



WE HAVE THE TOOLS TO END HIV:
***Benefits, Barriers, and Solutions to Expanded Utilization of
Pre-exposure Prophylaxis (PrEP) in the US Deep South***

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INTRODUCTION

The Southeastern United States has the highest HIV diagnosis rate of any US region.¹ In 2014, more than half of national HIV diagnoses reported were located in the Southern United States,² which accounted for only 38% of the total US population.³ The Deep South (the nine-state region comprised of Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, and Texas) has the highest rate of HIV-related deaths of any US region.⁴ From 2008-2013, 21,308 individuals in these states died from HIV as the underlying cause of death, representing 43% of deaths in the US where HIV was the underlying cause.⁵ In addition, each of the 9 Deep South states had higher death rates from HIV than the US average from 2008-2013.⁶ The Deep South region also

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leads in racial disparities. In 2013, nearly half (48%) of black gay/MSM diagnosed with HIV in the US lived in the Deep South and the HIV diagnosis rate for black women in the region was 37.5 per 100,000 while the rate for white women was 2.6 per 100,000.⁷ The statistics clearly indicate that individuals at risk of HIV infection in the Deep

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South, particularly African American men and women, are among those most in need of effective HIV prevention tools, and may stand to benefit most from the use of innovative new prevention strategies.

Today, one of the most innovative and effective HIV prevention tools available is PrEP (pre-exposure prophylaxis), which refers to the use of antiretroviral medications (which historically have been used as a method of treatment for HIV-positive individuals after diagnosis) by HIV-negative individuals as a means to prevent HIV infection. *Truvada*, a drug created and marketed by Gilead Sciences, is the only approved PrEP medication, and, if taken regularly, has been shown to be an extremely effective method of preventing HIV

¹ Centers for Disease Control and Prevention. HIV Surveillance Report: Diagnoses of HIV Infection in the United States and Dependent Areas, 2014, Table 22; <http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-us.pdf>.

² The US Census Bureau defines the South as including Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, Oklahoma, North Carolina, South Carolina, Tennessee, Texas, Virginia, West Virginia.

³ US Census Bureau. United States Population Growth by Region. 2015;

https://http://www.census.gov/popclock/data_tables.php?component=growth. Accessed October, 2015.

⁴ Reif S, Safley D, McAllaster C, *A CLOSER LOOK: Deep South has the Highest HIV-related Death Rates in the United States*. 2015.

⁵ Reif S, Safley D, Wilson E, Whetten K, *HIV/AIDS in the U.S. Deep South: Trends from 2008-2013*, 2016.

⁶ See Reif, footnote 5.

⁷ See Reif, footnote 5.

transmission.⁸ In the open label extension of the often-cited iPrEx study of PrEP efficacy, none of the men who took *Truvada* at least four times a week contracted HIV.⁹ And in a large study of PrEP users in a Kaiser Permanente Clinical Practice in San Francisco among 657 primarily gay and bi-sexual men, there were no new HIV diagnoses after two and a half years of observation.¹⁰

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In July of 2012, the US Food and Drug Administration (FDA) approved once-daily *Truvada* for PrEP, and in May of 2014, the US Centers for Disease Control and Prevention (CDC) recommended that people at 'substantial risk' should consider PrEP to prevent HIV infection.¹¹ The World Health Organization (WHO) has also recommended PrEP for people at 'substantial risk' of HIV infection.¹²

Despite its remarkable effectiveness at preventing HIV transmission and the positive response with which it has been met by national and international health organizations, use of PrEP as a prevention strategy has been slow to take hold among some at-risk populations.¹³ The CDC estimates that 1.2 million people in the United States have indications for PrEP use based on their substantial risk of acquiring HIV (24.7% of men who have sex with men, 18.5% of persons who inject drugs and .4% of heterosexually active adults.)¹⁴

A number of studies and surveys conducted primarily among vulnerable populations have revealed that barriers to PrEP use continue to exist.

⁸ Grant RM et al. *Preexposure chemoprophylaxis for HIV prevention in men who have sex with men*. *New Engl Jour Med* 363(27):2587-2599, 2010.

⁹ Grant RM et al. *Results of the iPrEx open-label extension (iPrEx OLE) in men and transgender women who have sex with men: PrEP uptake, sexual practices, and HIV incidence*. 20th International AIDS Conference, Melbourne, abstract TUAC0105LB, 2014.

¹⁰ Volk J, Marcus J, Phengrasamy T, Blechinger D, Nguyen D, Follansbee S, Hare C, No New HIV Infections with Increasing Use of HIV Preexposure Prophylaxis in a Clinical Practice Setting. *Clinical Infectious Diseases* 2015; 61(10):1601-3.

¹¹ Liz Highleyman, *Truvada PrEP use rising in United States, especially among men*, *aidsmap.com*, November 7, 2014, <http://www.aidsmap.com/Truvada-PrEP-use-rising-in-United-States-especially-among-men/page/2919654/> (citing Flash C et al. *Two years of Truvada for pre-exposure prophylaxis utilization in the US*. International Congress of Drug Therapy in HIV Infection, abstract P198, Glasgow, 2014.); See also, *Pre-exposure Prophylaxis for the Prevention of HIV Infection in the US-2014: A Clinical Practice Guide*. CDC 2014.

¹² WHO, *Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV*, Sept. 2015, <http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en/>

¹³ See Highleyman, footnote 11.

¹⁴ Centers for Disease Control and Prevention. *Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Preexposure Prophylaxis to Prevent HIV Acquisition—United States, 2015*, *MMWR*. November 27, 2015/ 64(46);1291-1295.

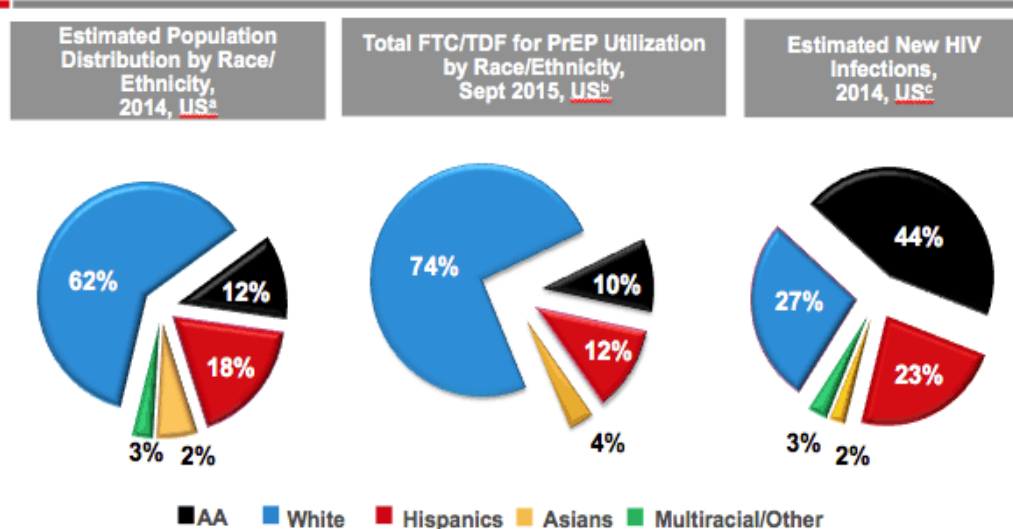
PrEP USAGE BY DEMOGRAPHIC

A recently-released Gilead Sciences survey analyzed retail pharmacy prescriptions and found that PrEP usage has increased 738% from January 2012 to December 2015.¹⁵ Major discrepancies exist between PrEP usage and HIV prevalence among specific demographic groups in the U.S. population. The breakdown of PrEP usage demographically underscores the need to reduce barriers to PrEP utilization for certain populations.

Race & Ethnicity |

The Gilead PrEP analysis revealed significant racial disparities in PrEP utilization. Forty-four percent of those diagnosed with HIV in the US in 2014 were African American, (27% were white, 23% were Hispanic, and 3% were Asian). In contrast, 74% of PrEP users were white; only 10% were African American, and 12% were Hispanic.¹⁶

FTC/TDF for PrEP Utilization Compared With Population and New HIV Infections



FTC/TDF for PrEP use among AA and Hispanics is low relative to the rate of new HIV infections

b. These data represent 43.7% (n=21,463) of unique individuals who have started TVD for PrEP from 2012-3Q2015.

a. <https://www.census.gov/quickfacts/table/PST045215/00>

b. These data represent 43.7% (n=21,463) of unique individuals who have started TVD for PrEP from 2012-3Q2015.

c. Other indicates American Indian or Alaska Native, and Native Hawaiian or other Pacific Islander. CDC. *HIV Surveillance Report*, 2014

¹⁵ Highleyman L, PrEP use exceeds 79,000 in US pharmacy survey, but some groups lagging behind, July 2016; <http://www.aidsmap.com/PrEP-use-exceeds-79000-in-US-pharmacy-survey-but-some-groups-lagging-behind/page/3072084/>.

¹⁶ Bush S et. al., *Racial Characteristics of FTC/TDF for Pre-exposure Prophylaxis (PrEP) Users in the US #2651*, ASM Microbe 2016 / ICAAC 2016, http://www.natap.org/2016/HIV/062216_02.htm.

Gender, Gender Identity |

In 2015, 82% of new PrEP prescriptions were written for men.¹⁷ In 2012, women accounted for 49% of new PrEP prescriptions but by the third quarter of 2015, they accounted for only 11% of new prescriptions.¹⁸ One factor may be that women have less ability to access PrEP, as their OB/GYNs and reproductive health clinics may not be as knowledgeable about PrEP as the sexual health clinics that are serving MSM.¹⁹ Despite this, data suggests that use of PrEP during pregnancy and breastfeeding may protect both mother and baby from HIV infection.²⁰ A recent study in New York City and San Francisco also showed that women frequently chose to use PrEP when it was offered pre-conception and during pregnancy and lactation.²¹

Transgender women are at particularly high risk of HIV infection. Although accurate data is lacking, the CDC acknowledges high HIV prevalence among transgender women and the disparate impact of HIV on African-American transgender women.²² Researchers conducted an analysis of the iPrEx trial to investigate differences in PrEP results among transgender women.²³ The study found that compared with MSM, transgender women more often reported behavior that results in higher rates of HIV transmission, including “transactional sex, receptive anal intercourse without a condom, or five or more partners within the past 3 months.”²⁴ The study also found that while PrEP appears to be successful in preventing HIV transmission for transgender women when consistently used, there are adherence barriers.²⁵

It is worth noting that the majority of US studies related to the efficacy of PrEP and potential barriers to effective PrEP utilization have been conducted among gay men and other men who have sex with men (gay/MSM), since gay/MSM are widely considered most at risk of acquiring HIV and of benefiting from PrEP in the US. Despite the fact that

¹⁷ U.S. PrEP Users Likely Exceeded 80,000 by End of 2015, *poz.com*, July 21, 2016, <https://www.poz.com/article/us-prep-use-likely-80000-end-2015>.

¹⁸ See Bush, Footnote 16.

¹⁹ Highleyman L, PrEP use exceeds 79,000 in US pharmacy survey, but some groups lagging behind, *aidsmap.com*, July 19, 2016, <http://www.aidsmap.com/PrEP-use-exceeds-79000-in-US-pharmacy-survey-but-some-groups-lagging-behind/page/3072084/>.

²⁰ Highleyman L, Study looks at use of PrEP during pregnancy and breastfeeding, *aidsmap.com*, September 1, 2016, <http://www.aidsmap.com/Study-looks-at-use-of-PrEP-during-pregnancy-and-breastfeeding/page/3081236/>.

²¹ Seidman, D. et. Al. Use of HIV pre-exposure prophylaxis during the preconception, antepartum and postpartum periods at two United States Medical Centers, *AmJObstetGynecol* 2016.

²² HIV Among Transgender People, April 2016, <http://www.cdc.gov/hiv/pdf/group/gender/transgender/cdc-hiv-transgender.pdf>.

²³ Deutsch MB et. al. HIV pre-exposure prophylaxis in transgender women: a subgroup analysis of the iPrEx trial. *The Lancet HIV* 2015, 2:512-519.

²⁴ See Deutsch, Footnote 23.

²⁵ See Deutsch, Footnote 23.

certain populations of cisgender women, who account for 20% of all new HIV diagnoses in America, and transgender women are also at high risk of acquiring HIV, US data regarding the efficacy and uptake of PrEP among women is underdeveloped.²⁶ Nonetheless,

...US data regarding the efficacy and uptake of PrEP among women is underdeveloped.

cisgender women who have been surveyed about their knowledge and attitudes towards PrEP had reactions similar to those recorded among gay/MSM, with some expressing initial frustration about their lack of knowledge of the availability of PrEP, and many articulating a willingness to learn more about the drug and an interest in utilizing it as a prevention method if they could gain access to it.²⁷ Furthermore, women surveyed about PrEP expressed many of the same reservations about the drug and identified many of the same potential barriers to widespread utilization that are explored in depth in the section below, including concerns about cost, side-effects, stigma, and potential lack of access due to medical mistrust or other factors.²⁸

Age |

Individuals under the age of 25 make up 22% of new HIV diagnoses overall, with 80% of these being MSM and over half of those being African American.²⁹ Despite this, Gilead found that individuals using PrEP were on average 36 years old³⁰ and only about 8% of those beginning PrEP were under the age of 25.³¹ Though 28% of women using PrEP were under 25, only 11% of the men fit into that category.³² This was comparable across all racial and ethnic groups.

Region of Residence |

In 2014, 51% of new HIV diagnoses occurred in the US South.³³ Although the South has a significant urban epidemic, in 2014, the South had almost three times the number of newly diagnosed people living outside the large urban areas (5183) than all other US regions

²⁶ See Auerbach JD, Kinsky S, Brown G, Charles V. Knowledge, Attitudes, and Likelihood of Pre-Exposure Prophylaxis (PrEP) Use Among US Women at Risk of Acquiring HIV. *AIDS Patient Care and STDs*. 2015;29:12-110.

²⁷ See Auerbach, footnote 26.

²⁸ See Auerbach, footnote 26.

²⁹ Centers for Disease Control and Prevention: HIV Among Youth, April 2016, <http://www.cdc.gov/hiv/pdf/group/age/youth/cdc-hiv-youth.pdf>.

³⁰ Highleyman L, AIDS 2016: San Francisco and New York Lead in PrEP Use, betablog.org, July 20, 2016, <http://betablog.org/aids-2016-san-francisco-new-york-lead-prep-use/>.

³¹ Highleyman L, PrEP use is rising fast in US, but large racial disparities remain, aidsmap.com, June 24, 2016, <http://www.aidsmap.com/PrEP-use-is-rising-fast-in-US-but-large-racial-disparities-remain/page/3065545/>.

³² Highleyman L, AIDS 2016: San Francisco and New York Lead in PrEP Use, betablog.org, July 20, 2016, <http://betablog.org/aids-2016-san-francisco-new-york-lead-prep-use/>.

³³ Centers for Disease Control and Prevention, HIV Surveillance Report: <http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-us.pdf>

combined (1756).³⁴ Gilead's survey data shows that PrEP uptake has primarily been in large US cities and is not wide-spread in smaller urban and rural regions, particularly in the US South. Five states (California, New York, Texas, Florida and Illinois) with large urban epidemics accounted for more than half of all PrEP prescriptions nationwide from 2012 to the third quarter of 2015 according to Gilead's utilization data.³⁵

BARRIERS TO WIDESPREAD PrEP UTILIZATION IN THE SOUTH

Lack of Awareness |

The first and perhaps most prohibitive barrier to widespread PrEP utilization is a simple lack of awareness of the drug's existence among at-risk populations.

In order for PrEP to be effectively employed as an HIV prevention strategy, potential PrEP users must know about it, understand its risks and benefits, and be willing to take it.³⁶ Some studies examining PrEP underutilization have shown that many high-risk individuals who would be excellent candidates for PrEP have not taken it simply because their knowledge about it is limited.³⁷

In one study conducted among young gay/MSM—by far the most high-risk population of any demographic—in 2013, only 27% of study participants reported prior awareness of PrEP.³⁸ A 2014 survey conducted on Manhunt, one of the largest social-networking sites geared towards men who have sex with men, found that only 3.1% of almost 9000 gay/MSM respondents had used PrEP and that “substantial numbers” had not heard of it.³⁹ A 2015 study conducted among young gay/MSM of color found that only 50% of participants were aware of PrEP prior to their participation in the study.⁴⁰ Among participants in this study who did report prior knowledge of PrEP, however, this information was obtained from a variety of sources including the CDC website, Facebook,

³⁴ Centers for Disease Control and Prevention, HIV Surveillance in Urban and Nonurban Areas, <http://www.cdc.gov/hiv/library/slideSets/index.html>.

³⁵ See Highleyman L, Footnote 19.

³⁶ Castel AD, Magnus M, Greenberg AE. Pre-exposure prophylaxis for human immunodeficiency virus: the past, present, and future. *Infect Dis Clin North Am.* 2014; 28:563–583.

³⁷ Krakower D, Mayer KH. What primary care providers need to know about preexposure prophylaxis for HIV prevention: a narrative review. *Ann Intern Med.* 2012; 157:490–497.

³⁸ Bauermeister JA, Meanley S, Pingel E, Soler JH, Harper GW. PrEP awareness and perceived barriers among single young men who have sex with men. *Current HIV Research.* 2013; 11:520.

³⁹ Mayer KH, Oldenburg CE, Novak DS, Krakower DS, Mimiaga MJ. Differences in PrEP knowledge and use in U.S. MSM users of a popular sexual networking site surveyed in August 2013 and January 2014. R4P Conference; A91. 2014 October 28–31; Cape Town, South Africa.

⁴⁰ Perez-Figueroa RE, Kapadia F, Barton SC, Eddy JA, Halkitis PN. ACCEPTABILITY OF PrEP UPTAKE AMONG RACIALLY/ETHNICALLY DIVERSE YOUNG MEN WHO HAVE SEX WITH MEN: THE P18 STUDY. *AIDS Education and Prevention.* 2015; 27:112-125.

television reports/news, information obtained from community health agencies, and friends, and from doing their own, independent research.⁴¹

...awareness of PrEP has been markedly lower among men of color.....

Across existing studies, awareness of PrEP has been markedly lower among men of color, those who are less highly educated, and those whose primary care providers are not aware of the fact that they have sex with men.⁴² Though men with more education or a higher income were much more likely to have heard of PrEP, they were not, according to one report, any more likely to have used it.⁴³ And in a study conducted among at-risk women (primarily African-American women) in six US cities, less than 10% of those surveyed expressed prior knowledge of PrEP as a preventative measure.⁴⁴ Among those high-risk individuals who were not previously aware of PrEP as an HIV prevention strategy, many who participated in studies or surveys about PrEP expressed interest in using it upon learning of its potential for preventing infection.⁴⁵

Although lack of awareness of PrEP among many high-risk populations remains one of the primary barriers to widespread utilization, evidence suggests that in recent years, knowledge of PrEP as a prevention strategy has noticeably increased.⁴⁶ According to data obtained by the CDC through large internet-based surveys of gay, bisexual and other MSM living in the United States (who were recruited via dating apps and websites, social media and gay websites), awareness of PrEP as a prevention strategy increased significantly from 45% in 2012 to 68% in 2015.⁴⁷

⁴¹ See Perez-Figueroa, footnote 40.

⁴² Barash EA, Golden M. Awareness and use of HIV pre-exposure prophylaxis among attendees of a Seattle gay pride event and sexually transmitted disease clinic. *AIDS Patient Care STDS*. 2010; 24:689–691; Mimiaga MJ, Case P, Johnson CV, Safren SA, Mayer KH. Preexposure antiretroviral prophylaxis attitudes in high-risk Boston area men who report having sex with men: Limited knowledge and experience but potential for increased utilization after education. *J Acquir Immune Defic Syndr*. 2009; 50:77–83.

⁴³ Peabody R, Rapid rise in PrEP awareness in US gay men, but only 5% have used PrEP, *aidsmap.com*, March 10, 2016, <http://www.aidsmap.com/Rapid-rise-in-PrEP-awareness-in-US-gay-men-but-only-5-have-used-PrEP/page/3042435/>.

⁴⁴ See Auerbach, footnote 26.

⁴⁵ See Auerbach, footnote 26; See Mimiaga MJ, Case P, Johnson CV, Safren SA, Mayer KH (2009) Preexposure antiretroviral prophylaxis attitudes in high-risk Boston area men who report having sex with men: limited knowledge and experience but potential for increased utilization after education. *J Acquir Immune Defic Syndr* 50: 77-83.

⁴⁶ See Krakower DS, Mimiaga MJ, Rosenberger JG, Novak DS, Mitty JA, White JM, et al. Limited Awareness and Low Immediate Uptake of Pre-Exposure Prophylaxis among Men Who Have Sex with Men Using an Internet Social Networking Site. *PLoS One*. 2012; 7(3):e33119. <http://dx.doi.org/10.1371/journal.pone.0033119>; Mayer KH, Levine K, Grasso C, Krakower DS, Mimiaga M. Recent increases in PrEP utilization among men who have sex with men in a Boston community health center 2011–2014: transition from research to clinical practice. Conference on Retroviruses and Opportunistic Infections (CROI); 2015 February 23–26; Abstract; Seattle, WA.

⁴⁷ Delaney KP et al. *Awareness and Use of PrEP Appear to Be Increasing Among Internet Samples of US MSM*. Conference on Retroviruses and Opportunistic Infections (CROI 2016), Boston. Abstract 889, 2016.

Even as levels of awareness of PrEP are increasing, however, levels of actual PrEP utilization (though also increasing) remain low. The most recent survey regarding PrEP awareness among American gay/MSM conducted by the CDC in 2015, 68% of respondents reported knowledge of the existence of PrEP, and 50% stated that they would be willing to use PrEP (up from 39% in 2012), but less than 5% reported having actually used it in the past twelve months (up from 0.5% in 2012).⁴⁸ Further, rates of PrEP use varied distinctly among respondents based on their location—while 17% of respondents who live in San Francisco reported using PrEP as prevention (along with 11% in Seattle, 12% in New York City, 16% in Washington DC and around 8% in Boston, Philadelphia, Chicago and Los Angeles), only 2% of respondents in rural areas reported doing the same.⁴⁹ This data indicates that even as more individuals become aware of PrEP as a tool for preventing HIV infection, there are other barriers in place, particularly for those who live in smaller cities and more rural parts of the country (like much of the Deep South), that prevent eligible candidates for PrEP from taking advantage of it.

Lack of Access |

For many high-risk individuals who may qualify as good candidates for PrEP, another barrier to utilization of the drug is lack of access. In order to obtain a prescription for PrEP, a prospective user must have ready access to a clinical care provider who is willing to prescribe it, must themselves be willing to discuss PrEP with their provider and be willing to undergo regular check-ups, as well as HIV tests and other lab tests, and must have access to a pharmacy or other location where the medication can be attained. Many individuals who would like to and would benefit from accessing PrEP may be unwilling or unable to take all the steps necessary to obtain access to it.

In numerous studies and surveys conducted among PrEP-eligible populations, concern about access to PrEP was among the most common barriers cited by participants as a reason they might not utilize it.⁵⁰ Many at-risk individuals are not linked to medical care relating to sexual health or otherwise, so the concept of having to visit a medical health professional and undergo medical tests regularly may seem daunting or overly complicated.⁵¹ Similarly, some individuals, whether they are linked to care or not, may simply not want to go through all of the necessary requirements to obtain a PrEP prescription for any number of reasons, which may include general mistrust of medical professionals (more common among people of color), perception (whether accurate or not) that doctors do not want to talk about sexual health and therefore will not initiate these

⁴⁸ See Delaney, footnote 47.

⁴⁹ See Delaney, footnote 47.

⁵⁰ Brooks RA, Kaplan RL, Lieber E, Landovitz RJ, Lee S, Leibowitz AA. Motivators, concerns, and barriers to adoption of preexposure prophylaxis for HIV prevention among gay and bisexual men in HIV-serodiscordant male relationships. *AIDS Care*. 2011; 23:1136-1145.

⁵¹ See Brooks, footnote 50.

conversations, or broader anxiety about/unwillingness to discuss sexual history/practices/needs with a physician.⁵²

Furthermore, some prospective PrEP users may have limited access to the drug because they have limited access to medical care in general (for financial or other reasons), or because they live in an area where there are no nearby PrEP/HIV clinics and no medical providers willing to prescribe PrEP.⁵³

..some prospective PrEP users may have limited access to the drug because they have limited access to medical care in general...

The fact that some medical providers are unwilling to prescribe PrEP or will only prescribe it in limited circumstances can be a severe barrier for many individuals seeking access to PrEP, so it is worth additional consideration. Though general knowledge about and support for PrEP have increased since the FDA approved Truvada and the CDC released the prescribing guidelines, knowledge of PrEP among providers has increased only slightly,⁵⁴ and actual prescribing rates remain relatively low.⁵⁵ In one survey of HIV providers in Washington D.C. and Miami (cities with above-average rates of HIV) regarding their knowledge and attitudes about PrEP and willingness to provide it, 53% of surveyed providers agreed that PrEP is effective as an HIV prevention strategy, but only 17% reported ever prescribing it.⁵⁶ In a subsequent national survey of infectious disease specialists, 74% of those surveyed supported PrEP as an HIV prevention strategy, but only 9% reported ever prescribing it.⁵⁷ An earlier online, cross-sectional survey of generalist and HIV specialist physicians in Massachusetts found that 95% of

⁵² Bernstein KT, Liu KL, Begier EM, Koblin B, Karpati A, et al. (2008) Same-sex attraction disclosure to health care providers among New York City men who have sex with men: implications for HIV testing approaches. *Arch Intern Med* 168: 1458–1464. doi: 10.1001/archinte.168.13.1458; Mimiaga MJ, Goldhammer H, Belanoff C, Tetu AM, Mayer KH (2007) Men who have sex with men: perceptions about sexual risk, HIV and sexually transmitted disease testing, and provider communication. *Sex Transm Dis* 34: 113–119. doi: 10.1097/01.olq.0000225327.13214.bf; Centers for Disease Control, Prevention (1994) HIV prevention practices of primary-care physicians—United States, 1992. *MMWR Morb Mortal Wkly Rep* 42: 988–992; Loeb DF, Lee RS, Binswanger IA, Ellison MC, Aagaard EM (2011) Patient, resident physician, and visit factors associated with documentation of sexual history in the outpatient setting. *J Gen Intern Med* 26: 887–893. doi: 10.1007/s11606-011-1711-z; Montano DE, Phillips WR, Kasprzyk D, Greek A (2008) STD/HIV prevention practices among primary care clinicians: risk assessment, prevention counseling, and testing. *Sex Transm Dis* 35: 154–166. doi: 10.1097/olq.0b013e3181574d97; Golub SA, Gamarel KE, Rendina HJ, Surace A, Lelutiu-Weinberger CL. From Efficacy to Effectiveness: Facilitators and Barriers to PrEP Acceptability and Motivations for Adherence among MSM and Transgender Women in New York City. *AIDS patient care and STDs*. 2013; 27:248-254.

⁵³ See <http://www.prepwatch.org/policies-and-programs/local-programs/> for a list of state-by-state PrEP providers.

⁵⁴ White JM, Mimiaga MJ, Krakower DS, et al. Evolution of Massachusetts physician attitudes, knowledge, and experience regarding the use of antiretrovirals for HIV prevention. *AIDS Patient Care STDs*. 2012; 26:395–405.

⁵⁵ Rawlings K, Mera R, Pechonika A, et al. *Status of Truvada (TVD) for HIV Pre-Exposure Prophylaxis (PrEP) in the United States: An Early Drug Utilization Analysis*. Denver, CO: ICAAC; 2013.

⁵⁶ Castel AD, Feaster DJ, Tang W, et al. Understanding HIV Care Provider Attitudes Regarding Intentions to Prescribe PrEP. *J AIDS Journal of Acquired Immune Deficiency Syndromes*. 2015; 70:520-528.

⁵⁷ Karris MY, Beekmann SE, Mehta SR, et al. Are we prepped for preexposure prophylaxis (PrEP)? Provider opinions on the real-world use of PrEP in the United States and Canada. *Clin Infect Dis*. 2014; 58:704–712.

participants said they would be willing to prescribe PrEP in theory, but only 4% had actually prescribed it in the past.⁵⁸

Providers who have not prescribed PrEP mentioned a laundry list of reasons as to why, including concerns over issues such as drug-related toxicities, the potential development of drug resistance, potential for funds to be diverted from behavioral HIV programs to biomedical programs, concerns over the efficacy data, and fear that PrEP could increase HIV risk behavior.⁵⁹ A 2013 survey of HIV health care providers in the United States found that drug resistance, risk compensation, and adherence were respondents' top 3 concerns, and drug cost was the fourth most common concern.⁶⁰ Other studies have also found that one of the most common perceived barriers to PrEP provision among infectious disease physicians was the belief that the protocol required for effective utilization of the drug is too time-consuming.⁶¹

Studies have shown that while HIV incidence is higher among African American MSM, this group tends to report less risky sexual behavior and drug use than white men.⁶² As such, many of the prescribing guidelines and risk factors will not apply to this group, leading to less access to PrEP for a high risk demographic.⁶³ “Clinicians may need to consider other factors besides risk behaviors, such as HIV incidence and prevalence in sub-groups of their communities, when considering prescribing PrEP.”⁶⁴

Additional surveys of HIV providers across America have indicated that many are hesitant/unwilling to prescribe PrEP based on previous encounters with HIV-positive patients who did not adhere to life-sustaining treatment and with HIV-negative patients who did not adhere to post-exposure prophylaxis regimens despite an awareness that they were at high-risk for HIV acquisition.⁶⁵ There seems to be a belief among many HIV providers, perhaps shaped by these past experiences, that adherence to PrEP would be low even if they were to prescribe it.⁶⁶ Additionally, lack of specific requests for PrEP by patients are perceived by providers as proof of patient ambivalence and community apathy regarding PrEP, which functions as a sort of self-fulfilling prophecy, confirming in their

⁵⁸ White JM, Mimiaga MJ, Krakower DS, Mayer KH. Evolution of Massachusetts physician attitudes, knowledge, and experience regarding the use of antiretrovirals for HIV prevention. *AIDS Patient Care STDS*. 2012; 26:395–405.

⁵⁹ See White, footnote 58.

⁶⁰ Tellalian D, Maznavi K, Bredeek UF, et al. Pre-exposure prophylaxis (PrEP) for HIV infection: results of a survey of HIV healthcare providers evaluating their knowledge, attitudes, and prescribing practices. *AIDS Patient Care STDS*. 2013; 27:553–559.

⁶¹ See Karris, footnote 57.

⁶² Hoots B. Willingness to Take, Use of, and Indications for Pre-exposure Prophylaxis Among Men Who Have Sex With Men—20 US Cities, 2014, *Clin Infect Dis*. 2016 Sep 1; 63(5): 672-677.

⁶³ See Hoots, Footnote 62.

⁶⁴ See Hoots, Footnote 62.

⁶⁵ Krakower D, Ware N, Mitty JA, Maloney K, Mayer KH. HIV Providers' Perceived Barriers and Facilitators to Implementing Pre-exposure Prophylaxis in Care Settings: A Qualitative Study. *AIDS and Behavior*. 2014; 18:1712-1721.

⁶⁶ See Krakower, footnote 65.

minds the already present notion that PrEP is ineffective or irrelevant.⁶⁷ Despite these misconceptions, however, most HIV providers believed that PrEP is efficacious if used consistently and that patient requests would motivate them to prescribe it.⁶⁸ The providers also suggested they would be more willing to prescribe PrEP if they knew their colleagues were also doing so.⁶⁹

Importantly, significant numbers of HIV providers have expressed that they are not in a position to prescribe PrEP since the majority of patients seen by HIV providers are HIV positive and therefore not candidates for PrEP. They also believe that, as a matter of general principle, primary care providers are better situated to make such decisions with their patients.⁷⁰ Surveyed primary care providers suggested the opposite: it is their belief that HIV specialists are better situated to prescribe PrEP.⁷¹ These differing opinions among categories of providers about who is in the best position to prescribe PrEP to eligible patients create a problematic “purview paradox,” which could limit the accessibility of PrEP for a number of prospective users.⁷²

Cost |

The cost of PrEP is another barrier that may inhibit those individuals who could most benefit from PrEP from gaining access to it. A prescription for Truvada for PrEP costs roughly \$1,300 per month.⁷³ The good news is that Medicaid and private insurance do generally cover the costs of PrEP. For those who are not privately insured, Gilead also offers a prescription assistance program that helps cover the costs of Truvada prescriptions for those eligible.⁷⁴ Gilead also offers a co-pay assistance program to help meet the needs of individuals who are privately insured and who may not be able to afford the co-pays associated with a Truvada prescription.⁷⁵ Furthermore, a small number of community-based organizations in some American cities, like Healthy San Francisco in San Francisco, which seek to make healthcare available to uninsured residents of the city will cover the cost of a PrEP prescription for individuals interested in utilizing PrEP as an HIV prevention strategy but who could not otherwise afford the medication.⁷⁶

Despite the fact that some financial assistance options are available to prospective PrEP users to help cover the costs of the drug, the fact remains for many individuals, particular

⁶⁷ See Krakower, footnote 65.

⁶⁸ See Krakower, footnote 65.

⁶⁹ See Krakower, footnote 65.

⁷⁰ See Krakower, footnote 65.

⁷¹ See Krakower, footnote 65.

⁷² See Krakower, footnote 65.

⁷³ *The Questions About PrEP*, prepfacts.org, <http://men.prepfacts.org/the-questions/>.

⁷⁴ Gilead, *Truvada for PrEP Medication Assistance Program*, <http://www.gilead.com/responsibility/us-patient-access/truvada%20for%20prep%20medication%20assistance%20program>.

⁷⁵ Gilead, *Paying for Truvada*, <http://www.truvada.com/truvada-patient-assistance>.

⁷⁶ See Healthy San Francisco, <http://healthysanfrancisco.org/>.

uninsured individuals, gaining access to PrEP can still be a costly and, in some cases, prohibitively complicated, process. Successful utilization of PrEP requires a number of actions beyond just taking the daily medication—including frequent doctor visits and regular HIV tests and other lab tests—all of which involve additional expenses that may or may not be covered by insurance or other financial assistance programs.

The costs associated with PrEP are often cited by potential PrEP users as one of the most significant barriers to meaningful PrEP utilization.⁷⁷ In one study conducted among high-risk gay/MSM, 80% of participants indicated that they would be likely to use PrEP if it was provided free of charge, but 89.3% reported that they would be unlikely to use PrEP if it cost money out of pocket each month.⁷⁸ In another study, 416 high-risk gay/MSM were provided with educational counseling regarding rates of HIV transmission and the effectiveness of PrEP as a prophylactic medicine.⁷⁹ Each participant was then presented for HIV testing and was offered a prescription for PrEP.⁸⁰ Of the 416, only 2 participants (both of whom had private insurance) accepted the prescription and eventually accessed PrEP.⁸¹ When the remaining participants were surveyed regarding why they did not accept the PrEP prescription that was offered to them, 48% reported cost as a major barrier.⁸²

Private insurance and Medicaid generally provide coverage for PrEP⁸³ and Gilead's Co-pay Assistance Program (CAP) provides assistance for insurance co-pays up to \$3,600 per year.⁸⁴ Most Southern states, however, have not expanded their Medicaid programs under the Affordable Care Act (ACA.) People with incomes below 100% of the federal poverty level remain uninsured because they fall into the so-called coverage gap. They earn too little to qualify for ACA insurance subsidies and they aren't covered by Medicaid because they live in a state without an expanded Medicaid program. The Kaiser Family

...90% of people in the
[Medicaid] coverage gap live
in the South...

⁷⁷ Brooks RA, Kaplan RL, Lieber E, Landovitz RJ, Lee S, Leibowitz AA. Motivators, concerns, and barriers to adoption of preexposure prophylaxis for HIV prevention among gay and bisexual men in HIV-serodiscordant male relationships. *AIDS Care*. 2011; 23:1136-1145; Bauermeister JA, Meanley S, Pingel E, Soler JH, Harper GW. PrEP awareness and perceived barriers among single young men who have sex with men. *Current HIV research*. 2013; 11:520; Golub SA, Gamarel KE, Rendina HJ, Surace A, Lelutiu-Weinberger CL. From Efficacy to Effectiveness: Facilitators and Barriers to PrEP Acceptability and Motivations for Adherence among MSM and Transgender Women in New York City. *AIDS patient care and STDs*. 2013; 27:248-254.

⁷⁸ Gersh JK, Fiorillo SP, Burghardt L, Nichol AC, Thrun M, et al. (2014) Attitudes and Barriers towards Pre-Exposure Prophylaxis (Prep) among High- Risk HIV-Seronegative Men who have Sex with Men. *J AIDS Clin Res* 5:335. doi:10.4172/2155-6113.1000335.

⁷⁹ King HL, Keller SB, Giancola MA, et al. Pre-Exposure Prophylaxis Accessibility Research and Evaluation (PrEPARE Study). *AIDS and Behavior*. 2014; 18:1722-1725.

⁸⁰ See King, footnote 79.

⁸¹ See King, footnote 79.

⁸² See King, footnote 79.

⁸³ <http://www.healthline.com/health-news/hiv-prevention-truvada-prep-covered-by-most-insurers-050814>

⁸⁴ <https://www.gileadadvancingaccess.com/hcp/financial-assistance/copay-support>

Foundation estimates that 90% of people in the coverage gap live in the South.⁸⁵

Because gaining access to PrEP can be expensive, especially for those without insurance, many high-risk individuals, particular people of color and those of lower socio-economic status do not consider PrEP a viable option for themselves.⁸⁶ Some have even reported feeling that PrEP is essentially a “white man’s drug” that is beneficial only for the wealthy, white gay men they feel are less likely to face financial barriers in obtaining PrEP.⁸⁷

Stigma |

Another factor that is known to negatively impact meaningful PrEP implementation is stigma, which can discourage PrEP use among high-risk individuals on a number of levels.⁸⁸

Many individuals who could benefit from PrEP may choose to avoid it simply because it is an HIV-related medication. Because HIV remains heavily stigmatized today, particularly in the Deep South,⁸⁹ even members of the most vulnerable populations may not want to be associated with it in order to avoid being subjected to stigma-related gossip and rejection.⁹⁰ Furthermore, the fact that HIV is also in many cases closely associated with other stigmatized subjects like homosexuality, sex work, and drug use may further alienate potential PrEP users and prevent them from seeking access to PrEP for fear that an association with one or more of these categories will be attributed to them.⁹¹ Indeed, studies and surveys of attitudes about PrEP use held by at-risk individuals reveal that many potential PrEP users do not take advantage of PrEP availability for fear that if they are seen doing so, it will make others think (or realize) that they are gay (this concern is especially common among young gay/MSM who are not out to their family or friends), that it will make others think that they are HIV positive, or that it will make their partner/spouse believe that they are

Many individuals who could benefit from PrEP may choose to avoid it simply because it is an HIV-related medication.

⁸⁵ Garfield R, Damico A, *The Coverage Gap: Uninsured Poor Adults in States that Do Not Expand Medicaid*, Henry J. Kaiser Family Foundation, Jan. 21, 2016. <http://kff.org/health-reform/issue-brief/the-coverage-gap-uninsured-poor-adults-in-states-that-do-not-expand-medicare-an-update/>

⁸⁶ See Perez-Figueroa, footnote 40.

⁸⁷ See Perez-Figueroa, footnote 40.

⁸⁸ See Calabrese SK, Earnshaw VA, Underhill K, Hansen NB, Dovidio JF. The impact of patient race on clinical decisions related to prescribing HIV pre-exposure prophylaxis (PrEP): assumptions about sexual risk compensation and implications for access. *AIDS Behav.* 2014; 18(2):226–240.

⁸⁹ Reif S, Sullivan K, Wilson E, Berger M, *HIV/AIDS Care and Prevention Infrastructure in the U.S. Deep South*, Feb. 2016, <https://southernaids.files.wordpress.com/2016/03/hiv-aids-care-and-prevention-infrastructure-in-the-u-s-deep-south1.pdf>.

⁹⁰ Parker R, Aggleton P. HIV and AIDS-related stigma and discrimination: a conceptual framework and implications for action. *Soc Sci Med.* 2003; 57(1):13–24; Haire BG, Preexposure prophylaxis-related stigma: strategies to improve uptake and adherence - a narrative review. *HIV/AIDS : Research and Palliative Care.* 2015; 2015:241-249.

⁹¹ See Parker, footnote 90.

engaging in sex outside of the relationship.⁹² These concerns were found to be particularly common among young African American men.⁹³

Potential PrEP users may be discouraged from accessing the drug because of relentless opposition by the AIDS Healthcare Foundation, led by Michael Weinstein, to the use of PrEP. Though no meaningful evidence has been produced to support the idea that widespread PrEP availability will engender more high-risk behavior, Weinstein argues that PrEP is little more than a “party drug” that will encourage high-risk individuals to engage in unsafe sexual practices further stigmatizing the use of PrEP by potential users.⁹⁴

A number of PrEP users have confirmed that they have in fact encountered and experienced many of the kinds of stigma that potential PrEP users have identified as deterrents to utilizing PrEP as a prevention strategy from medical providers, friends, sex partners, and others.⁹⁵ Combating this kind of stigma, some experts have suggested, will require a multi-faceted approach, including social-marketing campaigns, education for health care providers, and a broad recognition of PrEP users as individuals proactively using proven prevention strategies.⁹⁶

Adherence |

Another barrier that may inhibit eligible candidates for PrEP is the requirement of adherence. In order for PrEP to be effective prophylaxis, it must be taken regularly—it will not function as an adequate preventative measure if only taken on an as-needed basis. There are gender differences in the level of adherence that may be required. A recent study by University of North Carolina researchers sheds some light on why PrEP may be less effective in women than in gay/MSM. Researchers tested how well PrEP is absorbed

There are gender differences in the level of [PrEP] adherence that may be required .

⁹² Young I, Flowers P, McDaid LM. Barriers to uptake and use of pre-exposure prophylaxis (PrEP) among communities most affected by HIV in the UK: findings from a qualitative study in Scotland. *BMJ open*. 2014;4:e005717-e005717; Tangmunkongvorakul A, Chariyalertsak S, Amico KR, et al. Facilitators and barriers to medication adherence in an HIV prevention study among men who have sex with men in the iPrEx study in Chiang Mai, Thailand. *AIDS Care*. 2013;25(8):961–967.

⁹³ Smith DK, Toledo L, Smith DJ, Adams MA, Rothenberg R. Attitudes and program preferences of African-American urban young adults about pre-exposure prophylaxis (PrEP). *AIDS Educ Prev*. 2012; 24(5):408–421.

⁹⁴ Garcia M. Why Michael Weinstein gets blamed for PrEP Myths 2014. Available from: <http://www.advocate.com/31-days-prep/2014/10/31/why-michael-weinstein-gets-blamed-prep-myths>.

⁹⁵ Franks J, et al, Patterns of Sex and PrEP in Harlem MSM: A qualitative study (HPTN 067). 8th International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention. 2015. Vancouver. Liu A, Cohen S, Follansbee S, et al. Early experiences implementing pre-exposure prophylaxis (PrEP) for HIV prevention in San Francisco. *PLoS medicine*. 2014; 11:e1001613.

⁹⁶ Liu A, Cohen S, Vittinghoff E, 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. Presented at: Eighth International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention, Vancouver; July 19–22, 2015; Vancouver, BC. Abstract TUAC0202; <http://www.medpagetoday.com/MeetingCoverage/IAS/52697>.

by the rectum, vagina, and cervix while also looking at the levels of DNA material used by HIV to reproduce that was present. Based on the results and using modeling, researchers calculated the minimal PrEP dose that women and gay/MSM would need to take to achieve protection. They estimated that women would need to take PrEP almost daily while gay/MSM could conceivably achieve protection with two to three doses per week.⁹⁷ Despite this study and though the iPrEx Study found that participants who took PrEP medication at a frequency of approximately four times per week had a comparable level of protection to those who took the medication on a daily basis, it is still recommended that all those seeking to use PrEP as a prevention strategy take the medication once a day in order maintain the highest likelihood of avoiding infection.⁹⁸

In studies and surveys conducted among high risk populations that asked participants whether they would be likely to adhere to the required PrEP regimen, many said they would not, and offered a number of reasons why. First, the notion of having to take a pill every day was simply deemed burdensome by many and “difficult to sustain over the long term.”⁹⁹ Some participants suggested that they would be unlikely to adhere because they just do not like taking pills, while others commented that, because of irregular daily schedules/sleep patterns or other reasons, they would be likely to forget to take the pills on a consistent basis.¹⁰⁰ Among those who voiced concern along these lines, as-needed condom usage was generally pointed to as an easier to remember and less burdensome prevention strategy than daily PrEP usage.¹⁰¹

Real world research that looked at PrEP adherence...found that adherence levels were generally high.

Real world research that looked at PrEP adherence, however, found that adherence levels were generally high. In a study that examined PrEP adherence among 557 gay/MSM in San Francisco, Washington, D.C. and Miami clinics, “80% - 85% had achieved protective drug levels at follow-up visits,” according to Albert Liu, MD, director of HIV Prevention Studies at the San Francisco Department of Health.¹⁰² Lower rates of adherence,

⁹⁷ Cottrell M et. al, A Translational Pharmacology Approach to Predicting Outcomes of Preexposure Prophylaxis Against HIV in Men and Women Using Tenofovir Disoproxil Fumarate With or Without Emtricitabine. J Infect Dis. (2016) doi: 10.1093/infdis/jiw077. See also Science Daily, *Women need more of the HIV drug Truvada than men to prevent infection*, March 4, 2016, <https://www.sciencedaily.com/releases/2016/03/160304092014.htm>. “Twice as much of the drug is needed to prevent HIV infection in vaginal and cervical tissue than rectal tissue because fewer components of Truvada make it into those two tissue types. Also, there is more DNA material that the virus uses to reproduce present in vaginal and cervical tissues, thus requiring more of the drug to prevent infection.”

⁹⁸ Amico KR, Psaros C, Safren S, Kofron R, Flynn R, Bolan R, et al. Real time plasma TFV levels to support adherence in a pre-exposure prophylaxis demonstration project. 9th International Conference on HIV Treatment and Prevention Adherence; Abstract 350, 2014 June 8–10; Miami, FL.

⁹⁹ See Perez-Figueroa, footnote 40.

¹⁰⁰ See Young, footnote 90.

¹⁰¹ See Perez-Figueroa, footnote 40.

¹⁰² See Liu; footnote 96.

however, were found among African-Americans, young people, and those without stable housing.¹⁰³ One study concluded that young men who have sex with men in the US “may need access to PrEP in youth-friendly settings with tailored adherence support and potentially augmented visit schedules.”¹⁰⁴ A recent study found that African American MSM would utilize and adhere to PrEP if engaged and supported in “culturally appropriate” ways by providers.¹⁰⁵ Further research into the factors that contribute to the adherence gap and effective interventions must be considered seriously in any effort to understand and combat barriers to meaningful PrEP usage.¹⁰⁶

...young men who have sex with men in the US “may need access to PrEP in youth-friendly settings with tailored adherence support ...”

Attitudes and Misconceptions about Risk / PrEP |

Other barriers that may prevent good candidates for PrEP from utilizing it as a prevention strategy are general attitudes and concerns about the risk of HIV transmission and about the drug itself. In studies that looked at attitudes of young gay/MSM and transgender women¹⁰⁷, some individuals who were eligible for PrEP did not think it was necessary or would benefit them due to potentially incorrect perceptions about their own susceptibility to risk.¹⁰⁸ Some commented that other methods of prevention, like condoms, are effective, and are also cheaper, more widely available, and less burdensome to use than PrEP, so the need for PrEP is simply not present in their lives.¹⁰⁹ Though Truvada has been shown to be generally well tolerated by users,¹¹⁰ others expressed concern about possible side effects and the possibility of developing resistance to the medication¹¹¹ indicating the need for more widespread education about PrEP.

¹⁰³ See Liu, footnote 96.

¹⁰⁴ Hosek S, Rudy B, Landowitz R, et al. An HIV pre-exposure prophylaxis (PrEP) demonstration project and safety study for young men who have sex with men in the United States (ATN 110). Presented at: Eighth International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention (IAS 2015), Vancouver; July 19–22, 2015; Vancouver, BC. Abstract no TUAC0204LB.

¹⁰⁵ Cairns G, US PrEP study achieves high levels of engagement and adherence among black men who have sex with men, [aidsmap.com](http://www.aidsmap.com), August 27, 2016, <http://www.aidsmap.com/US-PrEP-study-achieves-high-levels-of-engagement-and-adherence-among-black-men-who-have-sex-with-men/page/3080023/>.

¹⁰⁶ Black Lives Matter: What’s PrEP got to do with it? An Annual Report 2016 Black AIDS Institute, p. 42. <https://www.blackaids.org/reports/black-lives-matter-whats-prep-got-to-do-with-it>.

¹⁰⁷ See Young, footnote 71; Golub SA, Gamarel KE, Rendina HJ, Surace A, Lelutiu-Weinberger CL. From Efficacy to Effectiveness: Facilitators and Barriers to PrEP Acceptability and Motivations for Adherence among MSM and Transgender Women in New York City. *AIDS patient care and STDs*. 2013; 27:248-254.

¹⁰⁸ See Young, footnote 92.

¹⁰⁹ See Perez-Figueroa, footnote 40.

¹¹⁰ Mascolini M. Weighing risks of TDF/FTC PrEP side effects in people without HIV. *Research Initiative/Treatment Action*. 2012; 17:41.

¹¹¹ See Young, footnote 92 and Golub, footnote 77.

In a United Kingdom study with gay/MSM and African heterosexual participants, some PrEP candidates indicated that PrEP would not meet their needs as it does not protect against sexually transmitted diseases other than HIV and does not prevent pregnancy.¹¹² Despite evidence to the contrary, others worried that, as a matter of policy, widespread PrEP use would encourage high-risk behaviors among high risk individuals.¹¹³

Further education about the extraordinary protective benefits of PrEP against HIV transmission and wide-reaching recommendations that PrEP be used combination with other measures such as condoms to prevent other STIs and contraceptives to avoid pregnancy, are needed.

CONCLUSIONS AND STEPS FORWARD

As discussed in this report, the benefits of PrEP are well established. It is critical that we overcome the multi-faceted barriers to achieving widespread PrEP utilization among vulnerable populations. Many of these barriers may be especially prohibitive in the South, where rates of poverty are higher than the national average, conservative attitudes about sex and HIV may heighten stigma concerns, where few states have expanded their Medicaid programs under the Affordable Care Act, and health outcomes are generally poor.

We know that PrEP, when taken as prescribed, is an effective tool to prevent HIV transmission. Reliance on condom use alone is unlikely to eliminate or even substantially decrease new HIV diagnoses in the US, especially in the South where rates of new diagnoses are highest. Despite the wide spread availability of condoms in recent years, the rates of new HIV diagnoses have remained constant at around 50,000 per year.¹¹⁴ According to the most recent data released by the CDC, which reports that an estimated 44,784 individuals were diagnosed with HIV in the US in 2014, rates of new HIV diagnoses show no meaningful signs of declining unless new preventative measures like PrEP increase.¹¹⁵ Because of this, the significance of working to eliminate barriers to widespread utilization of PrEP cannot be overstated.

...rates of new HIV diagnoses show no meaningful signs of declining unless new preventative measures like PrEP increase.

¹¹² See Young, footnote 92.

¹¹³ See Young, footnote 92.

¹¹⁴ CDC, HIV in the United States, *At a Glance*, <http://www.cdc.gov/hiv/statistics/overview/ataglance.html>.

¹¹⁵ Centers for Disease Control and Prevention. HIV Surveillance Report: Diagnoses of HIV Infection in the United States and Dependent Areas, 2014, Table 22; <http://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-us.pdf>. See CDC, footnote 94.

Some progress is certainly being made, primarily in larger urban areas. First, the number of PrEP clinics that offer access to Truvada for eligible candidates throughout the South is increasing.¹¹⁶ For example, in February of 2016, the Health Services Department of Fulton County, Georgia partnered with Gilead Sciences to launch a new PrEP clinic in Atlanta where prescriptions for once-daily Truvada, as well as regular HIV tests and other required

New PrEP clinic in Atlanta provides PrEP, regular HIV tests and required lab tests free of charge to those eligible.

lab tests will be offered eligible PrEP candidates free of charge.¹¹⁷ The new PrEP clinic represents a major step forward in what Fulton County Commission Chair John Eaves called the county's "aggressive approach" to combatting HIV. "We are going to be a leader like San Francisco, we are going to be a leader like New York City in terms of being aggressive," Eaves commented, stating at the clinic's opening "We are here because Fulton

County cares. We are here because we have one tool in the toolbox to address the issue."¹¹⁸ The idea that PrEP is now an important "tool" that can be utilized to help profoundly reduce rates of HIV transmission is beginning to take hold across the South, as a number of other major cities are poised to or have already launched clinics similar to Fulton county's, a trend which will hopefully prompt a noticeable decline in the number of new HIV diagnoses in the South.¹¹⁹

In addition to the increase in the number of clinics providing access to PrEP that are now opening across the South, the CDC has also recently introduced funding opportunities that are available to state and local health departments to encourage the provision of PrEP and PrEP-related services to at-risk individuals in larger cities. Among these funding opportunities are CDC-RFA-PS15-1509,¹²⁰ the purpose of which is to support health departments to collaborate with CBOs, healthcare clinics and providers, behavioral health providers, and social services providers to develop comprehensive models of prevention, care, behavioral health, and social services models for gay/MSM of color living with or at risk for HIV acquisition, and CDC-RFA-PS15-1506, the purpose of which is to support state and local health departments to implement PrEP and Data to Care demonstration projects for populations of gay/MSM and transgender persons at high risk for HIV infection, particularly persons of color.¹²¹ In its most recent distribution of funds under these categories, the CDC awarded a number of grants to health departments in the South,

¹¹⁶ See <http://www.prepwatch.org/policies-and-programs/local-programs/> for a list of state-by-state PrEP providers.

¹¹⁷ Matt Henrie, *Fulton fights HIV by opening no-cost PrEP clinic*, Project Q Atlanta (Feb. 6, 2016), http://www.projectq.us/atlanta/fulton_fights_hiv_by_opening_no_cost_prep_clinic.

¹¹⁸ See Henrie, footnote 117.

¹¹⁹ See e.g., information about the Open Arms Clinic in Jackson, MS, <http://oahcc.org/>.

¹²⁰ CDC, Funding Announcement PS15-1509: Health Department Demonstration Projects for Comprehensive Prevention, Care, Behavioral Health, and Social Services for Men Who Have Sex with Men (MSM) of Color at Risk for and Living with HIV Infection, <http://www.cdc.gov/hiv/funding/announcements/ps15-1509/>.

¹²¹ CDC, Funding Opportunity Announcement: PS15-1506: Health Department Demonstration Projects to Reduce HIV Infections and Improve Engagement in HIV Medical Care among Men Who Have Sex with Men (MSM) and Transgender Persons, <http://www.cdc.gov/hiv/funding/announcements/ps15-1506/>.

including CDC-RFA-PS15-1509 grants to the Virginia State Health Department, the Alabama Department of Public Health, and the Louisiana Department of Health, and CDC-RFA-PS15-1506 grants for PrEP support to large urban areas in Louisiana, Maryland, Virginia, Tennessee, and Texas.

The distribution of federal grants like these, which will be used to support PrEP provision in a number of Southern states and cities, also represents an affirmative step towards eliminating many of the primary barriers that are limiting PrEP utilization in the South. Efforts like these to combat barriers to PrEP need to continue and be expanded to include smaller cities and rural areas and vulnerable populations with heavy HIV burden so that the South will continue to make progress towards achieving widespread utilization of PrEP among high-risk populations. In order to facilitate the continuance of this positive change, a number of recommendations for how to remove barriers and further increase PrEP utilization in the South are offered below.

RECOMMENDATIONS:

TO INCREASE PrEP UTILIZATION IN THE SOUTH AND THE US.

Federal Policy Recommendations

- The Centers for Disease Control and Prevention (CDC) should work with the US Department of Health and Human Services, state health departments and community-based organizations to:
 - Develop best practices to reach at-risk persons who could benefit from PrEP;
 - Develop best practices to reach and train primary care medical providers on PrEP;
 - Develop a PrEP surveillance system to measure PrEP utilization.

- The CDC should ensure that CDC funding focused on PrEP:
 - Allows for flexibility to pay for labs and provider time.
 - Is broadened to include smaller cities and rural areas in the South with heavy HIV burden.

- Demonstration Projects are needed that are focused on:
 - PrEP uptake, adherence, and acceptability.
 - The efficacy and utilization of PrEP by and for women, including trans women, sex workers and women of color.

Pharmaceutical Company Policy Recommendations

- Gilead Sciences should:
 - Continue its investment in community-based projects supporting PrEP education for high-risk populations;
 - Invest in a larger PrEP mass media campaign to raise awareness and contribute to the normalization of PrEP use for those at risk.
 - Invest in comprehensive education for primary care providers related to PrEP.
 - Improve its Medication Assistance Program (MAP) for PrEP specifically to allow persons under the age of 26 who are on their parent's health insurance plan to access the PAP.

- Expand the cap on its Co-payment Assistance Program (CAP) contribution from \$3600 to match the out-of-pocket maximum cost for Affordable Care Act plans (\$6,850 in 2016.)
- Provide data on PrEP utilization broken down demographically by gender, race, age, geography and insurance status to identify patterns of and gaps in PrEP uptake.

State Policy Recommendations

- State governments, particularly those in the US South, should expand their Medicaid programs under the Affordable Care Act.
- Fund PrEP clinics for vulnerable populations.

State and Local Health Department Policy Recommendations

- State and local health departments should:
 - Fund PrEP clinics for vulnerable populations;
 - Raise awareness about PrEP in communities at risk;
 - Work with community-based organizations to educate and engage communities at risk about PrEP.
 - Provide comprehensive PrEP education for primary care providers.