HIV+HEP
POLICY INSTITUTE

December 8, 2021

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

Dear USPSTF:

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 this opportunity to comment on the Draft Research Plan: Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis (PrEP). First and foremost, thank you very much for initiating this review so quickly after we formally requested the USPSTF to conduct it. With a new long-acting injectable PrEP expected to be approved by the FDA by January 2022, it is important that USPSTF conduct this review as quickly as possible in an effort to help prevent new HIV infections. With other new PrEP drugs on the horizon, it will be important to evaluate those as well in a timely manner.

Timely reviews of PrEP will greatly address health equity and work to describe and address the growing disparities in PrEP access. In 2019, 40.3% of the people living with HIV were Black, while they only represent 13.4% of the overall population. Over 24% of people living with HIV were Hispanics/Latinos while they represent 18.5% of the population. In 2019, only 8% of African Americans and 14% of Hispanics/Latinos who were eligible for PrEP were prescribed it, compared to 63% of whites.[1] More must be done to understand these disparities and to identify best practices to address them.

In addition to responding to the questions online, we urge the USPSTF to consider the following two recommendations as it finalizes its research plan.

[1] Centers for Disease Control and Prevention, "2019 National HIV Surveillance System Reports," May 27, 2021, available at https://www.cdc.gov/nchhstp/newsroom/2021/2019-national-hiv-surveillance-system-reports.html.

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Ancillary Services that are part of the PrEP intervention

Research should also explicitly evaluate and describe the ancillary services, in addition to the medication, that are integral to the PrEP intervention. This should include evaluating and clearly describing and defining PrEP as inclusive of a medication and necessary services, such as regular HIV testing, kidney functioning testing, and sexually transmitted infection (STI) testing. New PrEP modalities – including long-acting injectable cabotegravir – may have a different set of services necessary for the intervention to be implemented effectively and safely. USPSTF should evaluate and enumerate these PrEP ancillary services, including the optimal intervals at which they should be provided, looking to the updated CDC guidelines anticipated to be finalized imminently.[2] USPSTF should also consider research on how these ancillary services can be adapted to facilitate access to "same-day" PrEP initiation. Successful programs, such as those implemented by the sexual health clinics in New York City, that have prioritized availability of immediate PrEP initiation have been able to streamline tests required to initiate PrEP and follow up with additional lab tests after initiation.[3]

Process for rapid review of emerging PrEP products

In its research plan, USPSTF only mentions TAF/FTC, long-acting injectable cabotegravir, and the dapivirine vaginal ring. However, the PrEP pipeline is more expansive, with additional anticipated products – including monthly oral medications and dual contraception/PrEP medications – making their way through the federal regulatory process in the next couple of years. Individuals cannot afford to wait for lengthy, multi-year USPSTF review periods to access these products, particularly in light of the national priorities to end HIV and Affordable Care Act's coverage and cost-sharing requirements attached to USPSTF Grade A and B recommendations. We urge USPSTF to adopt a more nimble and timely review of the PrEP recommendation as new products see clinical trial success.

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

[2] CDC, 2021 Draft Clinical Practice PrEP Guideline Public Comment Webinar (May 2021), available at https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-PrEP-GL-Webinar-2021-Presentation.pdf

[3] 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).