

December 21, 2018

U.S. Preventive Services Task Force Program Office
5600 Fishers Lane, Mail Stop 06E53A,
Rockville, MD 20857

Submitted via www.uspreventiveservicestaskforce.org

RE: Comments on Draft Recommendation Statement, Prevention of Human Immunodeficiency Virus (HIV) Infection: Pre-Exposure Prophylaxis

We are submitting public comment on behalf of the Fenway Institute at Fenway Health. The Fenway Institute works to make life healthier for those who are lesbian, gay, bisexual, and transgender (LGBT), people living with HIV, and the larger community. We do this through research and evaluation, education and training, and policy analysis. We are the research division of Fenway Health, a federally qualified health center (FQHC) and Ryan White Part C HIV clinic in Boston, MA that serves 32,000 patients each year. Some 2,200 of our patients are people living with HIV, about 15,000 of our patients are LGBT, and nearly 4,000 are transgender. A major focus of our work is HIV and other sexually transmitted infection (STI) prevention and research.

We write to express strong support for the USPSTF's proposed A rating for preexposure prophylaxis (PrEP) for persons at high risk of HIV acquisition. This important proposed move could expand access to PrEP for all who might benefit from it, and particularly for low-income and marginalized populations, thereby helping to reduce disparities in PrEP prescribing and use along lines of race/ethnicity, sexual orientation, and gender identity.

PrEP has been shown to not only prevent HIV transmission, but also to improve high-risk individuals' connection to preventive health care and STI screening.¹ It is essential that we expand access to PrEP for low-income and marginalized populations, as PrEP roll-out to date has been inequitable, and has not sufficiently reached populations with the highest HIV incidence. Although Black gay and bisexual men and other men who have sex with (MSM), Black transgender women, and Black cisgender women are disproportionately in need of PrEP for HIV prevention,² data indicate that most people who have accessed PrEP in the U.S. are White gay and bisexual men.

¹ Marcus JL, Levine K, Grasso C, Krakower DS, Powell V, Bernstein KT, Boswell S, Mayer KH. HIV Preexposure Prophylaxis as a Gateway to Primary Care. *Am J Public Health*. 2018 Oct;108(10):1418-1420. doi: 10.2105/AJPH.2018.304561. Epub 2018 Jul 19.

² Smith DK, Van Handle M, Grey JA. By race/ethnicity, blacks have highest number needing PrEP in the United States, 2015. Conference on Retroviruses and Opportunistic Infections, 6 March 2018, Hynes Convention Center, Boston, MA. Cited in Goldstein RH, Streed CG, Cahill SR (2018, September 19). Be PrEPared—Preexposure Prophylaxis and HIV Disparities. *NEJM*.

The Centers for Disease Control and Prevention (CDC) predict that, if current trends persist, 1 in 6 MSM in the U.S. will become HIV-infected in their lifetime.³ Within the MSM population, there are striking racial/ethnic disparities: 1 in 11 White non-Hispanic MSM will become infected, compared to 1 in 4 Latino MSM and 1 in 2 Black MSM. Of the 39,782 new HIV infections that occurred in the United States in 2016, nearly half were among Black or Latino MSM, and 52% occurred in the South.¹ Transgender women, and especially Black and Latina transgender women, are also disproportionately vulnerable to HIV infection, although fewer surveillance data are available on the transgender population.^{4,5}

Black Americans are less likely to access PrEP for a number of reasons, including the fact that half of Black Americans live in the South, where, by and large, Medicaid has not been expanded to low-income individuals without dependent children or a disability.⁶ Higher poverty and unemployment rates among Black Americans also play a role. Medical mistrust is another barrier that prevents Black people, including Black gay and bisexual men, from accessing routine, preventive health care.⁷ Finally, lack of culturally competent health care for Black LGBT people is a barrier to access.⁸

The USPSTF's proposed A rating for PrEP for HIV prevention would help increase the likelihood that both private and public insurance will fully cover the cost of PrEP and frequent HIV and STI screening, including the cost of copayments. This move will go a long way toward making PrEP more accessible, especially to low-income people in the U.S. This rating is also likely to motivate health care providers to prescribe PrEP to greater numbers of people who are at high risk for HIV infection, which could increase the public health impact of PrEP nationally.⁹

There are three items that we want to highlight to the USPSTF as it considers this A rating. First, CDC Clinical Practice Guidelines call for laboratory testing during the initial clinical evaluation for PrEP eligibility and every 3-6 months during PrEP use, and these should be covered by insurance along with the cost of PrEP medications. Recommended laboratory tests include HIV screening at baseline and at least every 3 months during PrEP use, STI testing every 3 months for sexually active persons with signs or symptoms of infection and for asymptomatic MSM at high risk for recurrent bacterial STIs (e.g., those with syphilis, gonorrhea, or chlamydia at prior visits or multiple sex partners), and STI testing every 6 months for sexually active adolescents and

³ Centers for Disease Control and Prevention. HIV surveillance reports, 2016.

<http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>

⁴ amfAR: The Foundation for AIDS Research. *Trans population and HIV: Time to end the neglect*. 2014. <http://www.amfar.org/issue-brief-trans-populations-and-hiv-time-to-end-the-neglect/>

⁵ Nuttbrock L., Hwang S., Bockting W., et al. Lifetime risk factors for HIV/sexually transmitted infections among male-to-female transgender persons. *J Acquir Immune Defic Syndr* 2009; 52(3): 417-21.

⁶ Kaiser Family Foundation (2018, November 26). Status of state Medicaid expansion decisions.

<https://www.kff.org/medicaid/issue-brief/status-of-state-medicicaid-expansion-decisions-interactive-map/>

⁷ Cahill S, Taylor SW, Elsesser SA, et al. Stigma, medical mistrust, and perceived racism may affect PrEP awareness and uptake in black compared to white gay and bisexual men in Jackson, Mississippi and Boston, Massachusetts. *AIDS Care*. 2017;29:1351-8.

⁸ Malebranche DJ, Peterson JL, Fullilove RE, Stackhouse RW. Race and sexual identity: Perceptions about medical culture and healthcare among Black men who have sex with men. *J Nat Med Assoc*. 2004 Jan;96(1):97-107.

⁹ 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(7):395-405.

adults.¹⁰ The CDC guidelines also recommend creatinine testing at least every 6 months to monitor for renal function during PrEP use, with more frequent monitoring or additional tests, such as urinalysis for proteinuria, among individuals with threats to renal safety such as hypertension or diabetes.¹¹ The USPSTF should ensure that insurance covers these routine monitoring tests with no copayments.

Second, while the currently recommended PrEP medication is daily oral co-formulated tenofovir disoproxil fumarate and emtricitabine, other dosing strategies, medications, and delivery methods (e.g., injectables and vaginal rings) are being developed. We request that the final USPSTF Recommendation Statement be broadened to allow full insurance coverage for other PrEP medications and modalities if they are approved by the U.S. Food and Drug Administration during the next few years.

Third, the USPSTF Draft Recommendation Statement considers PrEP for “persons at high risk of HIV acquisition.” We applaud the USPSTF for specifically enumerating MSM, transgender people, heterosexuals, and people who inject drugs. We also encourage you to add “and bisexual” after “heterosexual” in group 2, so it reads “Heterosexual and bisexual women and men who are sexually active...” Bisexuals are found in both same-sex couples and different-sex couples. Finally, we encourage the USPSTF to make it explicit that the proposed A rating also applies to prescribing PrEP to adolescents. The current language in the Draft Recommendation Statement about “weigh[ing] all these factors,” including the lack of adolescent PrEP trial results and the risk of “slightly less bone growth,” could cause insurers to believe that the USPSTF did not mean to include prescribing PrEP for adolescents in this Draft Recommendation Statement.

We strongly support this proposed A rating for PrEP and encourage USPSTF to move forward with this recommendation, while considering the changes recommended above. Thank you for considering this comment.

Should you have any questions, please contact Sean Cahill, Director of Health Policy Research, at 617-927-6016 or scahill@fenwayhealth.org.

Sincerely,

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¹⁰ Centers for Disease Control and Prevention: US Public Health Service: *Preexposure prophylaxis for the prevention of HIV infection in the United States—2017 Update: a clinical practice guideline*. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>. Published March 2018. Pages 47-48.

¹¹ Ibid.

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