



January 17, 2023

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

Re: Draft Research Plan: Prevention of Human Immunodeficiency Virus (HIV) Infection:
Preexposure Prophylaxis

On behalf of the **HIV+Hepatitis Policy Institute**, an organization dedicated to promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions, we thank you for the opportunity to comment on the U.S. Preventive Services Task Force (USPSTF) [Draft Recommendation Statement](#): Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis (PrEP). On October 1, 2022, **HIV+Hep** submitted a [request](#), supported by 62 additional organizations, asking the USPSTF to update the existing PrEP recommendation to include long-acting injectable PrEP. We commend you for conducting and completing this timely and thorough update.

As noted in USPSTF's review, PrEP is effective in preventing HIV and can be used to prevent the 30,000 to 40,000 new infections each year. The CDC has estimated that approximately 1.2 million people can benefit from PrEP, but only 301,000 people are using PrEP. Further, the uptake of PrEP has been marked by growing racial, ethnic, and gender disparities. For example, in 2020, only 9% of African Americans and 16% of Hispanics/Latinos who were eligible for PrEP were prescribed it, compared to 66% of Whites.¹ Given the significant role of the USPSTF in guiding clinical practice in preventive medicine, timely reviews of PrEP will improve health equity and combat growing disparities in PrEP access.

With a new long-acting injectable medication approved by the FDA for use as PrEP in January 2022, USPSTF's review also helps prevent new HIV infections by ensuring that innovation in PrEP clinical practice can be rapidly disseminated to providers working with the many populations not yet fully benefiting from PrEP use. With new drugs and medication administration modalities in the pipeline it will be important to continue to rapidly adopt

¹ Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2020. *HIV Surveillance Supplemental Report 2022*;27(No. 3). <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published May 2022. Accessed January 17, 2023.

HIV + HEPATITIS POLICY INSTITUTE

1602B Belmont Street NW | Washington DC 20009 | 202-462-3042 | 202-365-7725 (cell)
HIVHep.org | Twitter: @HIVHep | Facebook: HIVHep

innovative forms of PrEP as well. We recommend that USPSTF clarify the updated PrEP recommendation to encompass future medications approved as PrEP by the FDA.

We commend USPSTF for clarifying that clinical practice for PrEP requires a suite of ancillary services, including laboratory testing. For example, long-acting cabotegravir as PrEP requires a different cadence and type of laboratory testing than what is used for oral PrEP. We recommend that USPSTF explicitly incorporate current CDC clinical practice guidelines for PrEP within the overall PrEP recommendation, while also subsuming future CDC PrEP guidelines into the recommendation so that delays in the incorporation of the most recent science into clinical practice can be avoided.

It is important that USPSTF's PrEP recommendation makes clear that necessary STI testing be provided to patients on PrEP. Current CDC guidelines suggest that gay, bisexual, and other men who have sex with men on PrEP be screened for gonorrhea and chlamydia quarterly.² We note that USPSTF's recently issued recommendation on chlamydia and gonorrhea screening concludes that there is insufficient evidence to "assess the benefits and harms of screening for chlamydia and gonorrhea in [sexually active] men."³ We have already seen this guideline cited by commercial insurance plans in denying coverage of testing for these STIs to PrEP patients. We ask the USPSTF to clarify on both the PrEP and chlamydia/gonorrhea screening recommendations that these tests are indeed recommended for male PrEP patients.

CDC PrEP guidelines, most recently updated in 2021, included a recommendation that PrEP be discussed with all sexually active adults and adolescents, and that PrEP be offered to anyone who requests the medication, as many patients do not disclose stigmatized sexual or substance use behaviors to their providers. We strongly encourage USPSTF to endorse these new guidelines explicitly in the updated recommendation, as many providers, especially those who are not steeped in the provision of PrEP, will not be familiar with the evidence for this important recommendation. PrEP should be available to anyone who asks for it.

The draft recommendation contains a number of references to the question of whether PrEP use increases risk for STIs. We believe that is very important to note in this context that PrEP care increases detection of sexually transmitted infections, whether or not PrEP is shown to have any measurable effect on STI risk.

While we believe that the USPSTF has conducted a very thorough scientific review of PrEP, including the new long-acting injectable, and its value to HIV prevention, we recommend the following topics for consideration in the "Research Needs and Gaps" section:

² US Public Health Service. Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States: 2021 Update, <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf> (December 2021).

³ United States Preventive Services Task Force Final Recommendation Statement: Chlamydia and Gonorrhea: Screening, <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/chlamydia-and-gonorrhea-screening> (September 2021)

- Same-day PrEP initiation has been shown to be a critical intervention to improve adherence. Successful programs, such as those implemented by the sexual health clinics in New York City, have prioritized immediate PrEP initiation by streamlining tests required to initiate PrEP and follow-up with additional laboratory testing after initiation.⁴ We would welcome USPSTF guidance on laboratory testing to enable same-day prescription of PrEP.
- Post-exposure prophylaxis (PEP) is prescribed to many individuals with a potential recent exposure to HIV (within 72 hours). As such, many individuals with elevated risk for HIV (sexual or through injection drug use) may present with an indication for PEP. We would welcome USPSTF clarification on to what extent post-exposure prophylaxis may be subsumed with PrEP in future iterations of this recommendation.
- Justice-involved individuals pose particular challenges for HIV preventive care, both while incarcerated and after release from incarceration. We would welcome USPSTF review of evidence for HIV preventive care in this setting.

Thank you for the opportunity to comment. Should you have any questions or comments, please contact Carl Schmid at cschmid@hivhep.org or (202) 462-3042.

Sincerely,



Carl E. Schmid II
Executive Director

⁴ Tarek Mikati, Kelly Jamison, Demetre C. Daskalakis, New York City Department of Health and Mental Hygiene, Immediate PrEP Initiation at New York City Sexual Health Clinics, CROI, Abstract No.: 962 (March 2019).