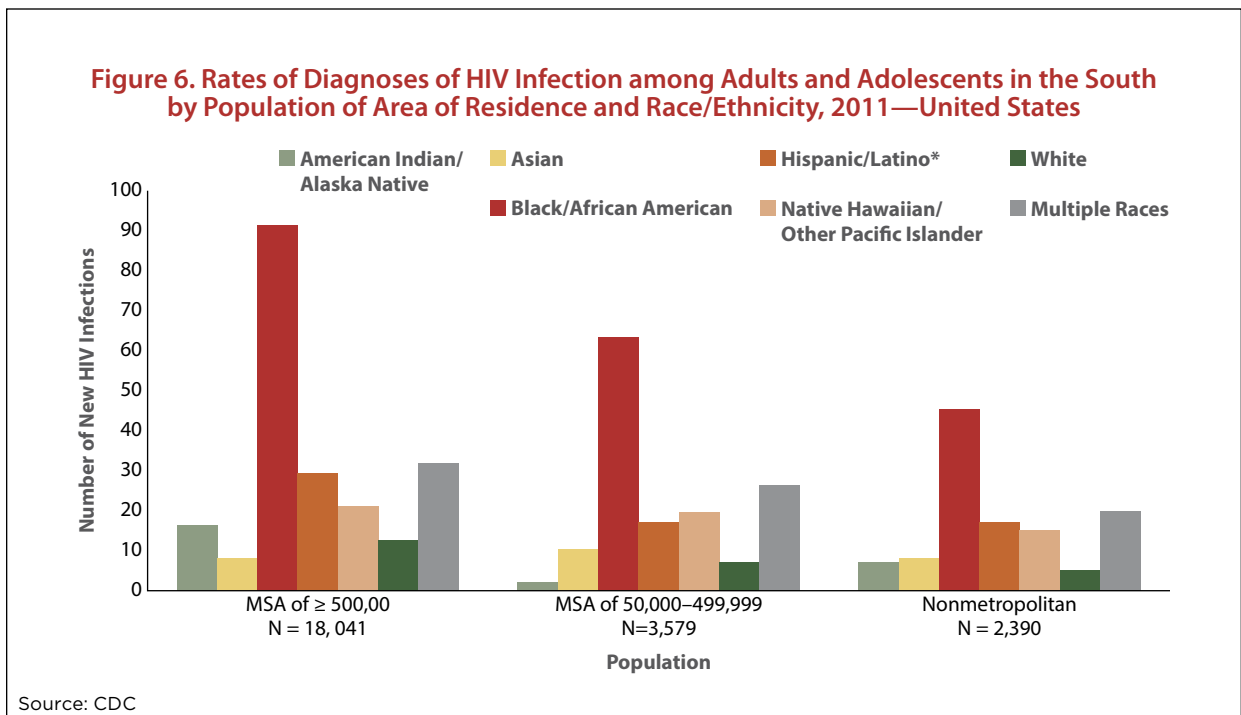
Figure 5. Lifetime Risk of HIV Diagnosis by State



Highest Risk

Lowest Risk

State	1 in "n"	State	1 in "n"	State	1 in "n"	State	1 in "n"
District of Columbia	13	Nevada	98	Michigan	167	West Virginia	302
Maryland	49	Illinois	101	Oklahoma	168	Wisconsin	307
Georgia	51	California	103	Kentucky	173	Iowa	342
Florida	54	Tennessee	103	Indiana	183	Utah	366
Louisiana	56	Pennsylvania	115	Washington	185	Maine	373
New York	69	Virginia	115	Colorado	191	Alaska	384
Texas	81	Massachusetts	121	New Mexico	196	South Dakota	402
New Jersey	84	Arizona	138	Hawaii	202	New Hampshire	411
Mississippi	85	Connecticut	139	Oregon	214	Wyoming	481
South Carolina	86	Rhode Island	143	Minnesota	216	Vermont	527
North Carolina	93	Ohio	150	Kansas	262	Idaho	547
Delaware	96	Missouri	155	Nebraska	264	Montana	578
Alabama	97	Arkansas	159			North Dakota	670



as likely to be diagnosed with HIV as those living in large cities in the Midwest. In mid-size cities (between 50,000 and 500,000 population), HIV diagnosis rates are nearly three times greater in the South than in the Midwest and more than twice as great as in the West (Figure 7). Among Americans living in rural areas, Southerners are more than twice as likely to test HIV-positive as rural Northeasterners and nearly four times more likely as in the Midwest or West.

The high rate of HIV infection in Black

communities is the primary driver of the disproportionate HIV burden in the South. In large cities, small cities and rural areas in the South, HIV diagnosis rates are several times higher among Black Americans than among other racial or ethnic groups.²² While the U.S. Census Bureau reports that the South is home to 54% of Black Americans, the region accounted for 62% of all new HIV diagnoses in Black America in 2014.¹

Figure 7. Diagnoses of HIV Infection among Adults and Adolescents by Population of Area of Residence and Region, 2011—United States

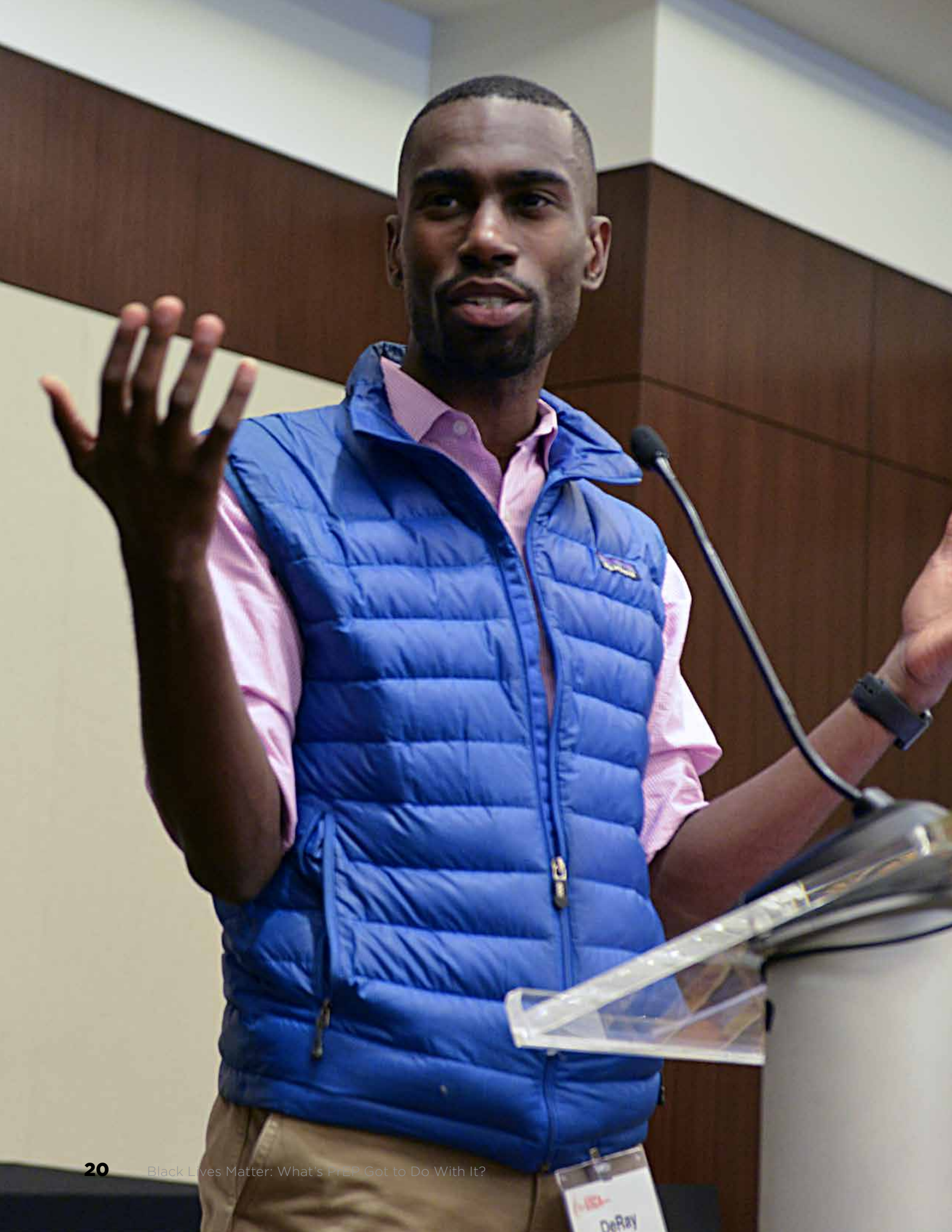
Region of Residence	MSA of ≥500,000		MSA of 50,000–499,999		Non-Metropolitan	
	Number	Rate	Number	Rate	Number	Rate
Northeast N=9,883	9,171	24.4	486	10.1	227	4.9
Midwest N=6,169	4,979	16.2	765	6.3	425	3.3
South N=24,011	18,041	31.7	3,579	17.8	2,390	12.7
West N=8,649	7,741	17.6	692	7.0	216	3.6

Source: CDC

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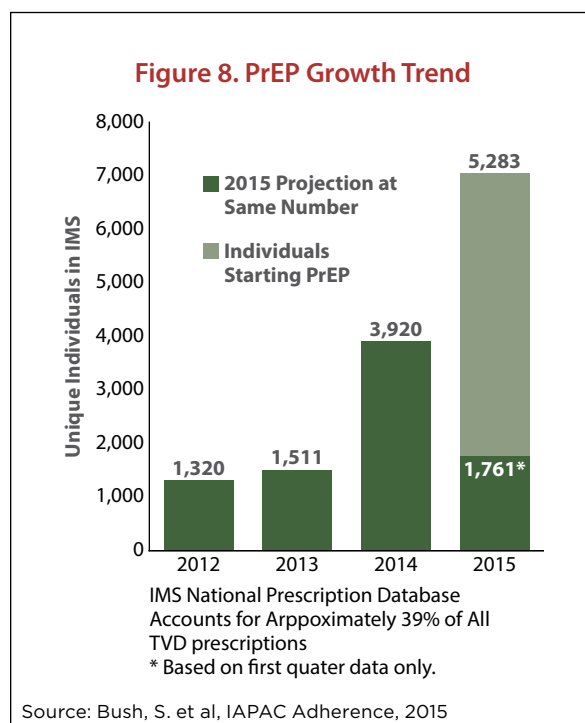
Who's Getting PrEP?

Although Black Americans are clearly more likely to need PrEP, they are not most likely to receive it. Indeed, available evidence suggests that Black communities to date have been badly under-prioritized in the scale-up of PrEP. As a new chapter in the nation's long struggle against HIV/AIDS unfolds, Black America is once again being left behind.

In the first two years after FDA approval of Truvada for PrEP, uptake was slow for the U.S. as a whole. However, according to a standard pharmacy monitoring database, the number of Truvada prescriptions for PrEP began to sharply increase in 2014, with this trend continuing in 2015 (Figure 8).²³ Extrapolating from this limited database, it has been estimated that at least 25,000 people across the country were receiving PrEP as of mid-2015.²³ Although the trend toward increased PrEP uptake is encouraging, the number of people receiving PrEP in mid-2015 still represented only 2% of the more than 1.2 million people estimated by the CDC to need PrEP.

In the first two years after FDA approval, women accounted for about half of all PrEP recipients.²⁴ However, virtually all of the increase in PrEP utilization in the last two years has been among men, with males now vastly outnumbering females among those using PrEP (Figure 9).

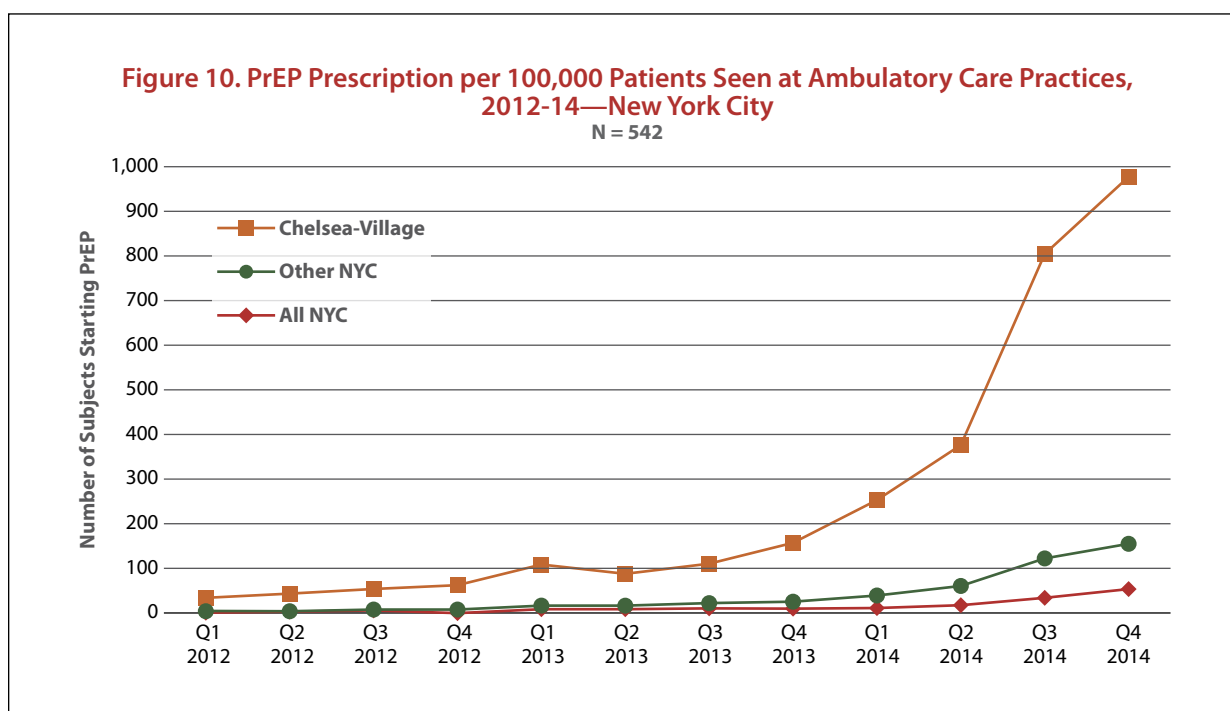
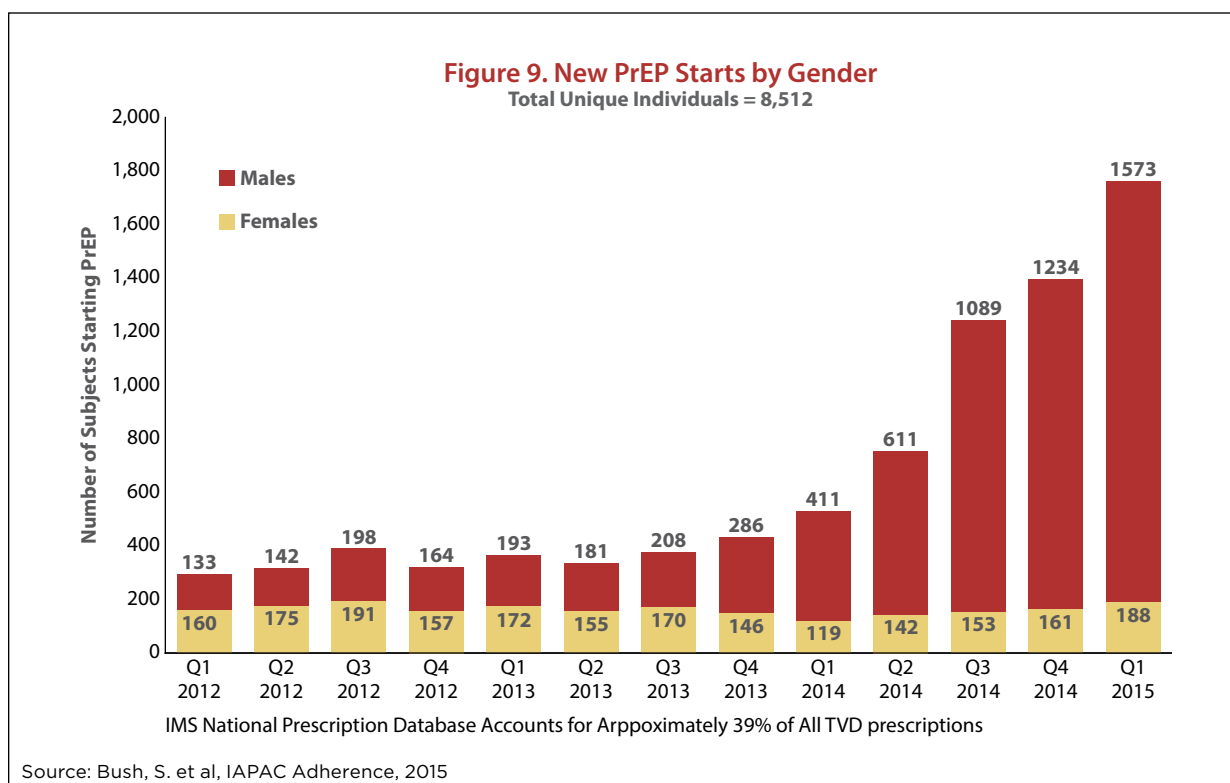
Limited information is available regarding the use of PrEP in Black communities. Among New York State's Medicaid recipients who filled prescriptions for PrEP in 2012-2015, 22.2% were Black.²⁵ This proportion of PrEP users for Black Americans is substantially lower than their share of new HIV diagnoses in New York



State—38.1% in 2013, the last year for which data are available²⁶—indicating that Black Medicaid recipients in New York are not receiving PrEP at a level commensurate with their risk of HIV infection.

This pattern is confirmed by early scale-up data in New York City. In 2012-2014, the overwhelming bulk of PrEP prescriptions occurred in the primarily white, affluent Chelsea and Greenwich Village neighborhoods (Figure 10).

Other real-world evidence suggests that Black communities' utilization of PrEP in some parts of the U.S. is likely to be even lower than



in New York's Medicaid program. In one national demonstration project of PrEP among gay and bisexual men and transgender women, only 7% of demonstration project participants were Black²⁷, although Black men account for 38% of all gay and bisexual men diagnosed with HIV in the U.S.²

Limited evidence also points to the need to improve PrEP access among young people. While young people (ages 13-24) accounted for 24% of all new HIV infections in New York State in 2013²⁸, young people (ages 13-24) represented only 19% of people who received PrEP through New York's Medicaid program in 2012-2015.²⁵



CHARLOTTE
City



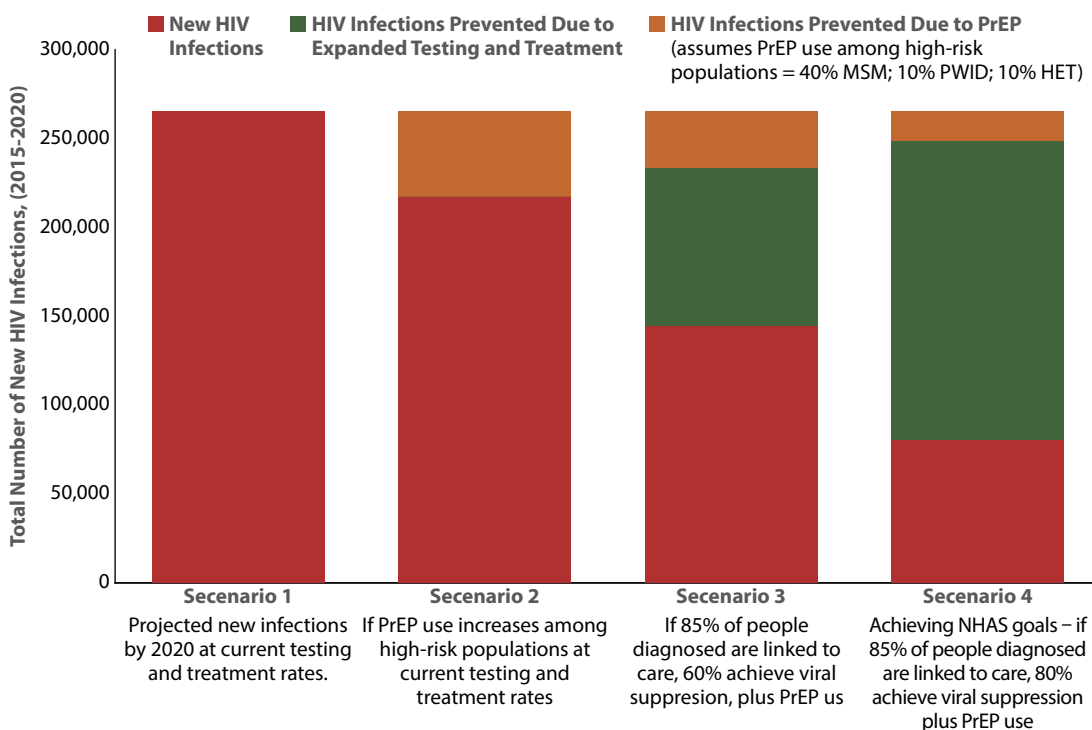
PrEP's Potential to Help End the AIDS Epidemic in Black America

PrEP has the potential to play a key role in driving down new HIV infections and laying the foundation to end the HIV/AIDS epidemic once and for all. Although PrEP has yet to be effectively leveraged for Black communities, it is evident

that PrEP is a vital tool for reversing the epidemic in Black America.

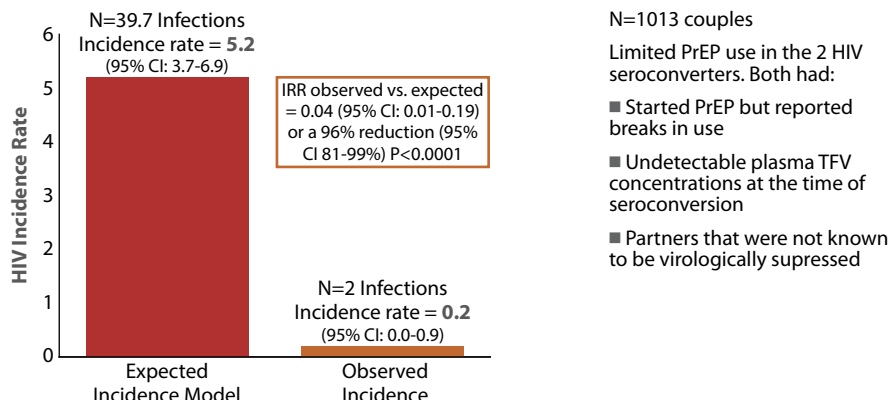
The CDC projects that scaling up PrEP alone among high-risk populations would avert more than 48,000 new HIV infections over six years in the U.S., or 18% of all new infections that

Figure 11. Four Scenarios of the PrEP Impact of Expanded HIV Testing, Treatment and PrEP, 2015-20—United States



Source: CDC

Figure 12. PrEP + TasP: HIV Incidence



Source: Baeten, J. et al, CROI, 2015

are likely to occur in the absence of stronger interventions (Figure 11).²⁹ Taking account of the share of new infections among Black people, it appears that scaling up PrEP in Black America would prevent more than 21,000 Black people from becoming infected during this six-year period.

The potential impact of PrEP is even greater if it is combined with other proven prevention strategies. By combining scale-up of PrEP among high-risk groups with achievement of the continuum-of-care goals in NHAS (90% knowledge of HIV status among people living with HIV, linkage to care within one month of HIV diagnosis of 85% of people who test HIV-positive, and viral suppression among 80% of people receiving HIV care), the U.S. could prevent 70% of all new HIV infections over six years. This degree of success could permanently alter

the trajectory of the U.S. epidemic and lay the groundwork to end the epidemic for good.

These CDC projections align with those undertaken by local researchers. In San Francisco, it is estimated that rapid scale-up of PrEP could cut the number of new HIV infections by 50-86%.³⁰ In New York City, providing PrEP to 50% of uninfected gay and bisexual men is projected to avert one in five new HIV infections, with cost-effectiveness especially pronounced if PrEP is focused primarily on gay and bisexual men at especially high risk of HIV infection.³¹

For individuals and couples attempting to negotiate sex in a world with HIV, PrEP represents a breakthrough. Among serodiscordant partners, for example, combining PrEP (for the uninfected partner) and treatment as prevention (for the infected partner) reduces the risk of HIV transmission by 96% (Figure 12).³⁰





What We've Learned from Clinical Trials

Well-designed clinical trials are our primary means for learning about new HIV prevention and treatment tools, and regulatory and public health agencies use trial results to determine whether a new tool should be approved for widespread use. As the strong endorsement of Truvada by the FDA and the CDC indicate, clinical trials have demonstrated beyond doubt that PrEP represents a critical new weapon in the HIV-prevention arsenal.

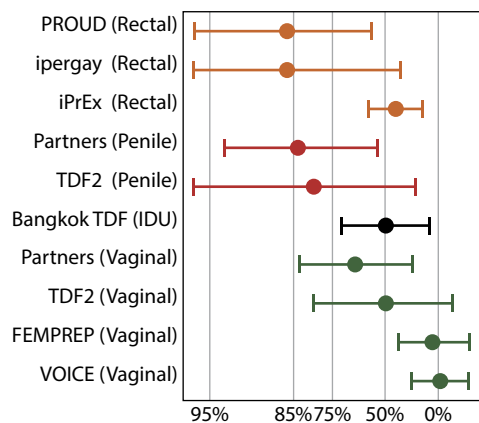
PrEP Works for Diverse Populations

The first clear evidence for the effectiveness of PrEP emerged in 2010, when researchers in the iPrEx study found that PrEP reduced new HIV infections among gay and bisexual men by 44%, including a 92% reduction among study participants with laboratory tests demonstrating high levels of adherence.³² Subsequent analyses found that PrEP conferred 99% protection among study participants who took PrEP every day.

Soon thereafter, two large clinical trials found that PrEP significantly lowered the risk of HIV transmission among heterosexual men and women, with reductions of 75% and 62% reported.^{33, 34} A large clinical trial in Thailand determined that PrEP reduced the risk of HIV acquisition among people who inject drugs by 49%.³⁵

No trial to date has specifically been

Figure 13. PrEP Efficacy as Documented by Clinical Trials



Source: AVAC

designed to evaluate the efficacy of PrEP among transgender women. However, the iPrEx trial included 339 people who researchers concluded were transgender*. Although the number of transgender women in the trial was too small to permit robust statistical analysis of the results, trial results strongly suggested that PrEP may be effective in preventing HIV acquisition among transgender women who have sex with men.³⁶

*The 339 individuals included participants who were born male but identified as female, participants who were born male but identified as transgender, and males who were born male and identified as male but used feminizing hormones.

Altogether, these trials indicate that PrEP reduces the risk of HIV infection by 90% or more among people who faithfully take Truvada.¹³ These findings suggest that PrEP, taken in accordance with the prescribed regimen, is more effective in preventing HIV transmission than condoms, which have been found to reduce the risk of heterosexual HIV transmission by 85%.³⁷

Adherence is Critical

Clinical trials have documented a clear correlation between adherence to the PrEP regimen and the effectiveness of the intervention.¹³ The more doses of PrEP one takes, the greater the protection against HIV transmission.

Although the importance of adherence is undeniable, recent evidence indicates that PrEP may actually be more forgiving than the original clinical trial data suggested. In an open-label extension** of the iPrEx study, no new HIV infections were reported among individuals who took at least four Truvada doses per week.³⁸

In 2015, evidence emerged that PrEP (taken before and after sex, rather than daily) reduced the risk of HIV acquisition by 86%.³⁹ (The regimen for the trial required taking two Truvada pills one to two days before having sex, as well as two additional pills 24 and 48 hours after sex, respectively.) Due to the frequency with which they had sex, men in the study were often taking four or more doses a week, making it difficult to discern how effective the protocol might be for men who have less frequent sex and therefore use the medication only infrequently. For this reason, individuals are still advised to take PrEP daily to maximize the prevention benefit. The effectiveness of on-demand PrEP suggests the need for further research on non-daily approaches to PrEP administration.

Side Effects Are Manageable

Serious adverse events have been extremely rare among PrEP users enrolled in clinical trials

**Unlike a blinded study, where participants (and, in the case of double blinded studies, the researchers as well) do not know which intervention is being administered, both participants and researchers in an open-label trial know what each person is taking.

or in observational studies of people receiving PrEP in community settings. Most PrEP users reported no side effects. Among the few who did have side effects nausea, diarrhea, joint pain and headache were most common, and these typically lasted no longer than a month. Few participants have chosen to permanently stop using PrEP because of side effects.¹³

Some people who take PrEP experience a loss of bone density on X-rays, but evidence to date does not demonstrate that this affects overall health.⁴⁰ Fortunately, bone density appears to be fully recovered once PrEP is stopped.⁴¹

PrEP may also affect kidney function, as measured by creatinine clearance.⁴² The potential effect of PrEP on kidney function explains why individuals are screened for kidney function prior to starting PrEP and why renal function is monitored at follow-up visits. Evidence indicates that PrEP does not cause long-term harm to kidneys.⁴³

Risks of Resistance Can Be Minimized

As drug resistance only occurs in the presence of HIV, uninfected individuals who take PrEP and remain uninfected have no risk of developing drug resistance. For individuals who become infected after taking PrEP, the development of resistance among PrEP users to the two drugs in Truvada is quite rare, although resistance among PrEP users has been documented.⁴⁴ Persons who become infected while taking PrEP (especially if not fully adherent to daily dosing) may acquire infection with a virus that already has resistance mutations. This occurs because persons with HIV infection who are being treated with antiretrovirals may develop a resistant virus and pass it to their sexual partners. In the rare case that resistance develops, evidence indicates that PrEP-selected resistance rapidly diminishes following cessation of PrEP.⁴⁵

Most cases of PrEP-related resistance have been among people who were HIV-infected at the time of PrEP initiation but whose early infection was missed by HIV testing technologies.⁴⁴ The risk that an individual taking PrEP develops resistance to Truvada can be minimized by coupling HIV screening with a rigorous assessment to identify possible signs of acute (or very early) HIV infection. Use of laboratory HIV tests that look for the virus itself as well as antibodies (4th generation tests) may

further reduce the odds that an HIV-infected individual begins PrEP.⁴⁶ In addition, the PrEP protocol, requiring quarterly HIV tests, also allows providers to identify cases of HIV infection early, mitigating the development of resistance, immediately administering resistance testing and initiating appropriate antiretroviral therapy to achieve viral suppression.

In any event, the rare risk of HIV drug resistance needs to be balanced against the clear, compelling prevention benefits of PrEP. For

example, in the recent study that identified five cases of drug resistance among trial participants who received PrEP, it is estimated that the trial also prevented 123 people from becoming infected.⁴⁶ According to CDC modeling estimates, access to PrEP means the potential that tens of thousands of people might avoid HIV infection in the coming years. While redoubling efforts to minimize drug resistance, efforts to scale up PrEP urgently need to continue.



What We've Learned from Real-World Experience

What happens in a clinical trial is one thing. What happens in the real world is often something else entirely. That is because clinical trials don't necessarily mimic real-world conditions. In clinical trials, participants are carefully selected, and they receive free access to the drug, regular medical monitoring, and careful counseling and support. But in the real world, especially in clinics that serve the most vulnerable, providers are often overburdened and systems are sometimes ill-prepared to handle new demands.

So while it is essential to know that clinical trials have found PrEP to be efficacious, we also need to know whether and how these findings can be translated in the real world.

We now have a substantial, and growing, body of evidence on PrEP's success under real-world conditions. Sources of this information include open-label trials undertaken in normal clinical settings, demonstration projects designed to answer key questions about how best to implement and scale up PrEP, and information on the thousands of people who have obtained PrEP through their medical providers.

In addition, the Institute has also obtained important community feedback about PrEP during its national PrEP tour in recent months. Through this tour, the Institute has encouraged and facilitated a community conversation on PrEP, which in turn has surfaced key themes, concerns and lessons learned.

PrEP Works

Real-world experience confirms the findings of clinical trials regarding the exceptional effectiveness of PrEP. Among more than 1,400 people receiving PrEP through Kaiser Permanente of Northern California, not a single person has been newly infected with HIV.⁴⁷ As previously noted, no new infections were reported among people in the iPrEx open-label extension who took at least four PrEP doses per week. In 13 health clinics in England, provision of PrEP to gay and bisexual men was associated with an 86% reduction in the risk of HIV infection.⁴⁸

In a national demonstration project for gay and bisexual men, HIV incidence was extremely low among PrEP users, with the only infections reported during follow-up linked to discontinuation of PrEP rather than PrEP failure.²⁷ Likewise, in a separate 12-city demonstration project for young gay and bisexual men, each of the individuals who became infected over 48 weeks were found to have very low levels of Truvada in their blood.⁴⁹ Other studies have generated similar findings, with new infections occurring only among people with no detectable drug in their blood.⁵⁰

Demonstration projects have also proven that it is possible to achieve strong adherence levels under real-world conditions. In a three-city demonstration project in the U.S., testing of dried blood spots provided by project participants found that 63% of participants had protective drug levels at all follow-up visits over 48 weeks, with nearly 90% of study participants exhibiting

The Institute's National PrEP Tour

When it comes to the fight against AIDS, the Institute has worked to reflect and promote a belief in the motto, "Our people, our problem, our solution." With the emergence of PrEP, the Institute and its partners in Black communities across the U.S. have recognized that if PrEP is to be effective in driving down rates of new HIV infections, Black America must understand it, own it, and devise its own solutions to overcome barriers to scale-up.

This spirit was the genesis of the Institute's national PrEP tour, launched in the fall of 2015. "We know that the uptake of PrEP in Black communities is considerably, dramatically lower than the uptake of PrEP among white gay men," said the Institute's President and Chief Executive Officer, Phill Wilson. "We did the PrEP tour because we wanted to find out why that was so."

The tour has already made a dozen stops (Atlanta, Baltimore, Baton Rouge, Boston, Broward County, Fla., Charlotte, Chicago, Columbia, S.C., Houston, New Orleans, Oakland, Richmond and Washington, D.C.), with additional PrEP summits planned in Los Angeles, Fredericksburg, Vir., Nashville, Dallas, Cincinnati Melbourne, Fla., Little Rock and

Detroit. Through March 2016, the Institute's national PrEP tour has trained and educated more than 700 community members on what PrEP is, how it works and on how to pay for it.

The PrEP summits highlighted the persistent gap in PrEP awareness and access experienced by Black communities across the country. "Many Black gay men don't know about PrEP," said Ron Simmons, the executive director of US Helping Us, People Into Living, and a participant in the Washington PrEP summit. "Many people, gay or straight, don't know about it. Doctors don't know about it. A number of gay guys have said, 'I asked my doctor about it and he sent me to an infectious disease specialist.' But the infectious disease specialist says, 'I treat infections and you're not infected. You should go to your primary care physician.'"

In addition to issues of access, community education and provider awareness, the PrEP tour also highlighted other barriers to PrEP uptake in Black America. These include the deterrent effects of mistrust of the health care system in many Black communities and the lack of information and awareness campaigns for Black women.

adherence levels deemed to be very good or excellent.²⁷

In 2016, the first case of HIV infection among an individual believed to be highly adherent to PrEP was reported.⁵¹ The individual, a man living in Canada, acquired HIV while having sex with a man whose HIV was resistant to Truvada as well as other classes of antiretrovirals. This case underscores that PrEP, like every other prevention strategy, is not 100% effective, but it does not alter the conclusion that PrEP is highly effective in preventing HIV acquisition.

Demand for PrEP Is Growing

PrEP consumers and HIV advocates cite 2014 and 2015 as pivotal years with respect to PrEP uptake. In each of these years, the number of people using PrEP doubled. According to key informants interviewed for this report, what had earlier been viewed as a peculiar sideline of the HIV prevention toolkit came to be regarded in 2014-15 as mainstream.

All signs indicate that the demand for PrEP continues to increase. A number of Black gay men interviewed by the Institute said that over the last year discussions about PrEP within social networks of Black gay men became more common. And more and more Black gay men taking PrEP began disclosing their PrEP use to their peers, helping to diminish the stigma associated with PrEP use.

The growth in demand for PrEP has not been uniform across the key populations affected by HIV. All signs indicate that Black utilization of PrEP continues to lag behind use by whites. And virtually all of the increase in PrEP use in recent years has been among men.

Controversies Regarding PrEP Are Lessening

PrEP's approval as a validated HIV-prevention tool provoked a vociferous backlash in a few parts of the AIDS community. In particular, opposition to PrEP was led by Michael Weinstein, President and CEO of the AIDS Healthcare Foundation (AHF).

AHF argued that data from the PrEP efficacy studies did not warrant widespread scale-up of Truvada for prophylactic use. In particular, AHF cited adherence challenges as a reason why PrEP was unlikely to have the desired public health

effect. Suggesting that PrEP is less effective than condoms—notwithstanding evidence that PrEP confers close to 100% protection among people who take Truvada every day—Weinstein termed Truvada a “party drug.”⁵²

At the grassroots level in gay communities, Truvada use was often highly stigmatized in the early years following its approval by the FDA. Users of the drug were sometimes referred to as “Truvada whores,” suggesting that only promiscuous people would use PrEP and that PrEP use was helping undermine condom use (notwithstanding little evidence of “risk compensation” as a result of PrEP).⁵³

Yet, these early critiques of PrEP have begun to fade. In 2014, as media attention to opposition to PrEP mounted, more than 100 AIDS organizations from across the U.S. joined together to express their strong support for PrEP as a key HIV-prevention tool. PrEP users began owning the “Truvada whore” label, proudly using it on T-shirts and in media commentaries to proclaim their personal use of PrEP and to encourage others to consider doing so.

But perhaps more than anything else, the steady increase in clear, undeniable evidence of PrEP’s effectiveness diminished critics’ traction. Many of these critics also appeared to reconsider their previous opposition, and even AHF endorsed PrEP for people who do not consistently use condoms and have multiple sex partners.⁵⁴ Black PrEP users interviewed by the Institute also confirmed that judgmental attitudes within Black gay social networks towards PrEP users also in some cases appear to have abated. All in all, slow uptake of PrEP appears to stem

more from lack of awareness and limited access than from any controversies associated with the intervention.

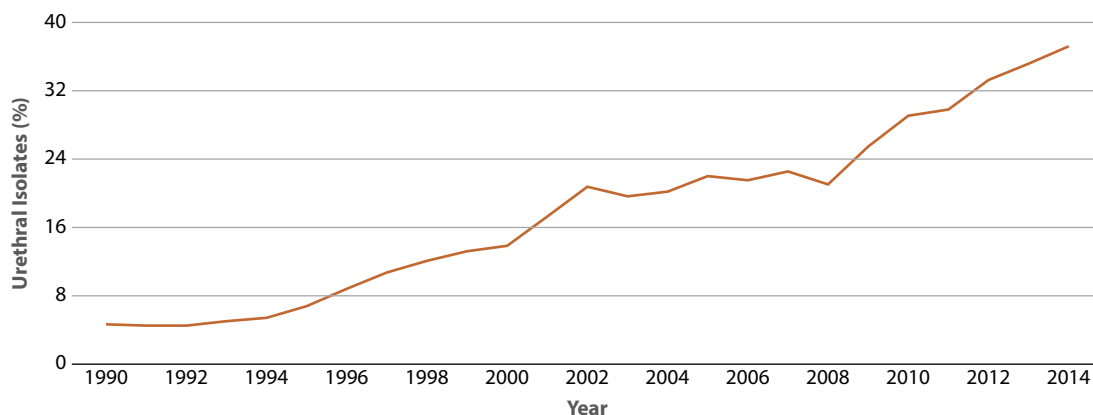
PrEP Offers Potential Benefits for STI Control

Some have suggested that PrEP itself is responsible for the high rate of STIs reported among PrEP participants. Yet, the CDC has reported that STI rates among gay and bisexual men have been rising for years, with sharp increases in STI rates predating the advent of PrEP (Figure 14).⁵⁵ In the large open-label PROUD study in 13 health clinics in England, STI rates among participants were high but no increase in STI rates occurred after participants began taking PrEP.⁴⁸

In reality, the PrEP protocol has important benefits for STI control. By requiring monitoring of STI symptoms every three months and STI laboratory screening every six months, PrEP enables rapid diagnosis and cure of STIs, helping block the chain of transmission and promoting public health goals.

People eligible for PrEP, who are at high risk of HIV infection, are also at high risk of other STIs. Among participants in the PROUD open-label trial, 64% had been diagnosed with an STI in the 12 months before starting PrEP.⁴² At Callen-Lorde Community Health Center, New York City’s largest LGBT health center, 21% of PrEP recipients had an STI prior to starting PrEP.⁵⁶ And in a 12-city demonstration project for

Figure 14. *Neisseria Gonorrhoeae*. Percentage of Urethral Isolates Obtained from MSM Attending STD Clinics, Gonococcal Isolate Surveillance Project, 1990-2014



Source: CDC

young gay and bisexual men, 22% of participants had a positive STI test when they enrolled in the project.⁴⁹

Given that a history of STIs is a recommended indication for prescribing PrEP, users of PrEP are, on average, a population at high risk of STIs. In a three-city PrEP demonstration project involving men who have sex with men (MSM) in the U.S., 51% of participants were diagnosed with an STI over 15 months.⁵⁷

The regular STI screening that is built into the PrEP protocol has particular potential to increase the detection of asymptomatic STIs and lead to treatment that will strengthen STI control efforts in Black America. Black Americans accounted for 69% of all gonorrhea diagnoses in the U.S. in 2010 and for 47% of all syphilis cases, and chlamydia rates among Black men and women were 11 and seven times higher, respectively, than among white men and women.⁵⁸ High background prevalence of STIs is one reason why Black gay and bisexual men are so vulnerable to HIV acquisition.⁵⁹

Rather than causing STIs, PrEP permits timely intervention to prevent STIs from spreading further in an environment where STI rates are rapidly rising among MSM.⁶⁰ However, the high rates of STIs reported among PrEP recipients has raised questions regarding the CDC protocol for STI screening, which recommends intensive, extra-genital screening for MSM every six months, coupled with testing whenever symptoms are reported. In a three-city PrEP demonstration project that conducted full STI screening more frequently than recommended by the CDC, it was estimated that 34% of gonorrhea cases, 41% of chlamydia cases, and 20% of syphilis cases among PrEP participants would have gone undiagnosed for at least three months had the program adhered to the recommended six-month screening protocol.⁵⁷ Findings from these and other demonstration projects suggest that STI laboratory screening for MSM should occur every three months to fully leverage the potential of PrEP to strengthen STI control.^{57, 56}

Most People Who Take PrEP Don't Increase Sexual Risk-Taking

Concerns have been expressed that the availability of PrEP could encourage people to increase risky sexual behavior, a phenomenon

known as “risk compensation.” These concerns are not unique to PrEP but are similar to concerns expressed for other sexual health innovations, such as female contraceptives and HIV treatment as prevention.⁶¹ On balance, clinical trials have not found an increase in sexual risk behaviors after initiating PrEP.^{61 62}

Several real-world demonstration projects with gay and bisexual men have similarly found little evidence of an increase in risk behaviors among men taking PrEP. In the three-city PrEP demonstration project, the mean number of anal sex partners fell in the 48 weeks that participants took PrEP.²⁷ A similar trend was seen among young gay and bisexual men in a separate 12-city demonstration project.⁴⁹ In a PrEP demonstration project in San Francisco, participants did not abandon their previous prevention strategies but instead tended to use PrEP in concert with other strategies, such as condoms, sero-sorting and serostatus disclosure.⁶³

Although most men who take PrEP do not abandon or reduce other risk-reduction measures, a notable minority of PrEP users do reduce condom use. Compared to the randomized IPERGAY study in France, those participating in the follow-up open-label study had lower rates of reported condom use.⁶⁴ Among the more than 1,400 men enrolled in PrEP by Kaiser Permanente of Northern California, 56% reported no change in condom use after starting PrEP and 3% said they used condoms more often when taking PrEP, but 41% reported using fewer condoms on PrEP.⁶⁵

Concerns about so-called “risk compensation” are most acute for marginally effective interventions, whose benefits might easily be overridden by incremental increases in risk behavior. By contrast, PrEP is highly effective, conferring benefits above 90% for people who take the regimen on a daily basis.⁶¹ It also must be borne in mind that the proportion of gay and bisexual men who report engaging in condomless sex has been increasing for some time.⁶⁶ In this regard, the decline in condom use among a minority of male PrEP users should be viewed as a continuation of previous trends rather than a PrEP-induced rupture in the so-called “condom code.”



Boston PrEP Summit

Black AIDS Institute - Multicultural AIDS Coalition - Take The Test B
Friday - February 26th, 2015

9:00am

Welcome and Introduction. - Gary Daffin and Amir Dixon

9:10am

Overview of the day and Explanation of BTAN - Rebecca Israel

- Basic housekeeping - silence cell phones, bathrooms, etc.
- Overview of BTAN / National PrEP Tour (USCA) and goals of local tours
- Review of agenda

9:30am

Overview of PrEP -- Gary Daffin

- What are PrEP? Is it Effective?
- Review of evidence of effectiveness
- Trends in PrEP Uptake and Personal Testimonies

10:30am

Addressing Black Mistrust of Med Establishment & Biomed Research - Matt Rose

- Discussion of the history of Black mistrust of medical establishment
- Review of previous unethical biomedical research practices
- Discussion of best practices in addressing medical mistrust and medical racism

11:45am

Break/Grab Lunch

2:15pm

Lunch Panel: The PrEP Experience: PrEP Consumer / Prescribing PrEP / Educator

- Personal experiences of taking PrEP
- Experience of medical providers prescribing PrEP and nPEP
- Approaches to educating Black communities about PrEP and nPEP

Influence of Intersectionality on Target Populations - Amir Dixon and Chioma Nnaji

- Black Gay, Bisexual & other MSM
- Black Transgender People
- Heterosexual Black Men & Women
- Black Youth Across Populations

Conclusion - Final Thoughts & Evaluation

Leveraging PrEP to Fight HIV in Black America: Key Challenges to Overcome

Here's what we know: PrEP is powerfully effective in preventing new HIV infections. Yet, despite growing momentum in PrEP uptake, Black people—those who need PrEP the most—are still being left behind.

Hope is good, but hope alone that PrEP access for Black people will improve won't get the job done. To make PrEP a meaningful weapon in the fight to end AIDS in Black America, we need to understand the factors that slow PrEP uptake in Black communities and take concerted action to address each of these factors.

Awareness of PrEP in Black America is Insufficient

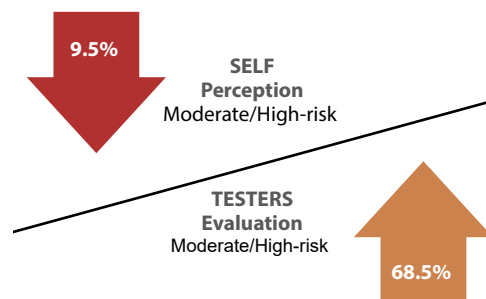
Although Black America has the greatest need for PrEP, there are signs that Black people are often less aware of PrEP than other groups. Following FDA approval of Truvada, for example, fewer than one in four Black gay and bisexual men in Atlanta reported being aware of PrEP.⁶⁷ The Institute's national survey of the HIV/AIDS workforce (in community-based organizations and state and local health departments) found that Black HIV staff were significantly less likely than white HIV staff to be aware of biomedical HIV prevention methods. "Currently, according to every survey I have seen, African-American men and women have less knowledge of PrEP and are using PrEP less than other pops, despite the fact that they have higher rates of new infections," said Dawn Smith, biomedical interventions

activity lead in the epidemiology branch of the CDC's Department of HIV/AIDS Prevention.

A failure to truly appreciate one's risk for HIV can also diminish PrEP uptake. According to National HIV Behavioral Surveillance, 67% of Black gay and bisexual men who tested HIV-positive in surveys were previously aware of their HIV status, compared with 90% of white gay and bisexual men.⁶⁶ Similarly, national surveys in a largely Black cohort of heterosexual men and women found that only 59% of women and 50% of men who were HIV-infected were aware of their positive status. While 9.5% of Black people in Philadelphia said they had moderate or high

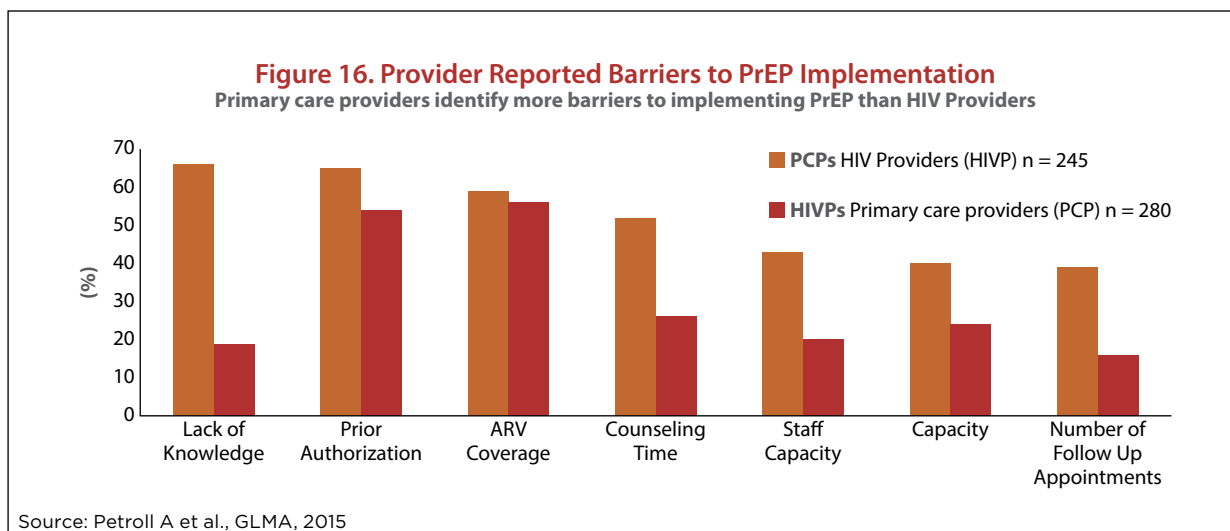
Figure 15. Self Perception of HIV Risk Is Low

Persons (N=3,533; >90% African-American) undergoing HIV rapid testing in Philadelphia were surveyed between July 2012 and Dec 2013



A large proportion of patients at high-risk for HIV infection do not perceive themselves at high risk

Source: KwaKwa et al., Melbourne IAC, 2014



risk for HIV, those administering an HIV test to the study population deemed that more than two thirds of participants were at moderate or high risk” (Figure 15). Self Perception of HIV Risk Is Low” on page 40.⁶⁸ Significantly, those with a lower risk perception were less likely to be open to taking PrEP.⁶⁸ These Philadelphia findings were echoed in a qualitative research study in New York City, with the acceptability of PrEP directly correlated with self-perception of HIV risk among young gay and bisexual men.⁶⁹

There are signs that awareness of PrEP is increasing in Black communities, especially among gay and bisexual men. Among Black PrEP consumers interviewed by the Institute in 2016, many said they saw a sea change in their social networks regarding PrEP in 2015, when discussions about PrEP intensified and openness to the intervention increased. In 2015, Harlem-based Black gay and bisexual men told researchers that they regarded PrEP as an important advance over existing prevention strategies⁷⁰, a finding that was echoed in a series of focus groups among Black women.⁷¹

Community education programs are urgently needed to demystify PrEP, provide basic information about this important prevention tool, and motivate people to talk to their health and social service providers about using PrEP.

Too Few Providers Are Promoting PrEP

People who need PrEP and are aware of its prevention benefits often struggle to find a doctor who is knowledgeable about PrEP and capa-

ble of prescribing and monitoring Truvada use.⁷³

While HIV providers are increasingly aware of PrEP, most HIV-uninfected people don't get

Building PrEP Literacy Among the Black HIV Workforce

In 2012-2013, the Institute partnered with the CDC, the Latino Commission on AIDS, the National Alliance of State and Territorial AIDS Directors and Janssen Pharmaceuticals to undertake the largest ever survey of the HIV/AIDS workforce. More than 2,100 people working in HIV/AIDS participated in the survey, offering the most comprehensive look yet at the state of knowledge of the HIV/AIDS workforce.

While survey participants demonstrated strong basic knowledge of the science of HIV (answering 76% of such questions correctly), literacy regarding clinical and biomedical interventions (including PrEP) was substantially lower (46% correct).⁷² Significantly, Black workers in the HIV/AIDS

field were notably less likely than white workers to have a strong understanding of PrEP and other biomedical prevention tools.⁷²

While awareness of PrEP within the HIV/AIDS workforce has undoubtedly grown since 2012-2013, it is less certain that actual working literacy regarding PrEP has similarly increased. As Black-serving community-based organizations and local health departments have critical roles to play in facilitating PrEP uptake in Black communities, urgent investments are needed in programs that build the capacity of the HIV/AIDS workforce to aid Black Americans in understanding, accessing and adhering to PrEP and other essential biomedical tools.

their medical care from HIV specialists. Like most other people who haven't been diagnosed with a chronic disease, they receive their regular care from their primary care doctors. However, Black Americans are substantially less likely than white Americans to have a primary care physician or make regular clinic visits.⁷⁴

Surveys indicate that HIV doctors are more than three times more likely to know about PrEP than primary care doctors (Figure 16). According to a 2015 survey, 34% of primary care doctors had never heard of PrEP, three years after Truvada was approved by the FDA and a year after the CDC issued clinical guidelines for PrEP.⁷⁵

In addition to a lack of awareness or knowledge about PrEP, surveys also suggest that many providers have little motivation to promote PrEP, even though it is a powerfully effective prevention method.⁷⁶ At a New York City community forum in November 2015, participants reported that many doctors were hesitant to prescribe PrEP, often making it difficult for people interested in using PrEP, especially in communities of color, to find a physician who is knowledgeable about PrEP and willing to prescribe it.⁷⁷

Paying for PrEP Can Pose Barriers for Many

PrEP costs \$13,000 or more per year. For most people, having meaningful health coverage is essential if they hope to use PrEP. Among ethnically diverse young gay and bisexual men surveyed in New York City, cost was cited as a primary obstacle to PrEP uptake.⁶⁹

The Affordable Care Act (ACA) has substan-

tially expanded access to health coverage, with 20 million more Americans insured in 2016 than before the ACA was implemented.⁷⁸ As utilization data from Denver health services illustrate, the ACA has substantially reduced the number of uninsured individuals using safety-net health facilities and increased the share of patients with some form of health coverage (Figure 17).

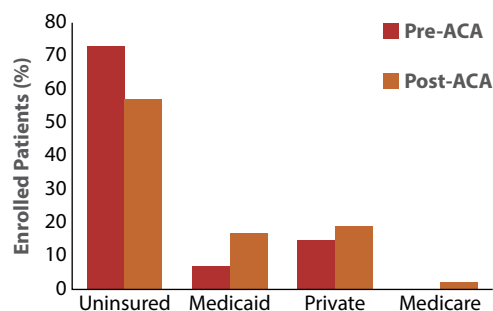
Yet, even in the era of the ACA, substantial numbers of Americans, including disproportionate numbers of Black Americans, still lack health coverage. In 2015, 12.7% of Black people in the U.S. were uninsured, with Black Americans being 40% more likely to lack health coverage than whites.⁷⁹ Among young gay and bisexual men, whites are more than twice as likely to have health insurance than young Black men.⁸⁰ Even for those who have health coverage, insurance plans may often require substantial co-pays for pharmaceuticals, diagnostic tests and doctor visits.

One gaping hole in the country's health care safety net is the failure of many states to expand Medicaid, as allowed and subsidized under the ACA. Currently, 19 states have declined to expand Medicaid (Figure 18), even though the federal government is footing nearly all the costs associated with Medicaid expansion. Notably, most of the states that have refused to expand their safety net for low-income people are in the South, where HIV infection rates are the highest and where epidemics are overwhelmingly concentrated in Black communities.

Gilead Sciences, the maker of Truvada, offers important avenues for access to Truvada for uninsured and underinsured individuals. The company's Medical Assistance Program offers access to Truvada without cost for individuals who are uninsured and have an annual income under 500% of the federal poverty line (or \$59,400 for a single individual). To aid consumers in covering co-pays for Truvada, Gilead also has a Co-Pay Program, which covers up to \$3,600 per year for out-of-pocket costs for a PrEP prescription.

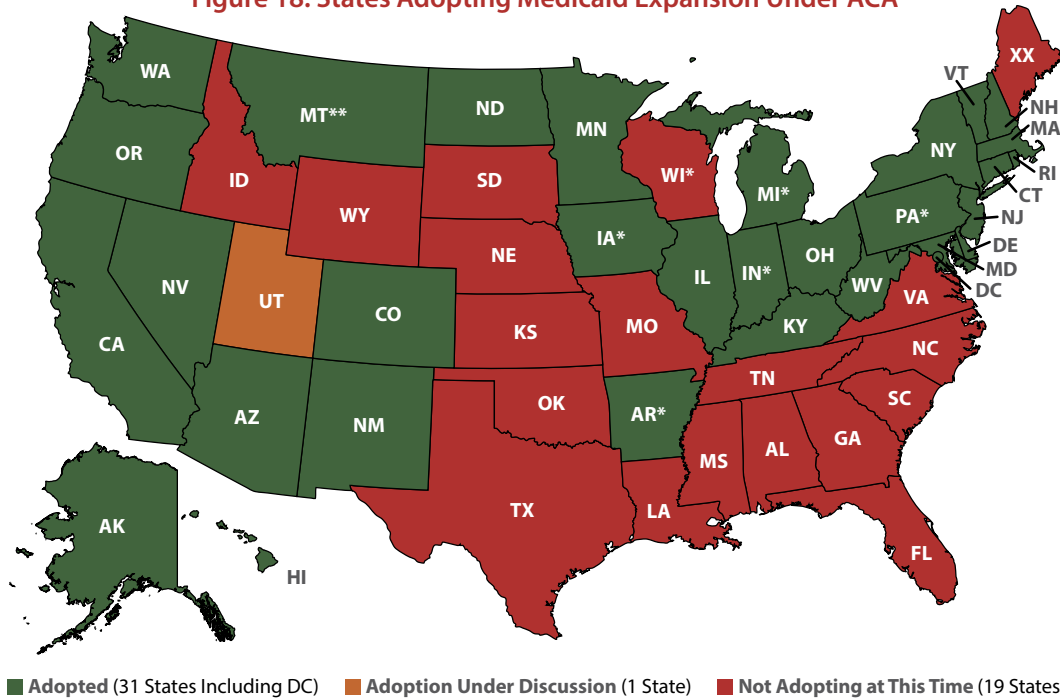
The ability to access these programs, however, depends on awareness of their existence and, in some cases, assistance in navigating the process of obtaining Gilead support. "Do young African-American men who have sex with men know how to access PrEP?" asks Staci Bush, Gilead's Associate Director of Medical Affairs. "Do they know there is a Medical Assistance Program? Do they know there are providers in their community that can prescribe PrEP?"

Figure 17. Percentage of Patients Enrolled in Varied Payer Plans, Denver Metro Health Clinic, 2013-14



Source: Thrun, National STD Conference, 2014

Figure 18. States Adopting Medicaid Expansion Under ACA



Source: Henry J. Kaiser Family Foundation, 2016

Many Black People Experience Obstacles to Adherence

Among Black people who are aware of PrEP and decide to start it, many have trouble remaining with the intervention and taking the pill regularly. In a three-city demonstration project that used dried blood spots to monitor drug levels among its gay and bisexual project participants, Black participants were more than 70% less likely to have protective drug levels in their blood than white participants.²⁷

Similarly concerning findings emerged from another national demonstration project for young Black gay and bisexual men. Although the trial succeeded in enrolling large numbers of young Black men, few of these men succeeded in sticking with the regimen for 48 weeks. Indeed, while overall adherence in the trial (as measured by drug levels in dried blood spots) remained robust, by 48 weeks not a single Black participant had detectable levels of Truvada in his blood (Figure 19).⁴⁹

Black Americans' higher probability of confronting acute life challenges helps explain the difficulties many Black Americans experience in

adhering to medication regimens. Compared to young white gay and bisexual men, Black gay and bisexual men are three times more likely to live in poverty and almost twice as likely to have experienced sexual abuse.⁸⁰ Black gay and bisexual men who are living with HIV are three times likelier to have low educational attainment than HIV-positive white gay and bisexual men.⁸⁰ As a result of these patterns, Black people affected by the HIV epidemic have higher rates of unemployment and housing instability, undermining their ability to adhere to medication regimens.

Adherence challenges experienced by many Black people who start PrEP underscore the essential need for strong, ongoing counseling and support to help PrEP users take Truvada, as well as for increased investments in community-based programs to build HIV science and treatment literacy. While PrEP is the latest form of what has come to be known as “biomedical HIV prevention,” the truth is that no HIV prevention tool is purely biomedical, in that all tools depend on the behavior of the user to be effective. A more meaningful term for PrEP may be “biobehavioral,” highlighting the need to couple access to Truvada with the behavioral and practical support needed to enable PrEP users to adhere.^{81, 82, 83} In a successful PrEP program at a

community health center in Rochester, New York, the clinic uses a PrEP Specialist who aids the patient in applying to the appropriate medication assistance programs and addressing other potential obstacles to adherence.⁸⁴

Women Face Particular Barriers

PrEP is an ideal tool for women at risk of acquiring HIV. Currently, PrEP is the only approved prevention method that women may initiate discreetly, on their own, without involving a male partner. PrEP is particularly valuable for women who have an HIV-positive partner and desire to conceive a child; use of PrEP to simultaneously facilitate conception and avoid HIV transmission is known as “PrEPception.”

However, utilization of PrEP by women has barely budged over the last two or three years. “We are not seeing much demand for PrEP among women,” reports Gilead’s Staci Bush.

One reason may be perceptions shaped by early clinical trial results that enrolled large numbers of women, which found a strong correlation between adherence and effectiveness. “The conversation in the media, the AIDS field and community circles after these early trial results suggested that women were the problem,” said Shannon Weber, director of San Francisco’s HIVE. “Women remain really ‘othered’ in the conversation about PrEP.” During the Institute’s PrEP

summits held in 12 cities, participants strongly urged that the community discourse on PrEP pay greater attention to women’s needs and bring more women to the table.

Even in San Francisco, where HIV services are plentiful, few providers prescribe PrEP for women, Weber reports. And identifying possible candidates for PrEP can be challenging, as, for example, obstetricians and gynecologists do not ask about a partner’s HIV status as a standard practice. Although Truvada is suitable for use during pregnancy, few physicians are often willing to prescribe PrEP to pregnant women.

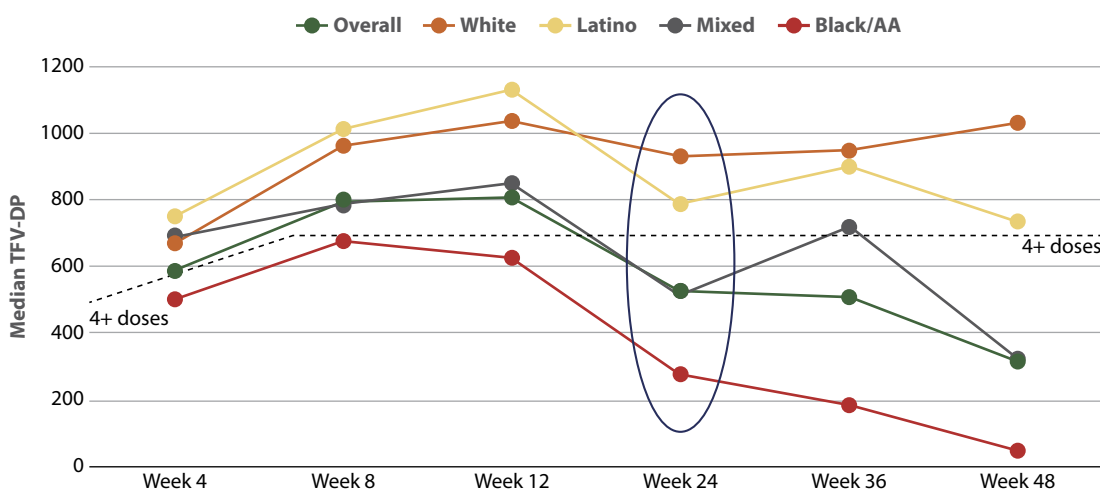
“We have places we can go where we can find and engage men who have sex with men,” Weber says. “We don’t have the same strategies to reach HIV-negative women with partners who are HIV-positive or have an unknown serostatus. There isn’t really a place to reach them.”

Transgender Women Face Major Challenges in Accessing PrEP

Although evidence suggests that PrEP may be effective in preventing transgender women from acquiring HIV, the CDC has yet to issue specific guidance recommending PrEP for transgender women. WHO, by contrast, has recommended use of PrEP to protect transgender women from infection since 2014.⁸⁵

Evidence suggests that transgender women

Figure 19. Adherence among Participants in Nationwide PrEP Demonstration Project, Median TFV-DP by Race/Ethnicity



Source: Hosek, IAS, Vancouver, 2015

are willing to take PrEP.⁸⁶ However, with PrEP, as with other types of health care, transgender people often have difficulties finding health care providers with the sensitivity and capacity to address their health needs. In health care

settings, many transgender patients experience hostility, discrimination and insensitivity.²¹

Some questions remain unanswered regarding the possibility of interactions between Truvada and hormones used by many transgender women.⁸⁶ For example, there are reasons to question whether estrogen might influence the pharmacokinetics of tenofovir in the colon, a potentially important site for protection for transgender women.⁸⁷

Advocates call for additional research on possible interactions between hormone therapy and PrEP and for greater inclusion of transgender women in future study populations.⁸⁶ In addition, steps are needed to build the capacity of health care providers to address both PrEP-related and other health issues for transgender people.

The Institute's Survey of Women about PrEP

At the annual Essence music festival in New Orleans in July 2015, the Institute interviewed more than 300 Black women about PrEP. Survey results highlighted both the challenges and opportunities that PrEP presents for sexually active Black women.

surveyed said they did not know where they could go to obtain information about PrEP.

However, a majority of women (53%) said they would consider taking PrEP if it was available, with only 13% of survey participants saying they were certain they wouldn't take it. Eighty percent

Figure 20. Before this survey, have you ever heard of PrEP?

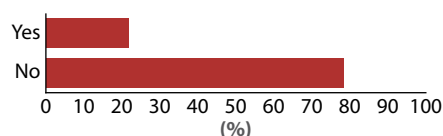
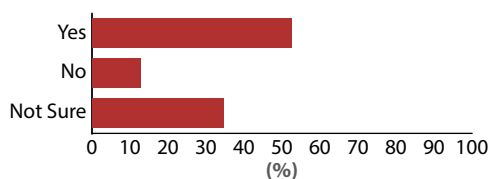


Figure 21. If PrEP was available to you would you consider taking it?



Fifty-seven percent of the women who were surveyed reported having had sex without a condom in the prior six months.

Three years after the FDA approved PrEP, only 22% of women surveyed at the Essence festival were aware of PrEP before the survey was conducted. Fifty-six percent of women

expressed interest in talking to their doctor about PrEP.

These survey results confirm that many Black women could benefit from PrEP but that lack of awareness of PrEP represents the single biggest obstacle to increased PrEP uptake among sexually active Black women.

Young People Struggle to Obtain PrEP and Other Medical Services

Of all age groups, young people need PrEP the most. This is especially true in Black America, where HIV acquisition typically occurs at a younger age than for other racial and ethnic groups.

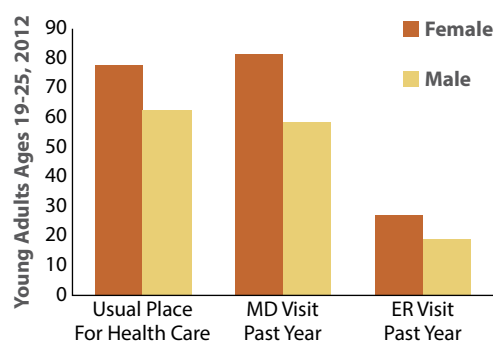
One challenge in making PrEP a meaningful option for young people is the fact that the intervention is delivered in clinical settings. Young people are less likely to have a usual place to receive health services, and less likely to seek health services (Figure 22). In part, this may stem from the longstanding shortage of health services that are specifically tailored to young people's needs.

Among young adults, Black people are less likely than whites to see a doctor or to have a usual place where they go for health services (Figure 23). People with health coverage (whether public or private) are twice as likely to have a usual place of health care than the uninsured and almost two times as likely to see a doctor (Figure 24). Young adults are less likely than other adults to have health insurance.⁸⁸

Mistrust, Myths and Stigma about HIV

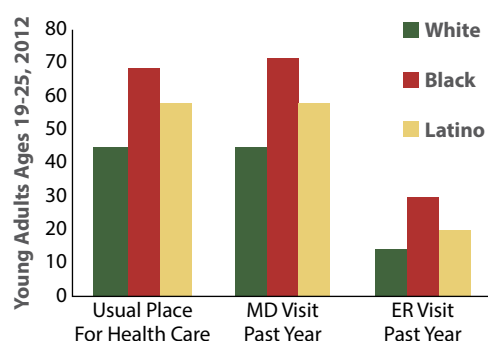
Participants in the Institute's PrEP summits in recent months advised that distrust of mainstream health services in Black communities and the persistence of myths about HIV undermine efforts to achieve robust PrEP uptake in Black America. Among more than 500 Black

Figure 22. Health Care Utilization, 2011



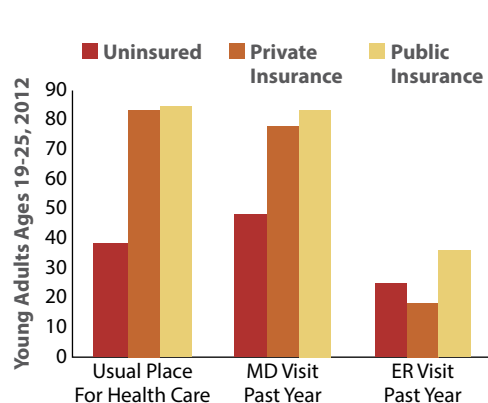
Source: National Center for Health Statistics

Figure 23. Health Care Utilization, 2011



Source: National Center for Health Statistics

Figure 24. Health Care Utilization, 2011



Source: National Center for Health Statistics

gay and bisexual men surveyed, nearly half (48%) said they mistrusted medical professionals.⁸⁹

Part of this mistrust of medical professionals stems from previous experiences of stigma and discrimination in health care settings. In the above-noted survey of Black gay and bisexual men, 29% reported having experienced

discrimination in health settings based on their sexual orientation.⁸⁹

“It’s hard to hear people say, ‘They want to kill us with AIDS,’ especially when you have additional knowledge, but those experiences and those perceptions can’t be dismissed, because they are prevalent,” said Josephine Ayankoya, former mobilization coordinator for the Institute. “We have to work to build that trust and meet people where they are.”

The Institute and its partners specifically addressed the obstacles posed by widespread medical mistrust during its PrEP summit in Baltimore, where a series of investigations and legal settlements exposed abusive practices by some health care providers toward Black residents of Baltimore. The Baltimore PrEP summit—co-convened by the Institute, the Maryland Department of health and Mental Hygiene, National Minority AIDS Council and the Baltimore chapter of the Black Treatment Advocates Network—situated the discussion about PrEP within the broader context of the longstanding distrust that many Black individuals have toward health providers. It was recommended during the meeting that health care providers and community organizations acknowledge the doubt and distrust that some Black individuals have and work to build stronger, more respectful relationships, both inside and outside clinical settings.

The PrEP summits also highlighted how stigma associated with PrEP use, or with HIV more generally, impedes uptake of PrEP in Black communities. “The stigma associated with PrEP is unfounded, and it’s really our job collectively to make sure we address that in the community and make sure that people understand that PrEP works,” said Dr. Eugene McCray, director of the CDC HIV/AIDS Prevention Division of the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, speaking at the Washington D.C. summit. “It’s not for everyone, but for people who want to use it, they should be able to use it. It doesn’t devalue who they are and what they’re doing.”

Gay and bisexual men in the Harlem neighborhood of New York City who participated in focus groups or in-depth interviews reported that disclosing PrEP use often resulted in stigmatizing and judgmental attitudes from others and that the anticipation of stigma served as a deterrent to PrEP use.⁷⁰ Continuing to invest in stigma reduction, in part by normalizing PrEP and other HIV services, remains urgently needed in Black communities and across the U.S. as a whole.



The Way Forward: New Clinical Trial Results Identify Strategies for Scaling Up PrEP in Black America

In February 2016, researchers announced results of the HPTN 073 trial, which found that a tailored, holistic approach generated robust PrEP uptake and adherence among more than 200 HIV-uninfected Black gay and bisexual men.⁹⁰

Undertaken in three U.S. cities—Chapel Hill, N.C., Los Angeles Calif. and Washington, D.C.—HPTN 073 recruited Black gay and bisexual men to participate in the PrEP trial. In

addition to daily oral PrEP, participants in the trial received client-centered care coordination. The client-centered care coordination model aims to address multiple factors—that the lived realities of Black gay and bisexual men are often not taken into account in health care settings, that such men often have multiple life issues that may affect their ability to take and adhere to PrEP, and that HIV, while important, may not be the most pressing issue in the minds of many Black gay and bisexual men. Counselors in the three study sites acknowledged and validated the unique experiences of the men who participated in the study and engaged in open, culturally appropriate dialogue with participants on psychosocial issues and other barriers they



confront in accessing health services. The counseling model is built on values of autonomy, competence, personal growth and the human tendency to master challenges and to integrate new experiences into a coherent sense of self.

“The whole model is predicated on beginning with you as a person, where you are and what is going on with your life,” said Dr. Darryl Wheeler, a study chair from the State University of New York at Albany. “Every time we speak with you as someone in the trial, we are communicating about your life. HIV and PrEP become secondary.”

Of those enrolled in the study, 166 identified as gay, with 45 identifying as bisexual. Study participants were followed for 12 months.

Over 90% of study participants opted to take PrEP. Nearly all (96%) of men with HIV-positive partners accepted PrEP, and 86% of men with casual partners who were HIV-positive or had unknown serostatus accepted PrEP. After a full year, 86% of participants had at least 50% adherence to the daily regimen, with 67% reporting adherence exceeding 90%. HIV incidence among men who accepted PrEP was more than 50% lower than among study participants who did not accept PrEP, with at least two of the five seroconversions among PrEP recipients linked to discontinuation of PrEP.

These findings indicate that culturally tailored programs that address men's holistic needs are capable of scaling up PrEP among Black gay and bisexual men and achieving strong adherence. Although specific to Black gay and bisexual men, these study findings may also point the way toward approaches to bring PrEP to other groups in Black America where utilization of PrEP lags, including women and transgender people. As HPTN 073 underscores, service systems need to adapt to the needs of their clients, rather than expecting clients to adapt to systems created by and for others. Effective health care delivery also involves more than a specific medication or intervention but must also address social and structural determinants that have a profound effect on health service utilization and health outcomes.

"There are solutions out there," said Wheeler. "We have the tools, but do we have the will? Attacking the structures (that influence health outcomes) requires the will to change these structures."

"The take-home message of HPTN 073 is that if given a choice, Black men will choose life," said Dr. Sheldon Fields, a study co-chair from the Charles R. Drew University of Medicine in Los Angeles. "In this case, that means they will choose PrEP. But the implication is clear that culturally relevant approaches are needed when dealing with this subpopulation."

Significantly, the approach in HPTN 073 that achieved such striking results for Black gay and bisexual men is not especially costly and can be grafted on to existing service systems if the will exists to change approaches. "Our model is applicable to all health care systems," said Fields. "It does not take an onerous amount of time. It involves a little bit of training, but there has to be a willingness to change and a commitment to cultural competence."





Know Your Status

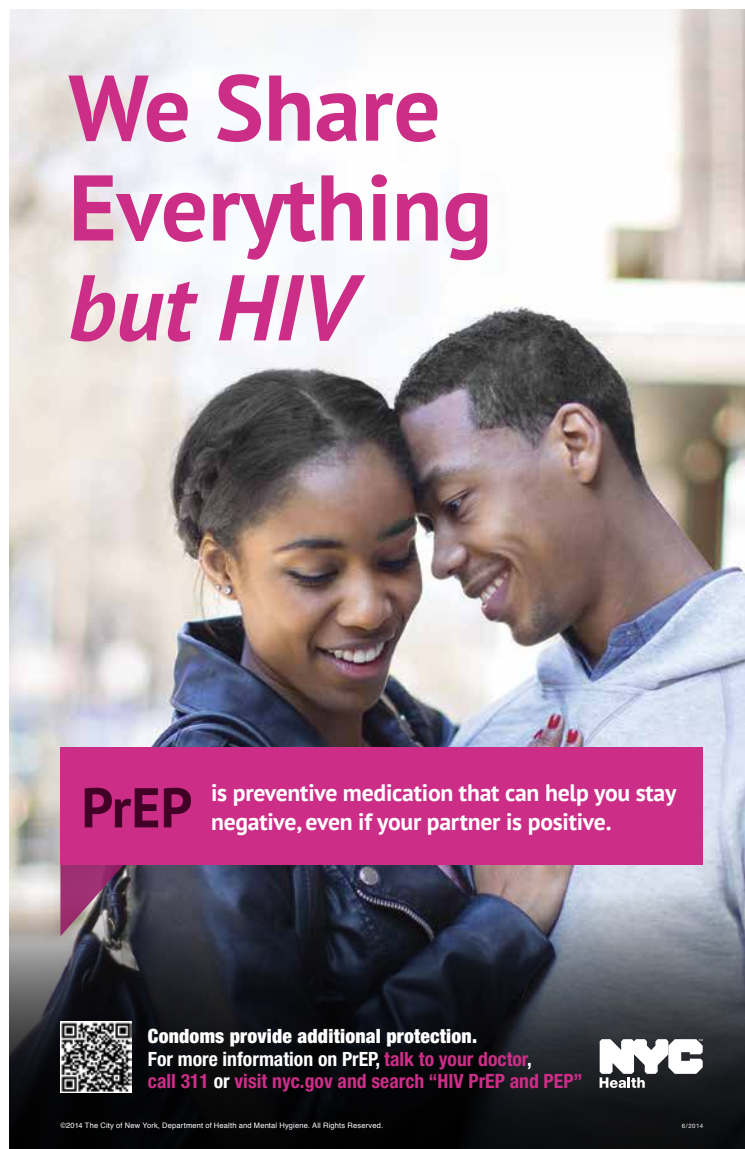


Making PrEP Real in Black America: The Public Health Perspective

Initially regarded as a “boutique” prevention option that only a few affluent individuals would ever use, PrEP has rapidly come to be understood as a pivotal public health tool. On its own, PrEP can avert one in five new HIV infections in U.S. if delivered to a larger number of persons at substantial risk and used with adherence to daily dosing. When combined with scaled-up HIV treatment as prevention, PrEP can effectively cripple the U.S. epidemic over the next five years.


Recognizing the public health potential of PrEP, health departments across the country are focusing considerable efforts on implementing PrEP programs and expediting PrEP uptake. “Because PrEP is new, there is a lot of work to do to get it implemented, particularly in communities at highest risk,” said the CDC’s Dawn Smith.

In its most recent cooperative agreement with state and local health departments for HIV prevention activities, the CDC has added PrEP as a required activity, and enhanced funding is being provided to 15 high-burden jurisdictions to increase service access, including PrEP, for gay and bisexual men and transgender women. Separately, the CDC is also requiring its directly funded community-based organizations to provide PrEP-



**We Share Everything
*but HIV***

PrEP is preventive medication that can help you stay negative, even if your partner is positive.

 **Condoms provide additional protection.**
For more information on PrEP, talk to your doctor,
call 311 or visit nyc.gov and search “HIV PrEP and PEP”

NYC Health

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Public Health Leadership: Leisha McKinley-Beach and Dr. David Holland, Fulton County Georgia Health Department

Leisha McKinley-Beach joined the Fulton County Health Department as HIV Prevention Program Administrator in December 2014. Dr. David Holland is the Health Department's Chief Clinical Officer for Communicable Diseases and a Professor of Medicine at Emory University. Both worked together to create the county's PrEP clinic, which opened its doors in October 2015. PrEP is an important element of the local plan to end AIDS, which was developed in collaboration with a host of stakeholders in the county and metro Atlanta area.

"We became aware that people were being made aware of PrEP but had no place to access those services," said McKinley-Beach. "Prior to the Health Department providing PrEP, there were perhaps two for-profit clinics where you could get PrEP. But to access PrEP at the private clinics, you had to have insurance or the ability to pay out of pocket."

For the professionals at the Health Department, the emergence of PrEP represented a public health opportunity that had to be seized. "All we've had are condoms for the last 30 years," Dr. Holland said. "It was clear from the data that promoting condoms, even in concert with treatment as prevention, wasn't making a dent in the number of new HIV diagnoses nationally, and

our rates here in Atlanta are actually going up, especially among young people. We need something new."

"We talk about everyone being

After it opened, it didn't take long for the clinic to experience rapidly growing demand. "Among the patients we've seen for PrEP, we have had quite a lot



Dr. David Holland



Leisha McKinley-Beach

responsible for HIV prevention," McKinley-Beach added. "I see PrEP as an opportunity to get HIV-negative individuals yet another tool to prevent HIV infection. Where condoms might not work or might not be a person's choice, now we have PrEP that we can offer them."

of diversity, in terms of gender, age and race," McKinley-Beach said. "For me that speaks to the need that exists."

In the early months of existence, the PrEP clinic relied on referrals, with half of the people seeking PrEP at the clinic having been referred by their

partners. While the Health Department has been gratified by the strong demand for PrEP in the clinic's early months, it is already finding that demand risks outpacing capacity. "Our STD clinic is not fully funded, and we are seriously understaffed," said Dr. Holland. "We've started using a volunteer physician from Emory, which has helped, and we should soon be able to get a couple of nurses [to help with PrEP delivery]."

Despite these staffing challenges, Fulton County is now moving beyond passive referrals to actively recruit individuals for PrEP. "We know that the majority of our patients are going to be Black," said McKinley-Beach. "We have outreach testing and mobile units, and we will actively be recruiting people from high-prevalence, predominantly Black neighborhoods and zip codes. [Community-based organizations] will also be trained on how to refer people to our PrEP clinic, and those agencies are already housed in our high-prevalence, primarily Black neighborhoods."

Thus far, Fulton County has seen no serious side effects among its PrEP patients, and people who start PrEP have remained adherent to the regimen. "The key is getting people to the appointment," Dr. Holland said. "If they make their first appointment, we are in good shape."

related services. The CDC provides extensive technical assistance to state and local health departments to implement PrEP services and is supporting three contractors to provide capacity-building assistance to help health care providers implement PrEP and other high-impact prevention strategies. PrEP information and themes are also being integrated into the CDC's social marketing campaigns for HIV prevention, including those focused on women and on gay and bisexual men of color. The CDC is also supporting research to inform efforts to roll out PrEP in community health centers that serve disadvantaged populations.

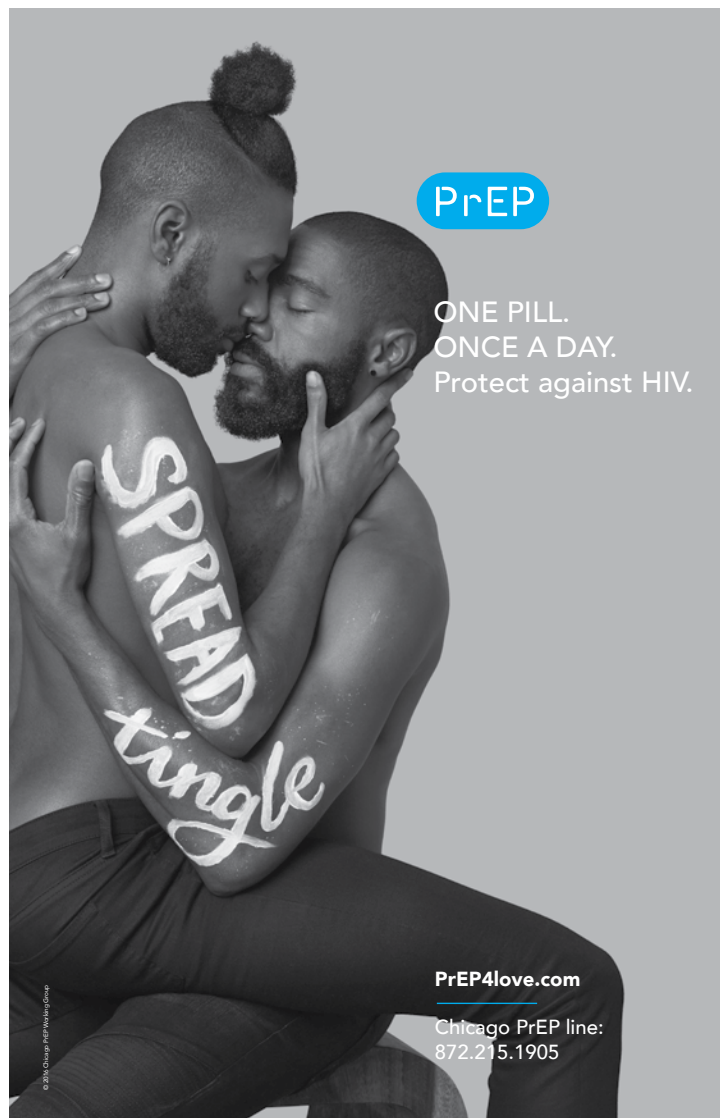
At the state and local levels, affected communities are joining with public health agencies to prioritize PrEP scale-up. In particular, PrEP is a key pillar of strategic plans for ending AIDS that have emerged in various parts of the country—such as Fulton County, Ga., New York state, San Francisco, Chicago and Washington state. What is particularly noteworthy about these efforts is the allocation of local funding to help make PrEP a reality for those who need it.

PrEP, for example, is a key focus of New York State's plan to end AIDS, which was developed through a visionary partnership between community advocates, service providers and public health officials from the state and local levels.⁹¹ New York City is allocating \$6 million in local funds toward efforts to bring PrEP to scale, including creation of a non-serostatus-specific navigation program to steer individuals toward appropriate prevention services, such as PrEP and post-exposure prophylaxis (PEP), as well as establishment of a PrEP program for adolescents. A team of health professionals from New York City's Department of Health and Mental Hygiene is visiting health care providers, providing technical support to increase providers ability to prescribe PrEP for patients who need it.

In Chicago, 150 stakeholders joined together to form the Chicago PrEP Working Group. The group is developing strategies to train health care providers, increase the capacity of existing safety-net health providers (such as community health centers) to deliver PrEP, and undertake extensive social marketing to promote PrEP.⁹²

With funding from a local foundation and pro bono support from marketing experts, a sub-committee of the Chicago PrEP Working Group developed a citywide social marketing campaign to support PrEP uptake. Launched in February 2016, the campaign includes major buys on city buses and subways, appears in 15 bars, and also has a major digital presence. A second wave of the campaign is planned for the summer of 2016.

In some settings, the challenge is not to encourage existing providers to increase their



efforts on PrEP but rather to create programs for PrEP where none previously existed. Facing the possibility that those most in need of PrEP—low-income people without health insurance—might be unable to obtain it, the Fulton County health department in Atlanta created its own PrEP clinic in 2015 (see Fulton County profile).

Black AIDS
Institute
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What's
PEP
do
with it?



Making PrEP Real in Black America: The Perspective of People Taking PrEP

The Institute interviewed several people currently taking PrEP. The perspectives of people who take PrEP are undoubtedly as diverse as any other group, but a number of common themes emerged.

PrEP is intended for HIV-uninfected individuals, with the aim of keeping them HIV free. While people diagnosed with a chronic disease like HIV get used to multiple doctor visits each year and daily medication, these activities are out of the ordinary for most healthy people, especially those who are young.

Having a provider you can trust—one with whom you are able to talk openly about sex and ask questions you might have about PrEP—is essential. In many parts of the U.S.—and even in pockets of cities where PrEP is being prioritized—there is frequently misinformation or a complete lack of information about what PrEP is and where one can get it. To the extent they know about it, many people view PrEP as a “gay drug,” although many Black gay and bisexual men still don’t have sufficient information about PrEP.

Awareness of PrEP has grown in Black communities, but the timing and extent of this awareness can depend on one’s proximity to community sources of information. For example, those working in public health or on LGBT issues often heard about PrEP even before the first trial results were released. Especially over the last year, PrEP has become a topic of discussion in

some social networks in Black America, although this is less true for Black women than for gay and bisexual men. In a number of cases, having someone in your friendship network who is open about taking PrEP can be an important prompt to consider taking PrEP yourself.

PrEP has had a powerful effect on the lives of many people who take it. In particular, PrEP relieves much of the anxiety that often surrounds sexual decision-making. Especially for Black gay and bisexual men, who read medical coverage of their one-in-two odds of acquiring HIV, PrEP means that an HIV diagnosis no longer feels inevitable. Many people find that taking PrEP increases their sexual autonomy and makes sex more pleasurable. For uninfected women who are in a relationship with an HIV-positive partner, PrEP offers the possibility of conception without the risk of acquiring HIV.

Some people who take PrEP confront stigma or judgmental attitudes within their social networks. PrEP users report that over time the stigma associated with PrEP use has lessened, especially as more and more people in their social networks opt to take Truvada.

Many PrEP consumers have thoughts about how best to promote PrEP. In particular, holistic approaches that emphasize healthy living and decision-making are preferred over those that focus solely on HIV. Visiting the doctor on a regular basis invites conversations between patients and providers regarding other health issues.

A Consumer's Perspective: Markea Cushion

A certified nurse's assistant, Markea Cushion lives near Atlanta. For three and a half years, she has been in a relationship with an HIV-positive man who is now her fiancé. Her physician never conducted a sexual history with her, and even after she disclosed her serodiscordant relationship did not advise her that PrEP was an option.

"I started seeing a lot of things about PrEP, in magazines and such," Cushion said. "It still wasn't clear to me, and it seemed costly. I tried reading up on it, but there wasn't much information around about PrEP at the time. I asked one of my fiancé's case managers about PrEP, and he told me it was a pill you could take every day to decrease your risk of getting infected. If my fiancé and I were to have unprotected sex or

if the condom breaks it decreases the chance of transmission.

"Then I saw a brochure that said Fulton County was going to offer PrEP to people who wanted it. I thought, 'Wow!' So I gave the PrEP line a call and set up an appointment. They gave me information about the pill and allowed me to ask any questions. I asked them how long I had to take PrEP, and they said it was basically up to me how long I took it but that I'd need to take the pill every day as long as I was on the medicine. They did an HIV test, and they also tested my kidneys."

Cushion started PrEP in late 2015, and she has found that the regimen has been easy to manage. "I was already taking medicine every day, so it goes right along with my routine," she said.



"I feel safer now with PrEP. I normally wear protection all the time [during sexual intercourse], but having a pill and knowing it increases my protection makes me feel a little safer if I loosen up." Meanwhile, her fiancé is happy with her choice, "as it means we can have a normal sex life."

She is concerned

that young women don't seem to be knowledgeable about PrEP. "Women of color are getting HIV," she said. "We need to make them aware. I heard someone in the waiting room at the Health Department say they think PrEP is just for gay people. But if it can save your life, then you should take it!"

A Consumer's Perspective: Noel Gordon

A 24-year-old gay man working in Washington, D.C., at the Human Rights Campaign, the nation's largest LGBT human rights organization, Gordon first heard about PrEP three years ago. After taking an online quiz that suggested that PrEP was something he should talk to his provider about, he approached his physician.

"My provider is a gay man, and he was in some ways the best person

to talk to about PrEP," Gordon said. "Having a welcoming provider was the key to my starting PrEP."

"When thinking about PrEP, I first started from the perspective of my personal risk, as my own risk profile weighed heavily on me. I am Black, and I have sex with men, many of whom are Black men. I know what the prevalence rates are for Black men."

After deciding to start PrEP, Gordon experienced no



resistance from his friends. “I don’t keep people who would stigmatize me as my friends. I always talk about PrEP from a first-person perspective and don’t make sweeping generalizations about who ought to be on PrEP. In terms of dating, I faced a few comments in the beginning [on dating sites], but I don’t encounter those anymore. I think it has to do with the growing acceptance of PrEP.”

Gordon thinks taking PrEP has had an important impact on his life. “In a world where so much is out of my control as a Black gay man, PrEP allows me to take control of my sexual health and live my sexual life as I want,” he said.

“I don’t have to justify myself to anyone. It’s one of the few things I have power over.

“When I first came out, it seems the trajectory for my life was that I would inevitably seroconvert and die a horrible death. But I no longer feel that I am destined to be a statistic.”

Among gay men, especially those of his generation, Gordon has found that PrEP has lowered, if not completely removed, the cultural divide between HIV-positive and HIV-negative men. “Before PrEP many gay and bisexual men swore off ever being intimate with a man who was living with HIV. PrEP has all but

eliminated that concern.”

Gordon also thinks PrEP has had broader health benefits for Black gay and bisexual men.

“Because PrEP requires you to consistently be in care and see your health care provider, it has allowed more opportunities to have constructive conversations with our doctors about something other than STDs.”

Gordon has some concerns, however, with the ways that PrEP is sometimes promoted or delivered. “There’s still a lot of misinformation among young Black gay and bisexual men about what PrEP is and isn’t. Many of these men are disconnected from the places where

they could get accurate information. They’re less likely to have health insurance, less likely to have a doctor.

“[When it comes to promoting PrEP, it is worth remembering that] Black gay and bisexual men don’t live their lives in a vacuum. They are experiencing a host of issues, such as family rejection, religious intolerance, incarceration, police harassment and bullying in schools. Approaching Black gay and bisexual men solely around HIV just infuriates us. Thus far, we’ve talked about PrEP in a silo. We need to talk about how PrEP improves your life rather than just how it prevents you from becoming a vector of disease.”

A Consumer’s Perspective: Blake Rowley

Blake Rowley began taking PrEP in 2011, when he worked at Boston’s Fenway Health, which is committed to healthy lives for LGBT people. He now lives in Washington, D.C., where he works as a technical assistance provider for the National Association of State and Territorial AIDS Directors, focusing on improving programming for Black men who have sex with men.

For Rowley, the decision to take PrEP was not especially complicated. “If there was an option to take a pill to prevent HIV and maximize my sexual pleasure, I thought I should probably take it,” he said. “My insurance was going to cover it, so why not do it? Many

people go through mental gymnastics about taking a pill to prevent HIV, but those things really didn’t cross my mind.”

The primary effect of PrEP on Rowley’s sex life was to relieve the anxiety he sometimes had about sex. “PrEP removed the fear of having to think about HIV. Did the person I slept with three weeks ago have HIV?

“Before PrEP, you had always had to negotiate sex. Now with PrEP I put everything on the table. This is what we are going to do, how we are going to do it. I’m not into that whole exploratory thing. I don’t have to negotiate my safety, because my safety is in my control.”

Removing the fear



in sex is one of PrEP’s biggest selling points, he thinks. “We need to have an open conversation about sex that doesn’t placate anyone and doesn’t shame anyone for what they do in bed. In AIDS, Inc., there is this whole condom culture

that arose out of the epidemic in the 1980s and 1990s. Since then, we’ve had fear-based sex, but we are now at a place where we need to talk about having good, pleasurable sex and what that looks like.”

A Consumer's Perspective: Gerald Garth

Three years ago the Outreach Coordinator for the Black AIDS Institute Gerald Garth first heard about PrEP through his work with the Institute. "I knew it was available and could be a really useful option for a lot of people, but I started to realize it could be an option for me," said Garth, who identifies as bisexual and who was having a relationship with an HIV-positive man when he started PrEP in October 2015. "When the guy I was dating disclosed to me he was HIV-positive, that was the first time where I felt like I was not in control of my own health."

Thinking about PrEP as a personal option, Gerald at first hesitated. "I took a moment to assess how my life would change and what would be different if I decided to go on PrEP," he said. "The only change I could come up with was that I would be taking a pill every day."

One challenge Gerald had to overcome after deciding to take PrEP

was finding a health care provider. "When I chose a health care network after moving to Los Angeles in 2015, I had selected a primary care provider but up until this time had only gone to see him for a couple of quick visits. When I raised the issue of PrEP with him, he had no idea what it was. I realized that I was the one educating him about a medical issue!" The doctor recommended that Gerald see someone else. Eventually, Gerald was connected to a PrEP nurse who proved to be terrific.

"What this PrEP nurse has done is work with me as a person outside of just being a client or a patient," Gerald said. "Having that personal element makes such a big difference, especially when an individual is thinking about a life-changing decision. The last thing you want to feel is judged or be made to feel you are just a number or less than a whole person."

At first, Gerald



hesitated about telling people in his social circle that he was taking PrEP. When he began opening up to his friends about PrEP, he discovered that most of them were not well informed about it and many were completely unaware that PrEP existed. "My immediate response was, 'Why aren't there commercials and billboards and signs for a drug that could be so instrumental in stopping the spread of HIV?'" he said.

Gerald reports having experienced

"zero side effects." Thanks to his health insurance through the Institute, his only PrEP-associated costs are \$15 co-pays for a 90-day regimen and a \$10 co-pay for lab tests during his follow-up visits.

Gerald has a message for his peers, especially Black men who have sex with other men. "When you look at the HIV rates in our communities, that should be motivating for young Black men to look at PrEP and to become advocates for our own health."





Making PrEP Real in Black America: The Perspective of Health Providers

While the providers with whom the Institute spoke are passionate about the role of PrEP for their patients, they also acknowledge that many medical professionals are woefully unprepared to aid PrEP uptake in Black communities. Many providers are uncomfortable conducting a sexual history or speaking frankly with their patients about their sex lives; as a result, opportunities to identify patients who could benefit from PrEP are missed. Far too many providers who are asked by their patients about PrEP don't know about it or are hesitant to prescribe it.

Providers say that most patients who enroll in PrEP demonstrate good adherence. The challenge, some providers say, is in getting the individual to the first appointment. In this regard, providers' ability to play their optimal role in scaling up PrEP relies on other partners for educational, awareness and outreach efforts to spread the word about PrEP in communities where HIV risk is high.

Providers need the infrastructure and capacity to deliver PrEP. In addition to being able to see PrEP users on a regular basis, providers also need the time to have unhurried, sensitive discussions with their patients about PrEP. This is often difficult in overburdened clinics or where coverage rules limit reimbursement to brief intervals.

Providers who administer PrEP will need to take account of how patients will pay for the medication and associated clinic visit and lab costs. For clinics that may lack the capacity to handle this on their own, partnering with a

community-based organization may be helpful.

The way PrEP is administered—with quarterly clinic visits required—has the potential to improve health care delivery and enhance the provider-patient relationship. In particular, these periodic visits offer the provider the opportunity to engage patients in discussions about other health issues, and to identify and treat cases of sexually transmitted infections.

A Provider's Perspective: Dr. Theo Hodge

A Washington, D.C., internist with a subspecialty in infectious disease, Dr. Theo Hodge has prescribed PrEP for more than 300 patients in his practice, which emphasizes improving health outcomes for Black gay men.

"My first impression of PrEP is different than what my thoughts are today," Dr. Hodge said. "At first I had trepidation because I feared that people would just pop a pill before a sexual encounter and soon there would be widespread

drug resistance.

"As more and more data came out, with more and more clinical trials, they've basically found that if you take the medication as prescribed you don't get HIV. Over time, my thinking has changed. I now view PrEP through the eyes of someone who has treated so many people with HIV."

Dr. Hodge said many gay men still have no clue about PrEP, but he said that awareness of PrEP has definitely increased, in part because organizations representing Black

gay men began talking a lot about PrEP. He emphasized that he takes a thorough sexual history for all of his patients.

“By the end of 2015, people had at least heard of PrEP,” Dr. Hodge said. “In my practice, most people are open and receptive to information in order to decide if PrEP is right for them. I present PrEP to my patients as a potential tool but something that is not right for everyone.

“When I bring up PrEP now with my patients, most say they’ve heard something about it or their friends have been talking about it. It’s very different talking about PrEP to people under age 30 than to people in their 50s, because younger people haven’t had lots of people die as a result of HIV in their lives. PrEP is easier to get across to young people than condoms.”

Results from people receiving PrEP in Dr. Hodge’s practice have been excellent, with strong adherence, few side effects and no signs of drug resistance. “Once an individual makes the decision to take PrEP, adherence is usually good,” he said. “It is actually now becoming a ‘thing’ to be on PrEP within some social networks.”

From a physician’s standpoint, one of the great benefits of the PrEP regimen is that patients receive periodic health monitoring when they return to get a refill on their medications. “Having people come back on a regular basis makes me a better steward in terms of monitoring their health,” Dr. Hodge said. “That makes a difference. It gives me an opportunity to educate people about sexually transmitted



infections and allows me to engage in dialogue on a more frequent basis.”

Among his patients on PrEP, Dr. Hodge has not detected major stigma as a deterrent to uptake, although he says that community perceptions about PrEP have evolved. “Black gay men account for a disproportionate share of new HIV

infections,” he said. “The community has become more aware and more open [about PrEP as a possible way to improve Black gay men’s health].”

Dr. Hodge urges that a national campaign be mounted to promote PrEP. “If Drake started talking about PrEP it would make a real difference,” he said.

A Provider’s Perspective: Shannon Weber

Shannon Weber—director of HIVE, a San Francisco organization dedicated to reproductive and sexual wellness for people affected by HIV—is disturbed that so few women are taking PrEP.

In collaboration with Project Inform, HIVE convened a focus group of largely Black women to talk about PrEP. “The women in the focus group were really angry they didn’t know about PrEP,” Weber said. “Here we are in the Bay Area, where we have the largest PrEP implementation outside New York,

and of the women in the focus group only two had heard about PrEP, and they learned about it from their gay friends. These women were incredulous that a pill exists that can prevent HIV infection but they weren’t being offered it by their providers.”

Weber thinks part of the challenge in scaling up PrEP for women has to do with some of the early trial results, which initially found little or no efficacy among women due to poor adherence. “When the iPrEx results came out, it was super exciting and we saw



PrEP as a potential tool for risk reduction. But then there was a shift in the conversation, with people suggesting that

PrEP might not work for women. When the results focused on adherence, the conversation began suggesting that women

were the problem. We continue not to see a lot of women on PrEP because we haven't created a safe space for women in this conversation."

Weber's organization has created a specific niche in San Francisco offering PrEP during pregnancy, sometimes referred to as "PrEPception." For uninfected women who

are in a relationship with an HIV-positive man, HIVE's program offers an option for those who wish to conceive without risking HIV infection.

"We've seen that HIV is a third party in many [serodiscordant] relationships," Weber said. "Having the choice of PrEP helps shift that dynamic. It can make the [HIV-positive] man

feel less guilty and helps the woman feel more empowered. PrEP is truly woman-controlled."

Weber sees PrEP not only as a key HIV-prevention breakthrough for the individual, but also as a tool that could unite different communities. "There is a huge opportunity with PrEP for gay men and women to come together to learn from

each other," she said. "A lot of gay men are being called Truvada whores for taking PrEP, but women have been called whores for a long time. In the Black community, PrEP is a chance for gay men, bi men, women, men who have sex with men to really come together to talk about what it is going to take to end HIV transmission."

A Provider's Perspective: Dr. Leo Moore

An HIV doctor with the Veteran's Administration, Dr. Leo Moore has prescribed PrEP to about 50 patients within the VA system of greater Los Angeles. Some of his patients started on PrEP after Dr. Moore discussed the option with them, while others came to him seeking PrEP.

"The first thing I look at is the individual's actual risk for HIV," Dr. Moore said. "This involves a one-on-one conversation about sex, how often they have it, who they are having sex with, and what kind of sex they are having."

Before prescribing PrEP, Dr. Moore discusses adherence issues, asking patients if they have ever taken medication on a daily basis. "Just because a person has never taken a medication daily doesn't mean they won't be adherent," he said. "Lots of people are taking multivitamins every day, and so a lot of people are open to taking medication once a day."

Dr. Moore regards the emergence of PrEP as an important breakthrough in HIV

prevention. "We know that while condoms work for certain people they don't work for everyone," he said. "I know from my conversations with other Black gay men and my patients that a lot of people aren't using them. When I think about ways to protect my patients who primarily bottom, PrEP seemed to me like it would be a great deal."

Dr. Moore has seen excellent adherence among his patients on PrEP. None of his patients on PrEP have complained about side effects, nor have his patients taking PrEP experienced "slut shaming" or other PrEP-related stigma.

Ensuring that a patient's Truvada prescription can be covered is an important focus in Dr. Moore's practice. "We look at our options to make sure the patient can afford it," he said. "Thankfully there are lots of options to make sure people can get it covered."

Dr. Moore called for a concerted effort to educate Black gay men about PrEP. "There needs to be a shift in the ways in which we are advertising



PrEP. Some of the advertisements I've seen don't speak to men of color. But we know the epidemic is largely in men of color. We need a brain shift to develop ad campaigns and messages that are focused on the people who present the greatest need.

"In order to reach Black gay men, we need to think about their whole health and not only about their sexual health. We need to put PrEP on the same level as getting your other kinds of preventive screenings, make it more about holistic health and keeping yourself fit

and healthy and making smart choices. It needs to be about more than, 'Don't get HIV, use PrEP.'

"A lot of Black gay men are thinking about much more than the risk of HIV. If you think about the Black Lives Matter movement, a lot of Black gay men are focused on what is happening in our country and finding ways to bridge HIV with the other disparities happening in our country. They are focused not just on health disparities but on social disparities, mass incarceration and other problems facing us."

A Provider's Perspective: Dr. David Malebranche

A longtime provider of HIV care in Atlanta and at the University of Pennsylvania, Dr. David Malebranche is a physician at the Cobb County detention center in Marietta, a suburb of Atlanta. As a physician treating HIV infection, Dr. Malebranche had prescribed Truvada as part of antiretroviral regimens for years.

When the iPrEx results were first reported in 2010, he was initially unimpressed. "The reduction in risk with 4,000 men who have sex with men was 40% or so," he said. "It wasn't a home run. My thought was, maybe PrEP would be good to use with condoms, but we need something better.

"In 2014, I saw a big increase in demand for PrEP. That had a lot to do with the subsequent studies. When you teased out the study results, it became crystal clear. Among people who took Truvada every day, no one got HIV. I became more convinced, and there seemed to be a cultural shift between 2014 and 2015."

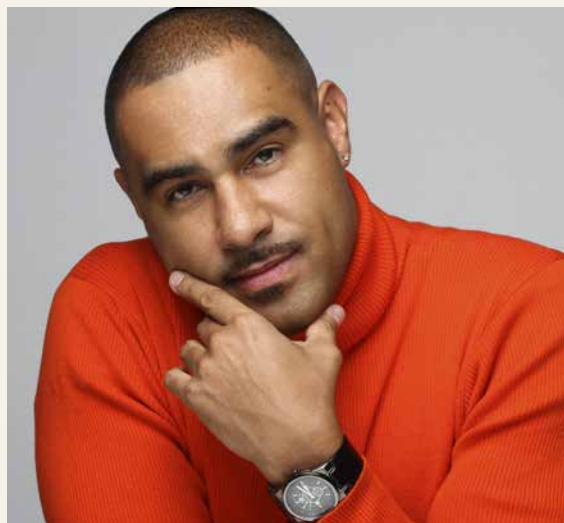
During his 12 years as a physician, Dr. Malebranche recognized that people weren't regularly using condoms. "We need to stop trying to condemn people for having sex without condoms," he said. "We need to stop being Judge Judy. If patients

are empowered in their sexual health and want to add PrEP to their arsenal to protect themselves, this is a good thing."

While PrEP advocacy, especially among young Black gay men, has grown, Dr. Malebranche said the "rate-limiting step [for PrEP scale-up] has always been the medical community. This is in spite of the science. If you look at condoms, they are associated with an 80% reduction in new infections at a population level. Here [with PrEP] you have a biomedical intervention that if taken as prescribed is 100% effective. Why wouldn't you discuss that with your patients? But the medical community is often rather conservative.

"The way health care is delivered, in brief 15-minute slots, is not conducive to having nuanced discussions about PrEP. Providers usually aren't good at taking sexual histories and doing sexual risk assessments. If you have a practice that relies on you to turn out patients, when are you going to have time to have a balanced discussion about PrEP?"

As a way around some of the systemic challenges in the health care system, Dr. Malebranche said clinics might link with community-based patient navigators



who refer people to appropriate providers. Another approach is to have PrEP-specific clinics or to have a PrEP clinic one afternoon a week at a larger clinic. "So many Black men who have sex with men have come in [to their primary care doctor] and told them they wanted to get PrEP, only to have their doctor tell them it doesn't work or they'll get bone or kidney disease. Those barriers have come up constantly."

Financial barriers also pose challenges. "There are ways you can get Truvada if you are broke or uninsured," Dr. Malebranche said. "The problem is that most of these options only cover the medication itself. People who go on PrEP need to be checked a month later and then every three to four months after that, and

that's where a lot of the additional costs come in."

To help Black patients adhere to PrEP, a holistic approach is needed. "A lot of people think they are doing LGBT health, but they don't focus on how LGBT experiences are informed by cultural, racial and ethnic differences. As providers, we sometimes don't want to look at ourselves and at what role we are playing. What does it mean for someone to come to a clinic and not see anyone who looks or acts like them? The big question for many clinics is whether they are in the role of social services—mental health, housing, education, insurance. If PrEP isn't fitting into the lives of our patients, we need to step back and take a look at the larger picture."





PrEP: The Next Frontier

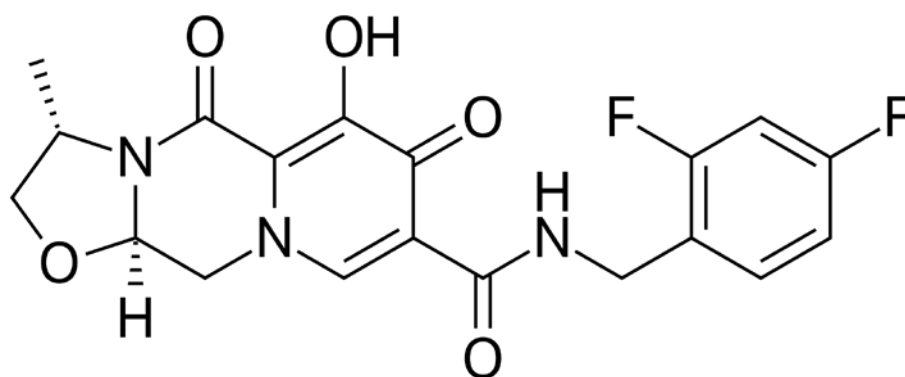
Even as efforts are made to scale up use of Truvada for HIV prevention, researchers are continuing to investigate new approaches to PrEP. In particular, ongoing research focuses on the development and evaluation of long-acting antiretroviral agents that may allow for less frequent dosing for PrEP. There are hopes of developing injectable PrEP regimens that would need to be taken only every several weeks rather than daily. The hope is that injectable, long-acting PrEP might improve adherence among those who find taking a daily pill difficult.

Multiple approaches to the development of injectable, long-acting PrEP are being explored, but many hopes are presently focused on the integrase inhibitor cabotegravir. One Phase II study of injections every 12 weeks of

cabotegravir found higher than anticipated reports of pain associated with the injection, although about three out of four study participants said they would like to continue taking cabotegravir as PrEP should it eventually be approved.⁹³

One area of concern for researchers has to do with the so-called “tail” of injected antiretrovirals. Some of the drugs being studied can still be detected six months after the injection. The persistence of the drug in the body raises concerns regarding the possible development of drug resistance among individuals who seroconvert after they have stopped using PrEP.⁹⁴

Multiple research efforts pertaining to the development of injectable, long-acting antiretrovirals are continuing.⁹⁵





Scaling Up PrEP in Black America: Recommendations for Action

To leverage the potential of PrEP to turn the tide against HIV/AIDS in Black America, urgent action is needed. All stakeholders—Black communities, policy makers, funders, public health leaders, health care providers and the private sector—will need to do their part to scale up PrEP in Black America.

The recommendations below offer a blueprint for leveraging PrEP to lay the foundation to end the epidemic in Black America:

Invest in smart, focused community education and awareness campaigns.

The CDC, state and local health departments, community organizations and other key stakeholders should support educational campaigns that speak directly to Black communities and individuals about PrEP. These campaigns will need simultaneously to encourage Black Americans to talk to their providers about sex and sexual health and to help Black Americans understand the availability and benefits of PrEP. Black communities themselves should be involved in the planning and execution of these campaigns, which need to speak to Black Americans in meaningful, culturally appropriate ways. Awareness campaigns should engage and leverage opinion leaders in Black communities, such as churches, celebrities and political leaders, to increase awareness about PrEP, highlight its benefits and diminish the stigma associated with PrEP.

Educate providers about PrEP and motivate them to undertake sexual histories and recommend PrEP for patients who could benefit from it.

The CDC, state and local public health agencies, professional medical societies and medical schools and providers of continuing medical education should collaborate to integrate PrEP education and training into existing educational programs and opportunities for physicians, including in-service trainings. Given the time pressures that many clinicians face, efforts are needed to develop quick references that aid physicians in conducting a sexual health screening and answering questions about PrEP (e.g., side effects). Particular initiatives are required to increase the capacity of physicians and other health care providers to provide culturally appropriate services to the groups in Black America that need PrEP the most, including gay and bisexual men, women, young people and transgender women.

Adapt delivery systems to facilitate rapid PrEP uptake and strong adherence among PrEP users.

Heeding the results of HPTN 073, clinical settings need to adapt to the needs and preferences of key groups in Black America who need PrEP the most. Through use of client-centered counseling and other approaches,

providers need to serve the whole person, situating PrEP within a broader effort to promote sexual health and taking account of life issues their patients experience beyond the risk of acquiring HIV. Clinical settings should offer navigation services to clients seeking to start and maintain PrEP use, third-party payers should ensure that PrEP-related navigation and counseling services are reimbursable, and the CDC's capacity-building program should develop and implement training programs for navigators. Specific efforts are needed to integrate holistic PrEP services in community health centers in majority-Black neighborhoods. To expand the universe of providers capable of prescribing PrEP, states should explore the use of public health standing orders to allow physician assistants, nurses, or other appropriate health personnel to prescribe PrEP and monitor PrEP use.

Remove financial barriers to PrEP use.

States that have yet to do so should expand their Medicaid program, as allowed under the ACA. Leveraging Medicaid expansion, the federal government should work with Southern states to expand the range of delivery sites where low-income people may receive PrEP and other health services. To maximize the reach and impact of its important patient-assistance programs, Gilead should intensify its efforts to ensure that providers, community organizations and patients have ready access to information about the company's patient-assistance and co-pay-assistance initiatives. The CDC should establish a funding mechanism, modeled on the AIDS Drug Assistance Program, to cover non-drug-related out-of-pocket costs (e.g., physician visits, lab costs) for patients with limited incomes, and the President and Congress should ensure sufficient funding for this program.

Implement specific measures to increase PrEP uptake among Black cisgender and transgender women.

The CDC, state and local health departments, and community organizations should implement outreach, advertisements, and other awareness initiatives to highlight PrEP as an option for Black cisgender and transgender women. The CDC should clarify its PrEP guidance for cisgender

and transgender women to help state and local health departments, health care providers, navigators and community organizations to prioritize their outreach and awareness efforts. As only eight states currently allow minors to consent on their own to preventive services, policy change is urgently needed to enable adolescents to have ready access to PrEP-related education, support and service delivery.

Strengthen the ability of PrEP programs to optimize STI control.

The CDC should expedite its exploration, currently underway, of policy changes to require laboratory screening for STIs every three months for people receiving PrEP. Fully leveraging the STI control potential of the PrEP protocol will also contribute to the reduction in new HIV infections in Black communities, as HIV vulnerability in Black America is closely tied to high background prevalence of STIs.

Ensure the involvement of Black America in a robust PrEP research effort.

Although evidence is more than sufficient to warrant urgent efforts to bring PrEP to scale now, additional implementation research is needed to identify and document best practices in PrEP uptake and adherence in Black communities. Additional research to document and clarify the benefits of PrEP among transgender women is essential. The National Institutes of Health should provide strong support for continued research on new PrEP approaches, including the use of other antiretroviral compounds and long-acting, injectable PrEP regimens, taking steps to ensure sufficient enrollment of Black participants in clinical trials.



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Glossary

Antiretroviral therapy (ART): Treatment for HIV infection that uses medicines that suppress replication of the virus.

Acute HIV infection: The period, typically two to four weeks, immediately following infection with HIV, when viral load is typically much higher than it is during chronic infection.

Bone density: The strength and durability of an individual's bones.

CDC: The Center for Disease Control and Prevention, the federal agency primarily responsible for the prevention of HIV and other diseases and health conditions.

Clinical trial: A highly regulated procedure for determining the safety and/or effectiveness of a new medicine, vaccine, or therapy, by giving the new agent to participants under strictly controlled conditions.

Creatinine: A common marker used by healthcare professionals to check the health of an individual's kidneys.

Demonstration project: A project designed to look at the impact in a specific setting of new methods of service delivery, coverage of new types of service, new technology, and new payment approaches on beneficiaries, providers, and/or health plans.

Drug Resistance: The reduced effectiveness of a drug over time.

Emtricitabine: A medicine from the nucleoside reverse transcriptase inhibitor (NRTI) class of antiretrovirals, used for the treatment of HIV infection in adults and, in combination with tenofovir, for the prevention of HIV in uninfected individuals.

Human immunodeficiency virus (HIV): A human retrovirus that weakens the body's immune system and, if untreated, leads in most cases to severe illness, disability, and death.

Intracellular concentration: The amount of a drug that can be observed inside of a cell.

IPERGAY: A clinical trial in France and

Canada that enrolled gay and bisexual men and transgender women who have sex with men who were at high risk of HIV infection. Participants in the study took pre-exposure prophylaxis (PrEP) before and after sex rather than daily.

iPrEx (Pre-exposure Prophylaxis Initiative): The first major trial of PrEP in humans to produce meaningful results. The trial was conducted in North and South America among gay and bisexual men and transgender women.

Men who have sex with men (MSM): Men who have sexual contact with other men, regardless of whether or not they also have sex with women or have a personal or social gay or bisexual identity. This concept also includes men who self-identify as heterosexual but have sex with other men.

Medication adherence: Taking one's medications as prescribed.

NHAS: The National HIV/AIDS Strategy for the United States. NHAS is the nation's comprehensive, coordinated HIV/AIDS roadmap with clear and measurable targets to be achieved by 2020.

On-demand PrEP: Taking PrEP based on potential exposure event rather than daily use (see IPERGAY).

Post-exposure prophylaxis (PEP): The use of antiretroviral medicines after exposure or possible exposure to HIV to reduce the risk of acquiring HIV. The exposure may be occupational, as in a needle-stick injury, or non-occupational, as in the case of sexual exposure or the sharing of needles during injection drug use.

Pre-exposure prophylaxis (PrEP): The use of antiretroviral medicines by an HIV-uninfected person to reduce the risk of acquiring HIV infection.

PrEPception: Use of PrEP to help a serodiscordant couple reduce the risk of HIV transmission when trying to conceive a child.

Prevalence: The proportion of people with

a particular condition in a given population at a given time.

PROUD: A PrEP demonstration project conducted in England among gay and bisexual men and transgender women who attended sexual health clinics in England.

Risk compensation: The adjustment of personal behavior in response to the perceived level of risk (e.g., becoming less careful when one feels more protected).

STI: Infections that are transmitted from one person to another during sexual contact.

Seroadaptive behaviors: Preventive strategies that take into account the HIV status of the individuals having sex (e.g., the decision by an HIV-uninfected individual to have receptive intercourse only with individuals they believe to be HIV-uninfected).

Serodiscordant relationship: A relationship in which one partner is HIV-positive and the other is HIV-negative.

Serosorting: Attempting to have sex only or primarily with individuals with your own serostatus.

Stigma: A pattern of prejudice, discounting, discrediting, and/or discrimination directed at people perceived to have or be associated with a particular circumstance, quality, condition, or status.

Tenofovir: An antiretroviral medication (tenofovir disoproxil fumarate) used to prevent and treat HIV and to treat chronic hepatitis B.

Transgender: A person whose gender identity differs from the one assigned to them at birth.

Truvada: A fixed-dose combination of two antiretroviral drugs used for the treatment of HIV/AIDS. The two drugs that make up Truvada are tenofovir disoproxil fumarate and emtricitabine.

TasP: The use of ART to reduce the risk of HIV transmission.



Key PrEP Resources

For Consumers

AIDS.gov: PrEP information page, www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/preexposure-prophylaxis

AVAC: Global Advocacy for HIV Prevention, www.avac.org/ht/d/sp/i/262/pid/262

Black AIDS Institute: www.blackaids.org

HIVE: PleasePrepMe: A number of short video interviews on PrEP use in different populations, access, knowledge, how to talk about risk and more, www.hiveonline.org/prep-implementation

My PrEP Experience: Real stories from real people who adopted PrEP for prevention in the U.S., www.myprepexperience.blogspot.com

NMAC PrEP for Life: www.nmac.org/prepareforlife

PrEP 101 from Callen-Lorde Health Center: www.youtube.com/playlist?list=PLJ2r321aYEpy6ADJ8axpxLoq8LJuOpEwF

PrEP Facts Facebook Group: Rethinking HIV Prevention and sex. www.facebook.com/groups/PrEPFacts

PrEP Provider Locator: Find a provider, www.PrEPLocator.org

PrEP Watch: Information and resources on gaining access to PrEP, www.prepwatch.org

Project Inform: Videos, publications and resources, www.projectinform.org/prep

Truvada Coupon: HelpRX, www.helprx.info/Truvada-discounts-coupons

Truvada for PrEP Medication Assistance Program: www.gilead.com

U.S. Centers for Disease Control and Prevention: Questions and answers about PrEP including guidance for how to use PrEP and some of the study, www.cdc.gov/hiv/prevention/research/prep

For Providers

Clinical Consultation Center PreEline: 855-488-7737. Consultation telephone service open 11 a.m.–6 p.m. EST, 8 a.m.–3 p.m. PST, www.nccc.ucsf.edu/2014/09/29/introducing-the-ccc-prepline/

Training Information and Resources: AIDS and Education Training Center, www.aidsetc.org

For Policy Makers

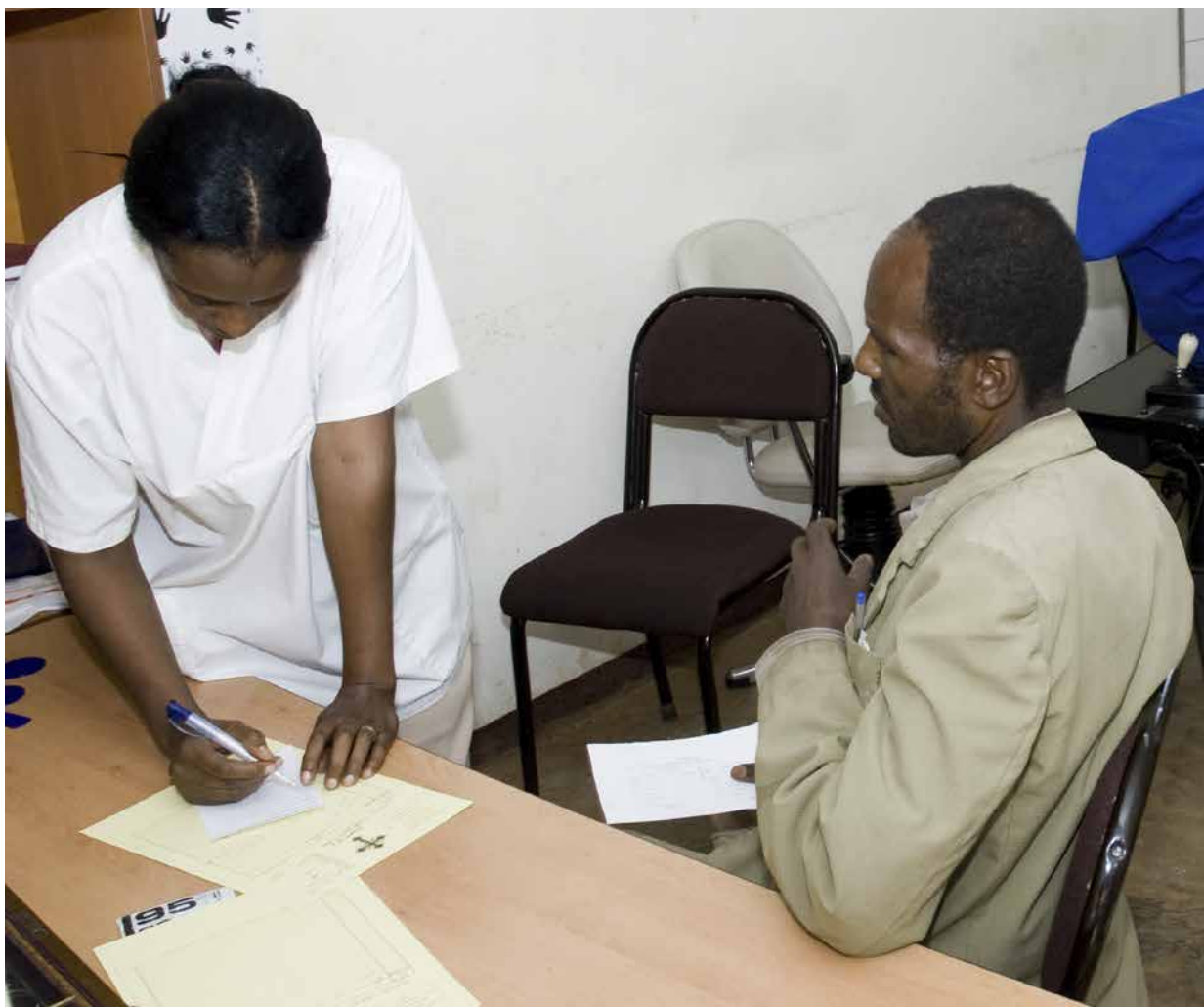
HIV Pre-Exposure Prophylaxis for Health Departments Supporting Implementation: A course to increase the capacity of health departments and their funded programs/providers to implement PrEP services in combination with other evidence-based HIV prevention interventions and public health strategies in order to reduce HIV transmission, www.chbt.org/prep.html

Implementing PrEP for HIV Prevention: State-wide Initiatives and Provider Experiences: Information regarding several state health department initiatives to promote and support the wider use of PrEP for HIV prevention for high-risk individuals who seek care in health centers, AIDS service organizations and other health care and community-based organizations, www.aidsetc.org/resource/implementing-prep-hiv-prevention-state-wide-initiatives-and-provider-experiences

PrEP Implementation Science: State-of-the-art and research agenda, www.jiasociety.org/index.php/jias/article/view/20527/html

Promoting PrEP Utilization in Washington: Drug assistance program for HIV-negative people who have risk factors, www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIVAIDS/HIVCareClientServices/PrEPDAP

WHO Guidance for PrEP Implementation: ww.who.int/hiv/pub/prep/prep-supplement-jias-2015/en/



How to Get Started with PrEP

You and your doctor will decide if PrEP is right for you based on an open discussion about your risk of getting HIV-1 infection through sex. If you decide that PrEP is right for you, you will have to take an HIV test to be sure you are HIV-negative before starting on PrEP. Tell your doctor about all of your medical conditions and about any medicines you are taking. If you are a woman, talk to your doctor about how Truvada for PrEP can affect pregnancy and breastfeeding.

Your doctor will test to make sure you are HIV-negative.

You cannot take Truvada for PrEP if you already have HIV or if you do not know your HIV status.

The HIV test might not detect a recent infection. If you have flu-like symptoms, you could have recently become infected with HIV. You cannot take PrEP if you have symptoms of a new HIV infection. Tell your doctor if you had a flu-like illness within the last month before starting PrEP or at any time while taking the medicine. Symptoms of HIV infection include:

- Feeling tired
- Fever, sweating at night
- Rash, vomiting, diarrhea
- Joint or muscle aches, headache, sore throat
- Enlarged lymph nodes in your neck or groin

HIV testing is the only way to know if you have HIV. Retesting every three months is recommended for people who are at high risk and for anyone currently on PrEP.

If you do become HIV-positive, you will need

to start Anti-Retroviral therapy (ARV). PrEP alone is not sufficient treatment for HIV and could lead to resistance.

Do you have any health problems? Are you taking any medicines? Tell your doctor.

Be sure to let your doctor know about all of your health problems including:

- Kidney problems or kidney dialysis treatment
- Bone problems
- Liver problems
- Hepatitis B virus infection. Your doctor may test for hepatitis B before prescribing PrEP
- If you are pregnant or plan to become pregnant

PrEP may interact with other medicines. Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

Keep a list of your medicines and show it to doctors and pharmacists when you get a new medicine.

Tell your doctor if you are pregnant, plan to become pregnant, are breastfeeding (nursing), or plan to breastfeed.

It is not known if PrEP can harm your unborn baby. Tell your doctor if you become pregnant while taking PrEP. Your doctor will decide if you should keep taking PrEP or not.

Pregnancy Registry: A pregnancy registry collects information about your health and the health of your baby. There is a pregnancy registry for women who take medicines to prevent HIV-1 during pregnancy. For more information about the registry and how it works, talk to your healthcare provider.

Do not breastfeed. The medicines in Truvada can pass to your baby in breast milk. If you become HIV-1 positive, HIV-1 can be passed to the baby in breast milk.

Find a Truvada for PrEP Provider

If you are ready to talk to a healthcare provider about Truvada for PrEP, this tool can help you find one.

Find a Truvada for PrEP healthcare provider near you by using the PrEP Provider Locator <https://PrEPLocator.org>

Financial Assistance for PrEP

If you have questions about how to pay for your prescription, your doctor may be able to help you find and apply for assistance. There are several programs that could help, including some that may be available from your insurance company.

If you have insurance:

The Gilead Advancing Access co-pay coupon card may help eligible patients save on their Truvada for PrEP co-pay. It is not available for patients who are enrolled in any state- or federally-funded prescription drug program, such as Medicare Part D and Medicaid. Patients in the Medicare part D prescription coverage gap (the “donut hole”) do not qualify.

For more information, or to see if you are eligible, see the full terms and conditions at www.GileadAdvancingAccess.com or call 800-226-2056.

Enrollees will have to answer a few questions to confirm eligibility; restrictions apply. The program is subject to change at any time.

If you need assistance or do not have insurance:

Gilead’s U.S. Medication Assistance Program provides assistance to eligible, HIV-negative people in the U.S. who need financial assistance to pay for Truvada for PrEP. To find out if you are eligible, call 800-226-2056 between 9 a.m. and 8 p.m. EST. You can also download the enrollment form to fill out with your healthcare provider.

Help may also be available through these government programs.

Medicare and Medicaid, 877-267-2323
Veterans Affairs, 877-222-8387

HIV PrEP Framework

Federal efforts to scale up prep and reduce new HIV infections

The federal government’s comprehensive framework to improve access to pre-exposure prophylaxis (HIV PrEP Framework) serves as a blueprint for federal activities to scale up PrEP

as a strategy to prevent HIV transmission and reduce new infections in the United States.

PrEP is a highly effective prevention strategy for people who are at very high risk of getting HIV. It involves taking a pill every day. Daily PrEP can reduce the risk of HIV by more than 90 percent. Given the strength of the scientific evidence and its ability to reduce new HIV infections, the National HIV/AIDS Strategy recognizes the importance of PrEP. It calls for full access to comprehensive PrEP services for those for whom it is appropriate and desired, along with support for medication adherence for those using PrEP. The indicators used to monitor annual progress toward achieving the goals of the Strategy now includes a measure of the number of persons prescribed PrEP. It calls for an increase of at least 500 percent, from the baseline of 9,375 persons in 2014 to 56,250 persons in 2020.

The HIV PrEP Framework is a model that highlights what is currently being done across federal agencies and programs and what additional activities need to be implemented to improve the awareness, use and monitoring of PrEP and decrease new HIV infections among those persons at very high risk who aim to take personal responsibility for protecting their health.

There has been concerted effort across the federal government to scale up PrEP. Subject matter experts in HIV prevention and care from 12 Federal departments and agencies developed the HIV PrEP Framework under the direction of the National HIV/AIDS Strategy Federal Interagency Workgroup. These experts provided information about major PrEP-related activities that were planned or already underway within their agencies and programs, reviewed these activities and identified new opportunities for collaboration, and defined the essential components of a comprehensive effort to increase the effective use of PrEP.

The resulting HIV PrEP Framework has seven essential components describing the major elements of a comprehensive federal response. The Framework allows for these activities and the roles of each department and agency to be easily described, opportunities for collaboration and potential duplication to be discovered, and potential gaps to be identified and addressed going forward. The essential components of the HIV PrEP Framework are:

- Policy, Practice Guidelines and Program Guidance

- Communications to the General Public and Persons at Increased Risk of Acquiring or Transmitting HIV
- Training and Technical Assistance to Health Care Providers, Grantees and Others
- PrEP Programs to Improve Access, Use and Adherence
- Monitoring and Evaluation
- Research
- Finance

Federal departments and agencies have implemented a wide range of activities related to all seven of the essential components of the HIV PrEP Framework. More than 60 PrEP-related activities were identified. Some of these actions, as well as the development of the HIV PrEP Framework itself, were previously committed to as part of the National HIV/AIDS Strategy Federal Action Plan. Other actions represent additional activities that complement and go beyond those in the Federal Action Plan.

Potential gaps

An important feature of the HIV PrEP Framework is that it helps identify potential gaps in federal efforts to scale up PrEP. The list of selected activities for each of the essential components reveals the following potential gaps and areas for further improvement:

Increase provider training to improve:

- Willingness of providers to engage patients about PrEP
- Ability of providers to better identify and screen people who may benefit from PrEP

Improve PrEP uptake by:

- Expanding PrEP navigation services
- Addressing disparities across race/ethnicity and age groups

Reduce barriers to PrEP medication by:

- Working to Increase the number of effective PrEP formulations that are approved for use (researching, reviewing and approving other formulations of PrEP including generic medications)
- Addressing the cost of PrEP, which can be a barrier for those without insurance or with high copays



- Supporting work to assess whether the strength of the evidence suggests that PrEP should be a covered preventive service

In addition, the HIV PrEP Framework suggests potential gaps in Federal efforts to support PrEP adherence among persons who are prescribed PrEP and to expand implementation research to identify best practices and evidencebased models.

Future directions

A broad array of PrEP-related activities are currently underway across the Federal government. These activities address all seven of the essential components in the HIV PrEP Framework. These activities and other existing data show, however, that there is a continued need to improve these efforts and their reach in order to ensure that our national goals are achieved and that all persons for whom PrEP is appropriate and desired are able to obtain it and use it effectively.

This will require that future PrEP-related efforts must address concerns and issues at the consumer, provider and system levels. Specifically, interventions must be developed to make it easier for atrisk populations to obtain and adhere to PrEP and to support the efforts of health care providers to identify patients who may benefit from PrEP, assess their need and readiness to take PrEP, and support their adherence to daily medication use. In addition, in developing future activities it is important

to continue to solicit input and feedback from stakeholders, grantees and consumers.

Successfully increasing access to and use of PrEP is a key element for reducing new HIV infections. Indeed, if combined with HIV care and treatment that leads to increasing the number of people living with HIV who are virally suppressed, as many as 185,000 infections could be prevented by 2020.

The HIV PrEP Framework will be maintained and used for planning and assessing progress by the HHS Office of HIV/AIDS and Infectious Disease Policy in coordination with the White House Office of National AIDS Policy as part of ongoing work of the National HIV/AIDS Strategy Federal Interagency Workgroup (cochaired by OHAIDP and ONAP).

NHAS Federal Interagency Workgroup— Prep Workgroup

A time-limited subgroup of the National HIV/AIDS Strategy Federal Interagency Workgroup was established in early 2016 to develop the HIV PrEP Framework.

The PrEP Workgroup was comprised of representatives with knowledge of PrEP and related department/agency activities and plans from the following:

- The White House
Office of National AIDS Policy (ONAP)
Office of National Drug Control Policy (ONDCP)
- Department of Defense (DOD)
- Department of Health and Human Services (HHS)
Office of the Assistant Secretary for Health
Office of HIV/AIDS and Infectious Disease Policy (OHAIDP)
Office on Women's Health (OWH)
Centers for Disease Control and Prevention (CDC)
Centers for Medicare and Medicaid Services (CMS)
Health Resources and Services Administration (HRSA)
Indian Health Service (IHS)
National Institutes of Health (NIH)
Substance Abuse and Mental Health Services Administration (SAMHSA)
- Department of Veterans Affairs (VA)



References

1. HIV Surveillance Report 2014. 2015, Centers for Disease Control and Prevention: Atlanta.
2. HIV Among African American Gay and Bisexual Men. 2016, Centers for Disease Control and Prevention: Atlanta.
3. QuickFacts: United States. 2016; Available from: <http://www.census.gov/quickfacts/table/PST045215/00>.
4. HIV Surveillance Report, 2014. 2015, Centers for Disease Control and Prevention: Atlanta.
5. National HIV/AIDS Strategy for the United States: Updated to 2020. 2015, White House: Washington DC.
6. Bradley, H., et al. Increased HIV Viral Suppression Among US Adults Receiving Medical Care, 2009-2013 (Abstract 53). in Conference on Retroviruses and Opportunistic Infections. 2016. Boston.
7. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States 2014, US Public Health Service, Department of Health and Human Services: Atlanta.
8. Pre-exposure Prophylaxis (PrEP) for HIV Prevention. 2014, Centers for Disease Control and Prevention: Atlanta.
9. About Truvada for a PrEP Indication. Available from: <http://www.truvadapreprems.com/pre-exposure-prophylaxis>.
10. Schackman, B. Cost-Effectiveness of PrEP. in Conference on Retroviruses and Opportunistic Infections. 2012. London.
11. Smith, D., et al., Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Preexposure Prophylaxis to Prevent HIV Acquisition -- United States, 2015. MMWR, 2015. 64: p. 1291-1295.
12. Lifetime Risk of HIV Diagnosis in the United States. 2016, Centers for Disease Control and Prevention: Atlanta.
13. McMahon, J., et al., Oral Pre-Exposure Prophylaxis (PrEP) for Prevention of HIV in Serodiscordant Heterosexual Couples in the United States: Opportunities and Challenges. AIDS Patient Care STDs, 2014. 28: p. 462-474.
14. Back of the Line: The state of AIDS Among Black Gay Men in America. 2012, Black AIDS Institute: Los Angeles.
15. Patel, P., et al., Estimating per-act HIV transmission risk: a systematic review. AIDS, 2014. 28: p. 1509-1519.
16. Millett, G., et al., Explaining disparities in HIV infection among black and white men who have sex with men: a meta-analysis of HIV risk behaviors. AIDS, 2007. 21: p. 2083-2091.
17. HIV Among Women. 2015; Available from: <http://www.cdc.gov/hiv/group/gender/women/>.
18. HIV Among Youth. 2015; Available from: <http://www.cdc.gov/hiv/group/age/youth/index.html>.
19. Baral, S., et al., Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. Lancet Infect Dis, 2013. 13: p. 214-222.
20. Herbst, J., et al., Estimating HIV prevalence and risk behaviors of transgender persons in the United States: a systematic review. AIDS Behav, 2008. 12: p. 1-17.
21. Trans Populations and HIV: Time to End the Neglect. 2014, amfAR, The Foundation for AIDS Research: Washington DC.
22. HIV Surveillance in Urban and Nonurban Areas. 2016, Centers for Disease Control and Prevention: Atlanta.
23. Cairns, G., At least 25,000 people in the US may now be using PrEP, in Aidsmap. 2015.
24. Flash, C., et al., Two Years of Truvada for Pre-Exposure Prophylaxis Utilization in the United States. J Int AIDS Soc, 2014. 17 (Supp. 3): p. 19730.
25. Laufer, F., et al., Vital Signs: Increased Medicaid Prescriptions for Preexposure Prophylaxis Against HIV Infection -- New York, 2012-2015. MMWR, 2015. 64: p. 1296-1301.
26. New York State HIV/AIDS Surveillance Annual Report. 2015, New York State Department of Health AIDS Institute: Albany.
27. Liu, A., et al. Adherence, sexual behavior and HIV/STI incidence among men who have sex with men (MSM) and transgender women (TGW) in the US PrEP Demonstration (Demo) Project. in 8th International

AIDS Society Conference on HIV Pathogenesis, Treatment & Prevention. 2015. Vancouver.

28. New York State HIV/AIDS Surveillance Annual Report: For Cases Diagnosed Through December 2013. 2015, New York State Department of Health, AIDS Institute: Albany.

29. Yaylali, E., et al. Impact of Improving HIV Care and Treatment and Initiating PrEP in the United States, 2015-2020 (Abstract 1051). in Conference on Retroviruses and Opportunistic Infections. 2016. Boston.

30. Grant, R., et al. Scale-up of Preexposure Prophylaxis in San Francisco to Impact HIV Incidence (Abstract 25). in Conference on Retroviruses and Opportunistic Infections. 2015. Seattle.

31. Kessler, J., et al., Evaluating the impact of prioritization of antiretroviral pre-exposure prophylaxis in New York City. AIDS (Epub ahead of print), 2014.

32. Grant, R., et al., Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men. *New Eng J Med*, 2010. 363: p. 2587-2599.

33. Baeten, J., et al., Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women. *New Eng J Med*, 2012. 367: p. 399-410.

34. Thigpen, M., et al., Antiretroviral Preexposure Prophylaxis for Heterosexual HIV Transmission in Botswana. *New Eng J Med*, 2012. 367: p. 423-434.

35. Choopanya, K., et al., Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomized, double-blind, placebo-controlled phase 3 trial. *Lancet*, 2013. 381: p. 2083-2090.

36. Deutsch, M., et al., HIV pre-exposure prophylaxis in transgender women: a subgroup analysis of the iPrEx trial. *Lancet HIV*, 2015. 2: p. e512-519.

37. Weller, S. and K. Davis-Beaty, Condom effectiveness in reducing heterosexual HIV transmission. *The Cochrane Collaboration*, 2011.

38. Grant, R., et al., Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. *Lancet Infect Dis*, 2014. 14: p. 820-829.

39. Molina, J., et al. On Demand PrEP with Oral TDF-FTC in MSM: Results of the ANRS Ipergay Trial. in Conference on Retroviruses and Opportunistic Infections. 2015. Seattle.

40. Borges, A., et al. Antiretrovirals, Fractures, and Osteonecrosis in a Large European HIV Cohort (Abstract 44). in Conference on Retroviruses and Opportunistic Infections. 2016. Boston

41. Grant, R., et al. Recovery of Bone Mineral Density After Stopping Oral HIV Preexposure Prophylaxis (Abstract 48LB). in Conference on Retroviruses and Opportunistic Infections. 2016. Boston.

42. McCormack, S., et al., Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. *Lancet*, 2016. 387: p. 53-60.

43. Solomon, M., Changes in renal function associated with oral emtricitabine/tenofovir disoproxil fumarate use for HIV pre-exposure prophylaxis. *AIDS* (online), 2014.

44. Lehman, D., et al., Risk of Drug Resistance Among Persons Acquiring HIV Within a Randomized Clinical Trial of Single- or Dual-Agent Preexposure Prophylaxis. *J Infect Dis*, 2015. 211: p. 1211-1218.

45. Weis, J., et al., Preexposure prophylaxis-selected drug resistance decays rapidly after drug cessation. *AIDS*, 2016. 30: p. 31-35.

46. Grant, R. and T. Liegler, Weighing the Risk of Drug Resistance With the Benefits of HIV Preexposure Prophylaxis. *J Infect Dis* (Epub ahead of print), 2015.

47. Volk, J., et al., No New Infections with Increasing Use of Preexposure Prophylaxis in a Clinical Setting. *Clin Infect Dis* (online), 2015.

48. McCormack, S. and D. Dunn. Pragmatic Open-Label Randomized Trial of Preexposure Prophylaxis: The PROUD Study. in Conference on Retroviruses and Opportunistic Infections. 2015. Seattle.

49. Hosek, S., et al. ATN 110: An HIV PrEP Demonstration Project and Safety Study for Young Men Who Have Sex with Men in the United States. in 8th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention. 2015. Vancouver.

50. Mannheimer, S., et al. Feasibility of Intermittent PrEP Among US MSM: Data from the Harlem Site. in 8th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention. 2015. Vancouver.

51. Knox, D., et al. HIV-1 Infection with Multiclass Resistance Despite Preexposure Prophylaxis (PrEP) (Abstract 169aLB). in Conference on Retroviruses and Opportunistic Infections. 2016. Boston.

52. Crary, D., Truvada, HIV Prevention Drug, Divides Gay Community, in *Huffington Post*. 2016 (Feb. 2).

53. Burrell, J., 'Truvada Whore' Stigma Endures Among Doctors and LGBTs, in *The Advocate*. 2014 (Aug. 11).

54. Peoples, K., Did AIDS Healthcare Foundation Just Change Its Tune on PrEP?, in *HIV Plus*. 2015 (Aug. 19).

55. Sexually Transmitted Disease Surveillance 2014. 2015, Centers for Disease Control and Prevention: Atlanta.

56. Golub, S., et al. STI Data from Community-Based PrEP Implementation Suggest Changes to CDC Guidelines (Abstract 869). in Conference on Retroviruses and Opportunistic Infections. 2016. Boston.

57. Cohen, S., et al. Quarterly STI Screening Optimizes STI Detection Among PrEP Users in the Demo Project. in Conference on Retroviruses and Opportunistic Infections. 2016. Boston.

58. Health Disparities in HIV/AIDS, Viral Hepatitis, STDs and TB: African Americans/Blacks. 2014, Centers for Disease Control and Prevention: Atlanta.

59. Millett, G., et al., Greater Risk for HIV Infection of Black Men Who Have Sex With Men: A Critical Literature Review. *Am J Pub Health*, 2006. 96: p. 1007-1019.

60. HA, G., How to Have Sex in a New Epidemic of STIs, in *The Body*. 2016: New York.

61. Blumenthal, J. and R. Haubrich, Risk Compensation in PrEP: An Old Debate Emerges Yet Again. *Virtual Mentor*, 2014. 16: p. 909-915.

62. Marcus, J., et al., No Evidence of Sexual Risk

Compensation in the iPrEX Trial of Daily Oral HIV Preexposure Prophylaxis. *PLoS One*, 2013. 8: p. e81997.

63. Hojilla, J., et al., Sexual Behavior, Risk Compensation, and HIV Prevention Strategies Among Participants in the San Francisco PrEP Demonstration Project: A Qualitative Analysis of Counseling Notes. *AIDS and Behavior* (Epub ahead of print), 2015.

64. Sagaon-Teyssier, L., et al., Uptake of PrEP and condom and sexual risk behavior among MSM during the ANRS IPERGAY trial. *AIDS Care* (epub ahead of print), 2016.

65. Hare, B. Delivery of PrEP: From Evidence to Practice. in *Conference on Retroviruses and Opportunistic Infections*. 2016. Boston.

66. HIV Infection Risk, Prevention and Testing Behaviors among Men Who Have Sex with Men -- National HIV Behavioral Surveillance, 20 U.S. Cities, 2014. 2016, Centers for Disease Control and Prevention: Atlanta.

67. Eaton, L., et al., Minimal Awareness and Stalled Uptake of Pre-Exposure Prophylaxis (PrEP) Among at Risk, HIV-Negative, Black Men Who Have Sex with Men. *AIDS Patient Care STDs*, 2015. 29: p. 423-429.

68. Kwakwa, H., et al. Underestimation of HIV risk associated with reduced openness to HIV pre-exposure prophylaxis among African Americans. in *20th International AIDS Conference*. 2014. Melbourne.

69. Perez-Figueroa, R., et al., Acceptability of PrEP Uptake Among Racially/Ethnically Diverse Young Men Who Have Sex with Men: The P18 Study. *AIDS Educ Prev*, 2015. 27: p. 112-125.

70. Franks, J., et al. Patterns of Sex and PrEP in Harlem MSM: A qualitative study (HPTN 067). in *8th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention*. 2015. Vancouver.

71. Auerbach, J., et al., Knowledge, Attitudes, and Likelihood of Pre-Exposure Prophylaxis (PrEP) Use Among US Women at Risk of Acquiring HIV. *AIDS Patient Care STDs*, 2015. 29: p. 102-110.

72. When We Know Better, We Do Better: The State of AIDS in Black America. 2015, Black AIDS Institute: Los Angeles.

73. Mayer, K., et al., Antiretroviral pre-exposure prophylaxis implementation in the United States: a work in progress. *Journal International AIDS Society*, 2015. 18 (Supp. 3): p. 19980.

74. Goodman, D., et al., Regional and Racial Variation in Primary Care and the Quality of care among Medicare Beneficiaries. 2010, Dartmouth Institute for Health Policy & Clinical Practice.

75. Highleyman, L. Many more people could benefit from HIV PrEP but not enough doctors are aware, says CDC. 2015 (Dec. 1); Available from: <http://www.aidsmap.com/Many-more-people-could-benefit-from-HIV-PrEP-but-not-enough-doctors-are-aware-says-CDC/page/3018425/>.

76. Krakower, D., et al., HIV Providers' Perceived Barriers and Facilitators to Implementing Pre-Exposure Prophylaxis in Care Settings: A Qualitative Study. *AIDS Behav*, 2014. 18: p. 1712-1721.

77. Osborn, D., Doctors' Embrace, Knowledge of PrEP Seen as Obstacle to Uptake, in *Gay City News*. 2015 (Nov. 27): New York.

78. Nicholson, L. Obama: 20 million Americans

insured thanks to 'Obamacare'. 2016 (Mar 3); Available from: <http://www.aidsmap.com/Many-more-people-could-benefit-from-HIV-PrEP-but-not-enough-doctors-are-aware-says-CDC/page/3018425/>.

79. Key Facts about the Uninsured Population. 2015, Henry J. Kaiser Family Foundation.

80. Millett, G., et al., Comparisons of disparities and risks of HIV infection in black and other men who have sex with men in Canada, UK, and USA: a meta-analysis. *Lancet*, 2012. 380: p. 341-348.

81. Auerbach, J. and T. Hoppe, Beyond "getting drugs into bodies": social science perspectives on pre-exposure prophylaxis for HIV. *Journal International AIDS Society*, 2015. 18 (Supp. 3): p. 19983.

82. Jain, S., D. Krakower, and K. Mayer, The Transition from Postexposure Prophylaxis to Preexposure Prophylaxis: An Emerging Opportunity for Biobehavioral HIV Prevention. *CID*, 2015. 60 (Supp. 3) (S200-2004).

83. Caceres, C., et al., The promises and challenges of pre-exposure prophylaxis as part of the emerging paradigm of combination HIV prevention. *Journal International AIDS Society*, 2015. 18 (Supp. 3): p. 19949.

84. Corales, R. PrEP in the Real World: Implementation of PrEP in a medium-sized city Community Health Clinic. in *8th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention*. 2015. Vancouver.

85. Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations. 2014, World Health Organization: Geneva.

86. Marquez, S. and S. Cahill, Transgender Women and Pre-Exposure Prophylaxis for HIV Prevention. 2016, National Center for Innovation in HIV Care: Boston.

87. Poteat, T. HIV in Transgender Populations: Charted and Uncharted Waters. in *Conference on Retroviruses and Opportunistic Infections*. 2016. Boston.

88. Smith, J. and C. Medalia, Health Insurance Coverage in the United States, 2013. 2014, U.S. Census Bureau: Washington DC.

89. Eaton, L., et al., The role of stigma and medical mistrust in the routine health care engagement of black men who have sex with men. *Am J Pub Health*, 2015. 105: p. e75-82.

90. Wheeler, D., et al. HPTN 073: PrEP Uptake and Use by Black Men Who Have Sex With Men in 3 US Cities (Abstract 883LB). in *Conference on Retroviruses and Opportunistic Infections*. 2016. Boston.

91. 2015 Blueprint to End AIDS. 2015, New York State Department of Health: Albany.

92. Pickeett, J. PREP4Love: Transmitting Desire Across Chicago. in *Conference on Retroviruses and Opportunistic Infections*. 2016. Boston.

93. Markowitz, M., et al. ECLARI: Phase 2A Safety and PK Study of Cabotegravir LA in HIV-Uninfected Men (Abstract 106). in *Conference on Retroviruses and Opportunistic Infections*. 2016. Boston.

94. McGowan, I. Promise and Challenges of Sustained Delivery of PrEP. in *Conference on Retroviruses and Opportunistic Infections*. 2016. Boston.

95. The Years Ahead in Biomedical HIV Prevention Research. 2016, AVAC: New York.



Black AIDS Institute

Founded in May of 1999, the Black AIDS Institute is the only national HIV/AIDS think tank focused exclusively on Black people. The Institute's Mission is to stop the AIDS pandemic in Black communities by engaging and mobilizing Black institutions and individuals in efforts to confront HIV.

The Institute interprets public and private sector HIV policies, conducts trainings, offers technical assistance, disseminates information and provides advocacy mobilization from a uniquely and unapologetically Black point of view.

Our motto describes a commitment to self-preservation: "Our People, Our Problem, Our Solution."

African American HIV University

The African American HIV University was developed in 1999 as a structural intervention program intended to change cultural norms and perceptions in the Black community around access to and utilization of HIV prevention services and to strengthen Black organizations' and individuals' capacity to address the HIV/AIDS epidemic in their communities.

AAHU is made up of two colleges. The Science and Treatment College is a four-stage program that raises HIV science and treatment literacy among HIV/AIDS workers and teaches them how to promote high-quality care in HIV/AIDS treatment and prevention, and implement

HIP that leads to better outcomes along the HIV/AIDS treatment cascade and care continuum. Through the program, ASOs develop Black Treatment Advocates Networks to improve treatment outcomes and move toward viral suppression in Black communities.

The Community Mobilization College prepares community-based and AIDS service organizations to engage traditional Black institutions—churches, civil rights and social organizations, political leaders, sororities/fraternities, academia and the media—in local strategies to fight HIV.

Black Treatment Advocates Network

Black Treatment Advocates Network is the only collaboration of its kind, linking Black Americans with HIV into care and treatment, strengthening local and national leadership, connecting influential peers, raising HIV science and treatment literacy in Black communities, and advocating for policy change and research priorities. Each BTAN chapter hosts annual trainings and conducts treatment education, patient navigation, voluntary disclosure and advocacy programming.

Greater Than AIDS

A collaboration between the Black AIDS Institute and the Kaiser Family Foundation, Greater Than AIDS is a national media campaign that increases awareness and encourages

communities to be greater than any challenge ever faced, including HIV/AIDS.

Local Trainings

The Institute hosts pre-conference strategic meetings and post-conference updates in connection with leading national and international HIV/AIDS conferences. In conjunction with AAHU Fellows and local BTAN chapters, the Institute also conducts one-day trainings on groundbreaking HIV/AIDS topics in local communities.

National Webinars

The Institute broadcasts national webinars featuring acclaimed experts on various HIV/AIDS-related topics. Webinars occur each quarter and typically focus on groundbreaking HIV/AIDS science and research updates.

Technical Assistance

The Institute provides customized technical assistance to health departments, ASOs/CBOs and clinical providers to enhance community engagement, improve HIV planning and facilitate linkages between health departments, clinical providers, ASOs/CBOs and people living with HIV and/or at high risk for HIV infection.

U.S. HIV Workforce Survey

The U.S. HIV Workforce Survey assesses the knowledge, attitudes and beliefs of the United States HIV/AIDS workforce.

Developed by the Black AIDS Institute in partnership with industry leaders, researchers and health departments, the survey provides a baseline assessment of what the HIV/AIDS workforce knows about HIV transmission, HIV, biomedical interventions and the National HIV/AIDS Strategy.

Brown Bag Lunch Program

The Brown Bag Lunch Program is a series of monthly train-the-trainer webinars that raise the HIV programming knowledge of participants.

Each webinar is conducted by renowned HIV experts who raise participants' levels of awareness about biomedical research, medical interventions and HIV-related policy, as well as other critical health issues such as STIs and hepatitis C.

Upon completion of the series, participants are better able to develop their own HIV/AIDS programming informed by the latest HIV research and science.



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